NATIONAL HEALTH INSURANCE PROPOSALS

HEARINGS

BEFORE THE

COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES

NINETY-SECOND CONGRESS

FIRST SESSION

ON THE

SUBJECT OF NATIONAL HEALTH INSURANCE PROPOSALS

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NATIONAL HEALTH INSURANCE PROPOSALS

THURSDAY, OCTOBER 28, 1971

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
Washington, D.C.

The committee met at 10 a.m., pursuant to notice, in the committee room, Longworth House Office Building, Hon. Al Ullman, presiding.

Mr. ULLMAN. The committee will be in order.

Our first witness today is H. Leonard Woodcock.

We are very happy to have you before the committee. You have always contributed to our deliberations. We are looking forward to hearing you on this most important subject.

If you will identify your colleagues we will be very happy to recognize you.

STATEMENT OF LEONARD WOODCOCK, PRESIDENT, INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE AND AGRICULTURAL IMPLEMENT WORKERS OF AMERICA (UAW), AND CHAIRMAN, HEALTH SECURITY ACTION COUNCIL; ACCOMPANIED BY I. S. FALK, PH. D., CHAIRMAN, TECHNICAL SUBCOMMITTEE FOR NATIONAL HEALTH INSURANCE, HEALTH SECURITY ACTION COUNCIL; MELVIN A. GLASSER, DIRECTOR, SOCIAL SECURITY DEPARTMENT, UAW; AND MAX W. FINE, SECRETARY, HEALTH SECURITY ACTION COUNCIL

Mr. WOODCOCK. Thank you, Mr. Chairman and gentlemen of the committee.

On my left is Dr. I. S. Falk who is professor emeritus of public health at Yale University; at my immediate right, Mr. Melvin Glasser, director of the social security department of our union and Mr. Max Fine who is secretary of the Health Security Action Council.

With your permission, Mr. Chairman, I would like to have the statement which we have given to the committee put in the record.

Mr. ULLMAN. Without objection your full statement and supplemental materials will be placed in the record and you may proceed as you see fit.

(The statement referred to follows:)

STATEMENT OF LEONARD WOODCOCK, PRESIDENT, INTERNATIONAL UNION, UNITED AUTOMOBILE, AEROSPACE AND AGRICULTURAL IMPLEMENT WORKERS OF AMERICA (UAW)

My name is Leonard Woodcock. I am President of the International Union, United Automobile, Aerospace and Agricultural Implement Workers of Ameri-

ca (UAW), and Chairman of the Health Security Action Council. I am accompanied by Dr. I. S. Falk, Professor Emeritus of Public Health of Yale University, by Mr. Melvin A. Glasser, Director, Social Security Department, International Union, UAW, and by Max W. Fine, Secretary, Health Security Action Council.

We wish to express our appreciation to you, Mr. Chairman, for holding these hearings on national health insurance at this time. We know of no single issue of greater importance to all of the American people than the subject you are considering today. In the last five years health services have increased in cost at twice the rate of the overall rise in the consumer price index. But runaway costs are not the only symptoms of the disease that afflicts our health system. It is a system beset by many problems, as you have noted, Mr. Chairman. Among these are disorganized services, physician shortages, quality control breakdowns, non-availability of services for millions and only the most limited, hurried, impersonal and often ineffective services for many more millions.

Americans share great expectations about health care. We are blessed with a scientific community which has earned 41 Nobel Prizes in medical research since 1901. Medical scientists from all over the world come to America for advanced training. We are justly proud of our achievements in discovering causes and cures for once-dreaded diseases. The relentless advance of scientific knowledge should be a cause for rejoicing. Its main result should not be a fear of the consequences in terms of unfilled expectations.

Mr. Chairman, we are here primarily to tell you about the National Health Security Act embodied in H.R. 22 introduced by Mrs. Griffiths, Mr. Corman and some 80 other members of the House of Representatives. Last week Secretary Richardson testified before your Committee. He called H.R. 22 "utopian." While accepting the principle of equal accessibility to all of health care services, he challenged what he called "the wisdom of raising expectations beyond all hope of fulfillment in the near future." He contended the resources were not in place to provide equal access. He said the National Health Security Act was "infeasible."

I think he missed the point. The real question is, shall we continue to subsidize a wasteful, archaic and non-productive health care and health insurance system which will continue to fail to meet the public need? Or shall we resolve to make the fruits of medical knowledge available to all, as rapidly as possible, through reform of the health care delivery system?

Mr. Chairman, in the wake of Secretary Richardson's testimony, we are obligated to indicate some comparisons and contrasts and to express some opinions on the issues specifically presented to you by the two proposals, the National Health Security Act on the one hand and the Administration proposal on the other.

At the outset, let's agree on the problems. Your own summation is a valuable contribution to understanding the problems. The health industry, as it has developed in this country is marked by:

Uneven quality of care.

Skyrocketing health care expenditures that now consume more than 7 percent of our gross national product.

Unplanned growth of hospital and nursing home beds, producing wasteful surpluses in many areas.

A chronic manpower shortage, particularly a physican shortage, exacerbated by our failure to use physicans wisely. A medical education system so restricted as to require importing of foreign medical graduates in large numbers.

A non-profit hospital system that often lacks enough incentives for efficient provisions of services.

And increasingly resentful consumers. Our system of medical care functions more and better for those who provide health care services and for those who insure its costs than for consumers. It should serve patients and providers equally well.

Appalling statistics brought out in your staff's excellent report show the problems in other dimensions:

> Among 20 advanced nations, the United States ranks 18th in life expectancy for males. The life expectancy at birth of the U.S. male—66.8 years—is nearly 5 years shorter than the life expectancy of the Swedish male. For females, the U.S. rank is somewhat higher . . . Ten nations, however have a life expectancy for females that exceeds the 73.7 year average for the United States.

Among 20 industrial nations in 1967, the United States ranked 14th in rate of infant mortality with 22 deaths per 1,000 births. Moreover, the U.S. rank has actually worsened in recent decades, decreasing from 5th in 1950. Had Sweden's infant mortality rate been achieved in the United States in 1967, it would have meant over 32,000 fewer infant deaths.

Infant mortality rates are 80 percent higher for minority race members than for whites. Despite an overall decrease in rate of infant deaths throughout this century, the racial disparity in infant mortality rates has not lessened over time.

By count of the Department of Health, Education and Welfare in the existing medical delivery system, we have a shortage of 50,000 physicians. Projections of the U.S. Bureau of Labor Statistics show we will not make a dent in this critical shortage in this decade. We would need to graduate more than 20,000 new physicians a year—more than twice our present 9,000—to end the shortage by 1980. It is clear, Mr. Chairman, that the physician shortage exists largely as a result of professional birth control exercised by the American Medical Association in the past, and the resistance to innovation such as prepaid group practice programs which provide more productive use of physicians' time and skill than does solo-practice, fee-for-service medicine.

Another fact of the physician shortage brought out in the staff report is that, despite the overall shortage, American surgeons are twice as numerous as English surgeons and perform twice as many operations.

These data tend to support other evidence of excessive rates of surgery in America on patients covered by commercial insurance and by Blue Cross and Blue Shield plans. This is an indictment of both the medical profession's quality control and peer review systems, on the one hand, and the negative effect of a medical insurance market place which encourages excessive surgery and unnecessary hospitalization, on the other.

The factors causing wasteful and inefficient hospital practices are varied. By our methods of insuring against health care costs we invite over utilization of the most expensive, often most irrational therapy. The status factor is another element; each institution and its medical staff want to furnish the full array of services. For example; studies show that at least one-third of hospitals with open heart surgery teams are performing insufficient open heart surgery to justify the cost of the heart-lung machines and other equipment. The studies raise serious questions about the value of many of the teams, because they do not perform enough operations to develop and maintain the high degree of expertise that is needed.

Mr. Chairman, the basic facts already before this Committee are like a litany of the breakdown of the health care system. The documentation of the health crisis is long and distressing, particularly when viewed in terms of human suffering, unnecessary illness and family bankruptcy resulting from unbelievable high costs for even a single serious medical-hospital episode.

The Washington Evening Star capsulized in one paragraph a growing assessment of our health care when it said:

"In this field the United States is in a third rate position among the industrial nations. It just muddles along, tolerating incredible disorganization, appalling inequities and financial ruin for people who get too sick for too long. For millions, adequate care simply is unavailable. Distribution of services is drastically uneven across the nation."

And Fortune Magazine served to alert not only business and industry but the entire nation when it stated last year:

"American medicine, the pride of the nation for many years, stands now on the brink of chaos . . . Much of U.S. medical care, particularly the everyday business of preventing and treating routine illnesses, is inferior in quality, wastefully dispensed and inequitably financed. Whether poor or not, most Americans are badly served by the obsolete, overstrained medical system that had grown up helter-skelter, without accommodating very well to changing technology, expanding population, rising costs or rising expectations."

Mr. Chairman, we are here not to rejoice in the general recognition of the problems, but to make our contribution in the search for solutions. Many proposals are before you. But we are convinced that we will not achieve good health care for all Americans unless we deal meaningfully with the major causes of the

health care crisis and with all of them. Each of the problems is interrelated with all of the others. Each must be acted upon, directly and not merely rhetorically, if we would have performance measure up to scientific promise.

A sound and adequate program must deal with all of the problems, simultaneously. And the dimensions and severity of the crisis, and the outlook that it will continue and worsen, dictate that we should deal with them now. And in dealing with them, I do not believe we should settle for less than we need.

NEEDED CHANGES

Let me suggest the nature of the changes that in our view are needed. We need more physicians and dentists and other health professionals, and we need them better distributed among specialties and better distributed geographically. We need more secondary personnel, and we need them better used to increase the productivity of the professionals. We need more prepaid group practice, in in the true sense of that term, to provide more and better services at lower cost. We need to make keeping people well more remunerative than treating them when they are sick, and for those who are sick we need incentives to treat them whenever possible as ambulatory patients. We need to persuade the health professions to exercise everywhere the self-discipline, both in the quality of services and in their utilization, that we find today in the best of our hospital medical staffs. We need fair but effective cost controls—not to deny health personnel incomes commensurate with their devotion and their skill, but to put an end to a rate of inflation that is badly out of kilter with the rest of the economy.

We need comprehensive protection—health security for all.

We have studied all proposals developed and put forward over the past three years, and we believe that only the Health Security bill deals with all the causes of the crisis and measures up to the needs and aspirations of the American people in personal health services.

CRITERIA FOR NATIONAL HEALTH INSURANCE

Mr. Chairman, the Health Security program was developed over a period of nearly three years by a knowledgeable and expert technical committee. Under the Chairmanship of my predecessor, the late Walter P. Reuther, the Committee for National Health Insurance was formed for the purpose of developing a program which would meet the needs of all of the American people. We established ten essential criteria for design of a national health insurance program:

1. The whole population should be eligible for all the benefits of the program, according to the need for health care and without financial tests or barriers;

2. The program should undertake to assure the availability of all useful and promising medical care services within the spectrum of its benefits;

3. The desired organizational pattern and delivery system should, as a practical matter, be achieved on an evolutionary course which starts with acceptance of current patterns and practices and also provides incentives and supports for developments toward the declared goals;

4. The national economy as a whole should be the underlying source of financing, both for the development of needed resources for the provision of services and for adequate and assured support of continuing functional performances;

5. To be acceptable as well as viable, the program design should be based on a partnership of—

(*a*) national public financing, "monolithic" as in our national social insurance, and

(*b*) private provision of the medical care services, "pluralistic" through self-elected diversities among providers of services, their location, organization, professional and fiscal operations, and participation in planning and administration;

6. Continuing financial supports should be assured through—

(*a*) Taxes which are earmarked for medical care and which automatically adjust to the state of the national economy,

(*b*) Matching or supporting appropriations from general revenues, made as nearly automatic as possible, and

(*c*) Utilization of the total yield through the mechanism of a trust fund permanently available for purposes of the program;

7. The program's fiscal operations should rest on prospective annual budgets for the support and compensation of those who provide medical care services and goods, in order to bulwark planning and to contain costs within levels determined by national decisions;

8. To assure the worth of services supported by public funds, the design of the program should provide for standards of quality, and the administration should be required to implement all practical measures for the observance of such standards;

9. Administration of the program should involve not only the public authority but also the participation of representatives of both consumers and providers of services; and

10. Mandatory provisions should assure public accounting of program operations and performances.

NATIONAL HEALTH SECURITY ACT

Mr. Chairman, of the proposals before your Committee, only the Health Security Act meets these criteria. It is the only national health insurance proposal which follows the problems where they lead. The things that we have suggested need to be done cannot be accomplished by fiat on the one hand, or by preachment on the other, but they can be brought about over a period of time if we have the will and the wit to consolidate and use wisely the huge sums of money that are spent every year for health services.

The Health Security Program is not a theoretical model to replace our present medical system with another. It would proceed on an evolutionary course not by striving for all its goals on an appointed day, but by processes of gradualism. It is a program designed to achieve an end to financial barriers that obstruct the ready availability of good medical care for the population.

The Health Security Program starts with effective recognition that health care is a right and a necessity, not a luxury. The fact that we are for health care as a matter of right means that all persons legally resident in the United States would be eligible for the benefits of the Health Security Program. Eligibility would not require either an individual contribution history or any means test, and no payment would be required when services are rendered. The advantages in terms of public acceptance and ease of administration have been clearly demonstrated by the success of Social Security, OASDHI programs, in contrast to the tangle of requirements, entitlements and benefits under Welfare and Medicaid. Separate health insurance programs created for the poor, for working people, for the elderly and the disabled cannot fail to compound further the intricacies, confusions and the inadequacies with which the medical care scene is more than sufficiently plagued.

Fragmentation of programs has another and even more serious effect—it deprives us of the means of bringing about the needed changes. The financial leverages of competitive and uncoordinated private insurance have brought us to the pass we are in, and if we are to reverse the direction of these leverages we must substitute centralized control of health care financing. It is too much to hope that programs administered by scattered Federal and State agencies and by insurance carriers could be brought to such unity of purpose and method as to produce a coherent force for change. A national program, on the other hand, could supply consistent incentives and encouragement which over the years would bring order out of our present chaos.

If the concentrated power of the Federal purse is used to construct a national system of highways, or to redirect our agricultural economy, why should it not be used to rationalize our system of health care? Promotion of the general welfare, after all, is one of the purposes for which this Nation was created—explicitly, one of the purposes for which the power of taxation was conferred on our central Government.

Universal entitlement under a single national program would free the money now spent to check such things as eligibility, current insured status, and deductibles, to actually pay for health services. The sums involved are not small. Carriers under the Medicare program now spend as much as $6 or more per claim in purely administrative expenses. Most of this money is wasted. It is not used to bring about constructive change, it is used to verify the application of rules designed to exclude beneficiaries whether they need the services or not.

A single national program of financing will create the opportunities for effective planning, cost and quality control. Health Security will provide the funds and the flexibility to encourage the development of new methods of organizing and delivering health services. It will allow for the implementation of a coherent national health policy. Most important, its administration will be public, it will be visible, and it will be accountable.

Secretary Richardson has questioned whether the Federal Government has or could develop the planning capacity needed to administer Health Security. He fails to observe, I think, that our proposal accepts at the outset the delivery system essentially as it is, and plans only for its gradual evolution thereafter under the influence of financial and professional incentives. I refuse to admit that this nation lacks the wisdom to chart a course, better—whatever may be its imperfections—than the rudderless drift we have accepted until now.

CLOSED-END BUDGETING

Health Security is the only national health insurance program which calls for payment of all covered services on a budgeted basis. Advance budgeting will restrain the steeply rising costs and provide a method of allocating available funds among categories of covered services. Through this process the bill can support a range of basic and auxillary services and modify the undue emphasis on high-cost services and facilities.

By a system of regional allocation of funds, annual budgetary review and approval of institutional service expenditures, by financial reviews and controls on service costs, this Bill provides the means of effecting important health cost controls.

Few aspects of the controversy over national health insurance have been as widely discussed and as little understood as the question of program costs. Many wild and misleading allegations have been made about the exorbitant costs of Health Security and other proposed plans. A step toward clarification of this important issue was taken in August with the release of HEW's Supplementary Report on Program Costs.

The report is flawed, but it does provide a valuable insight into the relative public and private costs of the various national health insurance plans. The dollar amount estimates of all the plans are artificially high because the report has lumped together projections for all health related spending rather than focusing on those which are relevant—the costs of personal health services. They are too high also because the rate of inflation projected between now and 1974—approximately 12% annually—is unrealistically high.

These estimates were of course made before the President's new economic policies were announced, and we suppose that diminution of the rate of general inflation will reduce somewhat the inflation of health care costs.

Despite its flaws, the report makes an important contribution by demonstrating that global spending under the various plans would *initially* be almost identical. Unfortunately, it fails to look toward future years when the variation in costs would be very significant. And it fails to take into account in its cost estimates the cost control provisions which are contained in the National Health Security Act.

We have prepared a detailed paper on the costs of Health Security which focuses directly upon *personal health service* costs and which utilizes a more realistic rate of inflation in the intervening years before any program could become operational—an inflation rate averaging 10% annually. The paper also provides estimates of Health Security's cost in subsequent years of operation when the many important cost control features of the program have become fully operational. Mr. Chairman, I ask your permission to have the entire report printed in the record, and I will summarize the results of our findings.

If Health Security had been operational in fiscal 1970, the last year for which detailed data are available, the program would have involved expenditures of about $40 billion, equivalent to about two-thirds of the expenditures actually made during that year for all personal health services. This would not have been $40 billion in new expenditures; but rather a rechanneling of existing expenditure patterns. Health Security in Fiscal 1970 would have absorbed about 69% of all private expenditures, and about 57% of expenditures under public programs. The Federal government expenditures of $9.3 billion for Medicare and Medicaid would be replaced, and state and local governments expenditures of more than $2.5 billion, absorbed by H.R. 22.

If we look to future *initial* year operating costs, we see that if Health Security were enacted this year with benefits first available in 1973–1974 the cost would be $56.7 billion—again representing not new money but a rechanneling of expenditures. If it is first effective in 1974–75, the program cost would be $62.5 billion—including in each case the cost of administration and resource development.

Beyond the first year in which benefits become available, we assume that the many systems improvement and cost control provisions of the program will moderate the average annual rate of increase from approximately 10% toward the level of 6% annually, including the cost of expanding services, the growth of population and price increases. Thus although the initial cost of Health Security might, as the HEW report shows, be comparable to other plans, the subsequent costs of personal health services to the American people under our program would be very substantially less than that under any other national health insurance program under consideration by this Committee and certainly substantially less than the future costs of the existing system which the Administration estimates will exceed $105 billion for personal health services by 1974.

Mr. Chairman, let me put the cost proposition this way: In the Health Security Program, with proper financing and quality controls, it is possible to provide comprehensive health services to all the American people at a cost no greater—possibly even a lesser cost—than what the nation is now spending for the fragmented services. And at present, many Americans receive little or no services at all. Furthermore, the current estimates of 12% annual inflation factor in health care costs would at least be halved in the first years of our program operations, and may even be reduced below that in subsequent years if price controls are even more effective than we have ventured to assume, as the reorganization of services becomes fully effective.

There is no magic involved in providing more and better services to more people with the same amount of funds we spend in any given year. The savings effected through elimination of waste and duplication and through the development of a reorganized and more rational delivery system provide the keys to the new economies.

The financial provisions of the Health Security program would be geared to where we are with respect to expenditures for medical care in the United States at the time the program becomes operational. The system would then operate on an annual budget basis. Program funds would be derived in part from general revenues (50 percent of costs) and in part from earmarked taxes on employers (3.5 percent of payrolls), on individuals (1 percent of earned and unearned income up to $15,000 annually), and on the self-employed (2.5 percent of income up to $15,000 annually.

The precise allocation of the costs among these various sources is endlessly arguable. However, the use of the several sources is, we believe, completely sound.

Since all resources of the program would go into a Trust Fund and remain available until expended—as in the Social Security programs—the functional operations would have secure and stable financing.

THE BENEFITS

With four modest limitations, the benefits are intended to embrace the entire range of personal health services—including care for the prevention and early detection of disease, the treatment of illness and physical rehabilitation. There are no restrictions on needed services, no cut-off points, no co-insurance, no deductibles and no waiting periods.

The principal limitations are:

Dental care, which is restricted to children through age 15 at the outset, with the covered age group increasing thereafter until persons through age 25 are covered; those who once become eligible remain eligible thereafter.

Skilled nursing home care which is limited to 120 days per benefit period.

Psychiatric hospitalization, which is limited to 45 consecutive days of active treatment during a benefit period; and psychiatric consultations which, when provided outside of a framework of organized care, are limited to 20 visits during a benefit period.

Drugs, when administered outside such a framework, are covered only when necessary for treatment of chronic diseases or conditions which require costly drug therapy.

In other respects, the program provides complete coverage for physicians' services, hospital services, and in accordance with regulations, coverage for optometry services, podiatry services, and approved devices, appliances and equipment.

A special feature of the Health Security Program will provide for a Resources Development Fund. A fixed percentage of overall program funds, by 1975, reaching $3 billion will be earmarked and used to strengthen the nation's resources of health personnel and facilities and upgrade the system for the delivery of care. This Fund would support education and training pinpointed to shortages of needed kinds of personnel—especially education and training of those disadvantaged by poverty or membership in minority groups—including programs for new kinds of health personnel. It would also provide financial support for the location of needed health personnel and facilities in both urban and rural shortage areas. This Fund will have far greater capability of supporting the development of new group practice and other organized patient care programs than the HMO proposals of the Nixon Administration, and will focus, as the Administration proposal does not, on integrated group practice arrangements.

Health Security will continue to pay physicians in private practice on a fee-for-service or other basis, at the election of each physician. The same amount of money, per resident of the area, will be available for payment to physicians receiving fees as to physicians receiving capitation. The income of fee-for-service physicians will vary with the amounts of service they render, but their basic compensation will *on the average* be the same as that of capitation physicians. Group practice organizations and professional foundations may, however, earn additional payments if they reduce hospital utilization, and this potentiality, along with various professional incentives, we believe will offer strong inducement to physicians to opt for such organized forms of practice as opposed to solo practice.

By a system of regional allocation of funds, annual budgetary review and approval of institutional service expenditures, and financial reviews and controls on service costs, this Bill provides the means for effecting important health cost controls.

The financial and administrative arrangements of the entire program are designed to move the medical care system toward organized programs of health services, utilizing teams of professional, technical and supporting personnel. Special development funds would be available to support the most rapid practicable development toward this goal. State statutes which restrict or impede the development of prepaid group practice programs would be superseded by provision of the Health Security Program.

The program includes significant provisions to safeguard quality of care. It would establish national standards for participating individual and institutional providers. Independent practitioners would be eligible to participate upon meeting licensure and continuing education requirements. Provision is made for professional review and competent peer judgments to assure a level of service delivery compatible with good medical standards.

Health Security takes note of the rising voice of consumerism, as opposed to leaving health economic decisions solely to health practitioners. Consumers will be assured a meaningful role at every administrative and decision-making level. A National Health Security Advisory Council, with a majority of consumer members, will work closely with the proposed Health Security Board in establishing national policy, standards and operating procedures. In addition, consumer organizations will be given technical and financial assistance to establish their own comprehensive care programs.

Rather than increasing the present mountain of paperwork as some critics have suggested, the proposed program would reduce it. The forms will not have to deal with deductibles or coinsurance, or with any facts relating to eligibility beyond, perhaps, entry of a social security number or similar identifying symbol. Under Health Security there will be one agency administering the overall program and its finances, and one system of forms—highly simplified. Both patients and practitioners will welcome the change.

The American people today recognize that health care is in crisis. But this is a crisis era—housing, poverty, the cities, the environment, education, the question of individual and collective accountability for an unpopular war.

While not intending to belittle the vast undertaking necessary to make our health delivery system more rational and responsive, I nonetheless suggest to you

that health care reform is one of America's more manageable problems. The danger is that America will be enticed to adopt patchwork approaches, and that our health problems will multiply, not diminish. Nothing less than Health Security, which deals not only with financing but evolution toward rational organization of the entire system through which health care services are delivered, will suffice.

Mr. Chairman, we strongly endorse the Health Security Program and H.R. 22 and we recommend its sympathetic study by your Committee.

ADMINISTRATION'S HEALTH STRATEGY

I turn now, Mr. Chairman, to President Nixon's program and others like it. When the President delivered his health message last February, we found much to support in it. We welcomed its expansion of the training of MEDEX and similar type physicians' assistants. Most conspicuous by its appearance was the President's endorsement of the Emergency Health Peronnel Act. New funds for medical schools and other professional education and training institutions, and for students and trainees were promised, as were continuing support for biomedical research and special programs to attack and conquer cancer and sickle cell anemia.

The President's program was strengthened by its provisions for more generous support for the family planning and food stamp programs, as well as its endorsement of expanded health education. The proposal for regional health professions education centers deserved and won our enthusiastic support.

We noted with special pleasure the great emphasis placed by the President and the Secretary of Health, Education, and Welfare on the need to support the development of HMO's—Health Maintenance Organizations—which they are presently stimulating vigorously.

All of these proposals were most commendable in the President's health message. Unfortunately, the Administration has not yet moved forcefully to implement some of them. Philosophical changes appear to have collared others. For example, HMO's appear now to be headed mainly into the profitmaking sector under the methods being encouraged by the Administration. Little funding has been proposed for the Emergency Health Personnel Corps and the program suffers from top level inertia. There was less than met the eye in the Administration's medical education supports.

But we were more astonished than disappointed to see the change-of-mind that took place before the very eyes of your Committee last week, Mr. Chairman. When the Administration backed off from its promise to require federal regulation of the health insurance industry, it frankly dashed our lingering hopes for the future of the Administration's objectives.

The National Health Insurance Partnership proposed by the Administration never was national health insurance. It was and is a patchwork of separate and less than equal programs.

Whole groups in the population are left out. Those covered are placed into seven different categories and five different income classes. In other words, there are 35 different categories with variable benefits, deductibles, co-insurance and premium payments—and those covered are subject to reclassification among the 35 categories twice each year.

I am convinced the program is not only exceedingly difficult for the consumer to understand, it is also not administerable.

Administration spokesmen talk frequently about the comprehensive benefits in their proposals, including the whole range of preventive and rehabilitative services. But their main insurance program (National Health Insurance Standards Act) provides substantially less coverage than is presently available in most group contracts. No provision is made, for example, for mental health services, prescription drugs, dental care, and a number of other services recognized as an integral part of comprehensive care.

And the HEW estimate that the main insurance benefit package would cost about $490 a year is clear indication that even the limited benefits promised could not be provided at present prices.

I am told it would require at least 50% more funds than presently planned if those covered are to expect reasonably comprehensive benefits.

The "Health Strategy" also provides for the perpetuation of the "separate but less equal" medical care system for the poor through a Family Health Insurance Program. Proposed benefits are less than under the main insurance plan. Costs

are expected to be lower than present Medicaid expenditures, but this merely reflects that the F.H.I.P. package will provide lower levels and quantities of care than presently prevail in most northern and western states.

And the Administration's program is silent about the millions of poor who will not be eligible—even for F.H.I.P. It is also silent on what provisions are to be made for the poor covered by F.H.I.P. when they exhaust their insured benefits.

Presumably we may expect enlarged state and local welfare programs to take care of these people.

We are told that there will be cost controls by making the consumer "cost conscious." Apparently, this will be done primarily through a tough co-insurance and deductible payments policy, which I am convinced, based on our union's experience, is antithetical to good health care—though it may be good insurance business.

We hear nothing about meaningful consumer participation in any phase of the development or implementation of these programs. We hear almost nothing about quality controls.

And now, in October 1971, before your Committee, Mr. Chairman, we hear a new and disturbing note about so-called regulation of the health insurance industry.

We have cause for concern. After all, organized labor helped to create the private health insurance industry. We have supported it with our hard-earned dollars for three decades. But the private health insurance industry has failed. It has failed to control costs. It has failed to control quality. It has failed to provide adequate benefits even for those with some form of coverage. After 30 years of effort, all private health insurance combined still covers only a little more than one-third of private personal health care expenses. All of these failures are known to this Committee. They are documented in material developed for you by HEW.

Since private health insurance has not lived up to expectations in the past and is doing no better at present, what basis for better future performance is proposed? Where is the quid pro quo? After all, the Administration is asking for mandated purchase of private health insurance—$30 billion worth or more in the very first year of the program—and progressively more year after year.

In February, of this year, when they first made their proposal known, the Administration officials stated: "You can't ask for an employer-employee health insurance program that will cover all employees of this country and let the States set the ground rules." In May, in the White Paper which you have placed in the Record, Mr. Chairman, the Secretary of Health, Education, and Welfare stated:

"In the past, some insurance carriers have abused their trust by not conveying to the consumer with clarity the coverage and exclusions in his contract. Some have failed to perform claims and utilization reviews, or excluded high risk groups, or cancelled policies suddenly. The Administration proposes to regulate the insurance industry, which is essentially unregulated at this time."

Mr. Chairman, this is October of the same year, and we now see that under the Administration's new concept, the insurance industry will continue to be essentially unregulated in the future. The longer it takes to receive the promised but still unseen regulation, the weaker it becomes. As of now, regulation will be left to the States, which have been regulating the industry all along. And the focal point of prospective regulation appears to be to assure solvency:—to assure that the companies won't go broke. That kind of regulation works fine for insurance companies.

But insurance companies can take care of themselves. It is time to help consumers, particularly since billions of dollars of consumers' money is being mandated into the hands of insurance companies. And in Year Two of their program, the $30 billion mandated premium costs assuredly would have increased substantially. By Year Three, the uncontrolled costs of the Administration's program—even by the faulty actuarial methodology they have employed—would result in higher national expenditures for health purposes than under much more comprehensive programs. The insurance companies are interested in controlling costs only under such conditions as are acceptable to the American Medical Association. And the AMA has yet to find acceptable any method of controlling costs of medical care. Nor are they likely to.

Mr. Chairman, it is time to cancel an insurance industry that places a premium on sickness rather than health and that puts the interests of consumers last in line.

THE SPECIAL ECONOMICS OF HEALTH

Mr. Chairman, however conscious or unconscious they are of other aspects of the health care crisis, most people are acutely aware of the crisis in health care costs.

In the midst of our present concern as a nation with the parlous state of the economy, I suggest to you that we need to pay special attention to the state of our medical economy. It's sick. Most informed observers are agreed on this, whether they use the terms "health care crisis," "non-system," "fragmentation," or "collapse."

The sickness of the health services economy is at least dual in causation. One set of factors reflects the state of the economy as a whole. A second set is unique to medical care itself.

Over the last ten years the costs of medical care have consistently increased at twice the rate of the increase in the cost of living. Medical care has an inflationary sickness all its own—which can't be cured by placebos or palliatives or general economic programs.

This is an increasingly grave problem for the consumer who is gradually being priced out of the health care marketplace, and for government, which is paying a larger and larger portion of the escalating health care bill.

Eleven years ago public funds paid 26% of all national health care expenditures. Today the figure is 37%.

In the health field, excessive inflation can be expected—assuming no major changes in public medical care programs, in the private financing system, in the organization and delivery of services, in the treatment and care of patients—and only a modest increase in population.

The myth continues to be advanced that prices in medical care are controlled by the laws of supply and demand in the marketplace—like soft drinks and refrigerators. In fact no such mechanism operates. How can it when providers are in short supply and hospitals are built largely with public funds. By and large when the consumer requires health services—when he is really sick—he does not have a choice whether or not to go for them, or to delay what the economists call "the gratification" of meeting his needs. He knows, and health services providers know even better, that delaying needed medical care has far different consequences than delaying the purchase of a new automobile.

It is therefore particularly important that the current public debate over methods to control inflation does not obscure the now well recognized need to rethink our ways of organizing and paying for personal health services. The President's proposed inflation controls, and those proposed by others, may help in the general economy, but they can do little in restraining health cost escalation.

CONCLUSION

For all of these reasons, Mr. Chairman, we ask you to evaluate the various proposals before you according to criteria that measures up to the true total needs. Health is too important to be left to an Administration which appears to believe that the insurance industry should be the foundation for all our aspirations in personal health care. We welcome the leadership that you and your Committee are assuming.

Improvement of the health of the people through improved personal health services cannot be achieved through piecemeal programs as proposed by the Nixon Administration. The problems are so complex and so inter-related that we must deal with them concurrently.

We have gone through a 30-year agony of tinkering with and patching up a health care system that can no longer be made to work without major overhaul. It works all right for the private financing institutions. It works all right for the providers of services. But it is not working well for the consumers. No amount of statistical gymnastics nor Madison Avenue sloganeering can hide that fact.

We believe the Health Security Act will do the job that is needed. It will effect controls on costs, as well as incentives for efficiencies and quality of care. It will provide an orderly and assured financing for covered health services. It will also undertake to increase the resources available to supply care. It will encourage the development of prepaid group practice plans, foundations and

other organizations of health providers, and it will offer physicians and other personal providers various choices of renumeration, including fee-for-service. The Health Security Act will free this nation from the frightening tyranny of steeply escalating health and health insurance costs. And it will enable us to build a better health care system.

Mr. Woodcock. Thank you, sir.

I think it can be said that there is no issue of greater importance before the country than the matter of health care. Most people are agreed on the diagnosis but there is wide disagreement on the remedy.

During the last 5 years, health service cost increases have risen at twice the rate of the Consumer Price Index rise and there are many problems in this field which have been noted by this committee; disorganized services, physician shortages, quality control breakdowns, nonavailability of service for millions of Americans, and limited, impersonal, sometimes ineffective service, for many more millions.

This is accompanied by the fact that we have medical scientific knowledge in this country which is by far the best in the world.

I am here this morning, Mr. Chairman, to support the National Health Security Act, H.R. 22, introduced by Mrs. Griffiths, Mr. Corman, and by some 80 other Members of the House of Representatives.

Before this committee the Secretary of HEW, Mr. Richardson, has said that H.R. 22 is "utopian" and "infeasible."

We have a choice in this country between continuing to subsidize a wasteful, archaic, nonproductive system which is not doing the job or utilizing our medical knowledge to reform the health care delivery system.

This committee's summation has been a valuable contribution to understanding the problems before us and the staff of this committee has filed excellent reports which show other dimensions of the problem.

We will, therefore, let that record speak for itself. There are many proposals before you but we believe we will not achieve good health care for all Americans unless we deal meaningfully with the major causes of the health care crisis and with all of those causes.

We need more physicians, more dentists, other health professionals. We need a better distribution among the specialties of medical skills and a better geographic distribution.

We need more secondary personnel to be used to increase the productivity of the professionals. We need more true prepaid group practice, a system that has proved itself against very stiff obstacles.

We need to make keeping people well more remunerative than treating them when they become sick. We need incentives for less costly but effective ways of care, for preventive services, for care of ambulatory patients, and we need self-discipline of the professions to control the quality of service and the utilization of that service.

The health security bill, H.R. 22, goes to these problems. The program was developed carefully over 3 years by topflight and knowledgeable people.

It meets 10 predetermined criteria which that group set itself:

No. 1, the whole population to be eligible according to need and without financial barriers.

No. 2, assuring the availability of service within the spectrum of the benefits proposed.

No. 3, it begins with the system as it is and, through evolution, provides incentives and supports to move to the declared goals.

No. 4, the total economy should be the underlying source of financing, for development of resources, and continuing on-going support of services.

No. 5, there should be a partnership of the national public financing plus private provision of services.

No. 6, continuing financial support should be based upon the earmarked taxes which would adjust with the economy, and general revenue support feeding through a trust fund permanently available for program purposes.

No. 7, fiscal operations through prospective annual budgets to maximize planning and containing costs within national decisions.

No. 8, program design to include quality standards and administration for their implementation.

No. 9, administration to include the public authority but also direct representatives of the providers of services and consumers.

No. 10, public accountability for the program operations and performances.

We believe these these are not "utopian" or "infeasible" criteria. Meeting them is within the reach of America and H.R. 22 rests on them and meets them.

Mr. Chairman, the single national program of financing will allow effective planning, cost controls, quality control. It will provide funds and flexibility for new methods of organizing and delivering health services. It will allow implementation of a coherent national health policy based on evolution. It will be public. It will be accountable.

Health security is the only program, which calls for payment of all covered services on a budgeted basis which brings us to the critical question of costs.

In this area there have been wild and misleading allegations. HEW's August release of the supplementary report on program costs is a step toward clarification of this critical issue.

The report is not perfect but it does give insight. We believe its dollar estimates are too high. It dumps together all projections for all health-related spending and not simply the relevant costs of health service.

The 12-percent inflationary rate from now to 1974 we believe is unrealistically high. Of course, it was issued before the steps were taken toward the new economic policy. But the report makes a contribution by demonstrating that global spending under various plans would initially be almost identical, but it fails to acknowledge that future cost increase variations would be very significant.

It totally overlooks cost control provisions in the National Health Security Act.

We have prepared a detailed study on costs which focuses directly upon percentage health service costs. The study allows for an inflationary rate of 10 percent per year and it provides estimates of costs for future years of operation when cost controls are fully operational.

I understand, Mr. Chairman, in allowing the introduction of the supplementary material which we have filed that that includes this cost study made by Dr. Falk and his associates.

Mr. ULLMAN. Yes. We have the study before us, Mr. Woodcock, and if there is no objection this full cost report will be included in the record.

(The study referred to follows:)

THE COSTS OF A NATIONAL HEALTH SECURITY PROGRAM AND THEIR FINANCING

(Prepared for the Committee for National Health Insurance by I. S. Falk, Ph.D., Chairman, Technical Subcommittee)

EXPLANATORY NOTE

As may be noted from the title, this report does not undertake to deal comprehensively with all aspects of the Health Security Program; it is concerned primarily with the expected costs of the Program and with their financing. The substantive elements of the program are summarized, however, in order to explain the bases for the fiscal studies.

The content of this report developed out of discussions over a period of more than two years in the Technical Subcommittee of the Committee for National Health Insurance. In the preparation of this document, I have drawn freely upon position papers and other documents prepared for the Subcommittee by members, consultants, special task forces and others.

By arrangement with the secretary of DHEW, we have had assistance from staff of the Social Security Administration. We are indebted to them for needed data not otherwise available to us and for technical reviews; but they assumed no responsibility for assumptions or decisions utilized in these studies.

The staff of the Social Security Department of the AFL–CIO also reviewed the report and is in agreement with its conclusions.

I. S. FALK,
Chairman, Technical Subcommittee.

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The Costs of a National Health Security Program and Their Financing

(By I. S. Falk, Ph. D.[1])

I. INTRODUCTORY

The National Health Security Program was formulated to include both a system of national health insurance and many collateral provisions required toward meeting the Nation's need for good medical care. Here we summarize the costs involved in such a program and how they may be financed.

The objective is a program which undertakes to make comprehensive personal health services available, as rapidly as practicable, to substantially all who are resident in the country. The intention is not only to build the prospective system upon the resources which we already have for personal health services, but also to provide incentives and supports for the development of needed resources and for an orderly evolution toward more adequate organization for the availability and delivery of medical care.

Starting with the resources we have in the Nation, and how they function and are utilized, the financial analysis inevitably starts with our knowledge of current expenditures and the sources of the funds. In the last completed fiscal year for which detailed data are available (July 1969–June 1970), as a Nation we spent in excess of $67 billion for all kinds of health services, personal and community-wide. About 90 percent of this total—over $60 billion a year—was expended for personal health care exclusive of capital investments in medical care facilities. It is highly likely that the aggregate national health expenditures incurred in the fiscal year which ended in June 1971 will be found to have reached about $75 billion,, and that the expenditures for personal health care were about $67 billion. Since the costs of health services are still rising steeply, the figures will probably be higher by the end of the year 1971.

These figures indicate the general magnitude of the annual amount which would be involved in the finances of a wholly comprehensive national health security program if it were enacted now. The actual amount would be less in the early years of such a system if currently wasteful expenditures could be reduced and if the new program would encourage more economical practices than are prevalent now, or if the health security program started with less than a total range of personal health services. And the actual amount would become more if the program enabled people to receive needed services which otherwise they do not receive, if the resources for services and their utilization were to become more adequate, if population continued to grow, or if the unit costs of the services continued to rise whether because of further increase in complexity or of inherent cost or because of the persisting inflation of prices, charges or costs. In the main, however, the costs of a national health security program now—whether smaller or larger than current cost—would not be new expenditures for personal health care, but a re-routing, through the new system, of expenditures already being

[1] Chairman, Technical Subcommittee, Committee for National Health Insurance; and Professor Emeritus of Public Health (Medical Care), Yale University School of Medicine, New Haven, Connecticut.

made through private and public channels. If health service costs continue to rise, this will still be the case in future years though at a higher level of expenditure.

II. RECENT AND CURRENT NATIONAL EXPENDITURES FOR HEALTH CARE

Our starting point is therefore the magnitude and the pattern of current national expenditures for health care. As is widely known, these expenditures have being rising steeply, whether they derive from private sources or are incurred under governmental programs, the total having reached $67.2 billion in the fiscal year 1969–70 (Table 1).

TABLE 1.—NATIONAL HEALTH CARE EXPENDITURES IN SELECTED RECENT FISCAL YEARS

National expenditures	1949-50	1964-65	1968-69	1969-70
Expenditures in billions:				
Total	$12.1	$38.9	$59.9	$67.2
Private	9.0	29.4	37.1	42.2
Public	3.1	9.5	22.8	25.0
Percentage distributions:				
Total	100	100	100	100
Private	74	76	62	63
Public	26	24	38	37
Per capita expenditures:				
Total	$79	$198	$292	$324
Private	59	149	181	204
Public	20	49	111	120
GNP (in billions)	$263	$656	$900	$956
Percent for health care	4.6	5.9	6.7	7.0

Source: "National Health Expenditures, 1929-70," by Dorothy P. Rice and Barbara S. Cooper. Social Security Bulletin, January 1971, 34:1, pp. 3-18, table 1.

The rise has been even steeper than the rapidly growing gross national product. The total expenditures for health care, which were 4.6 percent of a GNP of $263 billion in 1949–50, reached 6.7 percent of a GNP of $900 billion in 1968–69 and 7.0 percent of the still larger GNP of $956 billion in 1969–70. The proportion derived from private sources had been about 75 percent of the total between the years 1949 and 1965. Then, with the enactment of Medicare, Medicaid, and other new Federal and Federal-state health programs of 1965–67, the private share declined sharply to about 63 percent of the total, with a corresponding rise of the public expenditure portion from about 25 percent to 37 percent of the total. A small portion of the increase in health care expenditures reflects growth of population; most of the increase, however, reflects other factors, witness that total expenditures *per capita* which were about $79 in 1949–50 and $198 in 1964–65 had attained the level of $292 in 1968–69 and then rose by another 11 percent to reach $324 one year later—in 1969–70.

Throughout all recent years, the expenditures for *personal* health care—with which national health insurance is particularly concerned—have been responsible for approximately 90 percent of the total expenditures for *all* health care, though the amounts have increased so much that they are now between five and six times as large as they were shortly after the end of World War II (Table 2). As indicated from the changes in the total expenditures, the composition of personal health care expenditures has been changing, mainly reflecting a transfer from the private to the public sectors—and the public expenditures themselves have been changing because of a larger proportionate increase in Federal as distinguished from state and local governmental expenditures. This is evident in the dollar figures shown in Table 2 and the percentage distributions in Table 3.

TABLE 2.—NATIONAL EXPENDITURES FOR ALL HEALTH CARE AND FOR PERSONAL HEALTH CARE SERVICES IN SELECTED FISCAL YEARS

[In millions of dollars]

National expenditures	1949-50	1964-65	1968-69	1969-70
All	$12,130	$38,912	$59,905	$67,240
Personal health care [1]	10,841	34,739	54,044	60,099
Percent of total	89.4	89.3	90.2	89.4
Other health care	1,289	4,173	5,861	7,141
Personal Health Care Expenditures: [1]				
Total	$10,841	$34,739	$54,044	$60,099
Private, total	8,721	27,763	35,006	39,253
Direct payments	7,146	17,590	20,278	22,909
Insurance benefits	879	8,281	12,333	13,813
Expenses for prepayment	274	1,212	1,581	[2] 1,667
Other	422	680	814	864
Public, total	2,120	6,976	19,038	20,846
Federal	996	2,858	12,609	13,876
State and local	1,124	4,118	6,429	6,970

[1] Personal health care services includes all expenditures for health services and supplies other than Government public health and related activities, expenditures of private voluntary agencies for other health services, medical research, and medical-facilities construction. The figures shown here exceed those for personal health care expenditures in the source document by inclusion here of expenses for prepayment in the private sector and expenses for administration in the (Federal) public sector.

[2] Preliminary.

Source: "National Health Expenditures, 1929-70," by Dorothy P. Rice and Barbara S. Cooper, Social Security Bulletin January 1971, 34:1, pp. 3-18, tables 2 and 5; and Research and Statistics Note, No. 25-1970, Dec. 15, 1970, by Barbara S. Cooper and Mary McGee (Office of R and S, SSA, DHEW), table 2.

TABLE 3.—PERCENTAGE DISTRIBUTIONS OF PERSONAL HEALTH CARE EXPENDITURES, 1949-50 AND 1969-70

[In percent]

	1949-50		1969-70	
Total expenditures	100.0		100.0	
Private, total	80.4	100.0	65.3	100.0
Direct payments	65.9	81.9	38.1	58.4
Insurance benefits	8.1	10.1	23.0	35.2
Expenses for prepayment	2.5	3.1	2.7	4.2
Other	3.9	4.9	1.5	2.2
Public, total	19.6	100.0	34.7	100.0
Federal	9.2	47.0	23.1	66.6
State and local	10.4	53.0	11.6	33.4

Thus, whereas about 80 percent of all expenditures for personal health care services were formerly (1949–50) private, and about 20 percent were supported by tax funds, in the fiscal year 1969–70 only about 65 percent were still private and about 35 percent were incurred under public programs.

Of the *Private* expenditures, whereas more than 80 percent were formerly direct payments by persons receiving personal health services, these accounted for less than 60 percent in 1969–70; and private insurance, which formerly accounted for about 13 percent, had become responsible for over 39 percent. Of the *public* expenditures, the Federal share, which was somewhat less than one-half, had become two-thirds of the total.

The composition of $60 billion of expenditures for personal health care services in 1969–70 is shown in Table 4—by object of expenditure and source of

funds. Percentage compositions and some comparisons with the preceding fiscal year are shown in Table 5. As is well-known, hospital care has become the largest item of expenditure, accounting in 1969–70 for nearly 43 percent of the total (almost equally divided between private and public sources of funding), having increased by nearly 15 percent since the preceding year and having become about twice as much as for physicians' services.

TABLE 4.—NATIONAL EXPENDITURES FOR PERSONAL HEALTH CARE SERVICES, BY TYPE OF EXPENDITURE AND SOURCE OF FUNDS,[1] FISCAL YEAR 1969-70

[In millions of dollars]

Object of expenditure	Total	Source of funds					
		Private			Public		
		Total	Consumer	Other	Total	Federal	State and local
Total	$60,099	$39,252	$38,389	$863	$20,847	$13,876	$6,970
Hospital care	25,625	13,292	12,926	366	12,333	8,029	4,304
Physicians' services	12,930	9,655	9,644	11	3,275	2,364	911
Dentists' services	4,147	3,906	3,906	.....	241	134	107
Other professional services	1,434	1,186	1,160	26	248	194	54
Drugs and drug sundries	6,741	6,297	6,297	.....	444	222	222
Eyeglasses and appliances	1,802	1,742	1,742	.....	60	32	28
Nursing home care	2,844	1,068	1,047	21	1,776	1,058	718
Other health services	2,526	439	.....	439	2,087	1,460	626
Expenses for prepayment	1,667	1,667	1,667	.....	.....	.....	.....
Expenses for administration	383	.....	.....	.....	383	383	.....

[1] Personal health services differs from total national health care expenditures by exclusion of Government public health and related activities, expenditures of private voluntary agencies for other health services, medical research, and medical-facilities construction. The totals here exceed those in various tables published by the Social Security Administration because of inclusion here of expenses for prepayment and for (Federal) administration.

Source: "National Health Expenditures, 1929–70," by Dorothy P. Rice and Barbara S. Cooper. Social Security Bulletin, January 1971, 34:1, pp. 3–18, tables 2, 3, and 5.

TABLE 5.—PERCENTAGE DISTRIBUTIONS OF PERSONAL HEALTH CARE EXPENDITURES BY OBJECT OF EXPENDITURE, FISCAL YEARS 1968-69 AND 1969-70

Object of expenditure	Percentage composition		Percent increase in dollar amount 1968-69 to 1969-70
	1968-69	1969-70	
Total expenditures	100.0	100.0	11.2
Hospital care	41.2	42.7	14.9
Physicians' services	21.8	21.5	9.5
Dentists' services	7.1	6.9	8.7
Other professional services	2.5	2.4	7.9
Drugs and drug sundries	11.7	11.2	6.4
Eyeglasses and appliances	3.2	3.0	3.9
Nursing home care	4.6	4.7	15.6
Other health services	4.4	4.2	6.7
Expenses for prepayment and administration	3.5	3.4	8.2

Source: "National Health Expenditures, 1929–70," by Dorothy P. Rice and Barbara S. Cooper. "Social Security Bulletin," January 1971, tables 2 3 and 5.

As a result of the changes which have occurred in both private and public expenditures for personal health care services, the distributions according to the sources of the funds in the fiscal year 1969–70 were taking on a newly developing pattern (Table 6). It will be noted that direct payments by patients and their families still constituted the largest single category of expenditures for personal health care services, accounting for 38 percent of the total. Federal expenditures (23 percent) had to come to exceed private insurance payments for benefits, though still somewhat less than the combined expenditures for private insurance benefits and expenses for effecting private insurance (26 percent). Private in-

surance benefit payments themselves ($13,813 million) which constituted 35 percent of total *private* expenditures (Table 3) are here seen to account for 23 percent of the combined private and public expenditures for the personal health care services. The Federal expenditures involved funds from various sources: Of the $13.9 billion, $4.4 billion (31 percent) were derived from the Medicare, Part A, payroll taxes; $1.1 billion (8 percent) were financed by the Medicare, Part B, premiums; and $8.4 billion (61 percent) were from general revenues. State and local government expenditures were responsible for nearly 12 percent of the total in fiscal year 1969–70. All other expenditures—from industrial sources and philanthropic activities of private agencies—were a small portion of the total (1.4 percent).

TABLE 6.—TYPE OF EXPENDITURE AND SOURCE OF FUNDS FOR PERSONAL HEALTH CARE, 1969-70

Expenditure	Amount (millions)	Percent
All expenditures	$60,099	100.0
Direct payments by patients	22,909	38.1
Private insurance, total	15,480	25.8
Insurance benefits	13,813	23.0
Expenses for insurance	1,667	2.8
Federal expenditures, total	13,876	23.1
From general revenues [1]	8,412	14.0
From payroll taxes [2]	4,378	7.
From premiums [3]	1,086	1.
State and local government expenditures	6,970	11.6
All other	864	1.4

[1] Expenditures from Federal general revenues for direct Federal programs, Federal-State programs, health insurance for the aged (medicare) etc.
[2] Hospital insurance expenditures financed by payroll taxes (medicare part A).
[3] Premium payments by or on behalf of subscribers for supplementary medical insurance (medicare, part B).

Source: Tables 2-4; and "Social Security bulletin," June 1971, 34:6, pages 30-31, Tables M-7 and M-8.

III. PROSPECTIVE COSTS OF HEALTH CARE

The national expenditures which have been summarized here carry the accounts through the fiscal year 1970. As noted earlier, there are preliminary indications that the total health care expenditures—$67 billion in that year—have already risen to about $75 billion for the fiscal year July 1970–June 1971 and that they are still escalating—at an upward rate of nearly 12 percent a year. We are therefore concerned with projections for the years ahead. Will these national expenditures continue to rise—at the same rate as in the recent past, at a steeper or at a more moderate rate of escalation?

The level of expenditure to be expected in the next few years has critical importance for a new program of health services and their financing. If a prospective program is designed on evolutionary principles, obviously the initial expenditures for its benefits must begin approximately at the levels prevailing for those services when the program first becomes effective. This assumes that, if expenditures continue to rise in the interim between now and the effective date of a new program, it would be impractical to turn the clock back to some preceding lower level of health care utilizations, unit costs, prices and charges. Consequently, the cost estimates for a program proposal will be directly affected by what happens to health care expenditures in the years ahead and by the year in which the program is to come into operation.

The "SSA" Projections

Some time after our preliminary fiscal studies had been completed, estimates of national health expenditures to 1975 and 1980 were published by the Social Security Administration in October 1970.[2] The underlying assumptions for those

[2] "Projections of National Health Expenditures, 1975 and 1980," by Dorothy P. Rice and Mary F. McGee. *Research and Statistics Note*, No. 18–1970, October 30, 1970, 12 pages.

"SSA" projections were: continuation of medical care evolution approximately as in the recent past (1960–68); no major changes in public medical care programs, in the proportionate financing of health care services from private and public sources, in the organization and delivery of the services, or in the treatment and care of patients; increase in population in accordance with the Census estimates; continued expansion of private health insurance, covering nearly all the population under age 65 for hospital-related expenses; continued increase *per capita* in services used, but the annual rate of increase declining slightly by 1980; a leveling off in the rate of increase in medical care prices beginning in 1970, with the rate decelerating thereafter; and the future rates of increase for the various types of service rising at different annual rates, based on past experience. The main results of the "SSA" projections, based on the data for the calendar years 1960–68, are summarized in Table 7. The actual expenditures in fiscal year 1969–70 (the latest available at this time) are included to give perspective to the projections.

TABLE 7.—ACTUAL EXPENDITURES IN 1969-70 AND "SSA" PROJECTIONS TO 1975 AND 1980 FOR ALL HEALTH CARE AND FOR PERSONAL HEALTH CARE SERVICES

[National dollar amounts in billions]

National expenditures	Actual fiscal year 1969–70 [1]	"SSA" projections [2]			
		1975		1980	
		Low	High	Low	High
All (amount)	$67.2	$110.7	$120.1	$155.7	$189.2
Per capita	$324.0	$509.0	$552.0	$670.0	$814.0
Percent of GNP	7.0	7.9	8.6	8.0	9.8
Health services and supplies	$61.9	$104.8	$113.5	$148.9	$180.6
Research	1.9	$2.2	$2.5	$2.6	$3.1
Construction of facilities	3.4	$3.7	$4.1	$4.2	$5.5
PERSONAL HEALTH CARE EXPENDITURES [3]					
Total (amount)	$60.1	$102.9	$111.4	$146.5	$178.0
Percent of all expenditures	89.4	93.0	92.8	94.1	94.1
Per capita	$290	$473	$512	$630	$766
Percent of GNP	6.3	7.4	8.0	7.6	9.2
Hospital care	$25.6	$48.2	$52.4	$76.4	$92.6
Physicians' services	$12.9	$22.1	$24.0	$29.2	$36.5
Dentists' services	$4.2	$6.6	$7.1	$8.4	$10.6
Other professional services	$1.4	$2.2	$2.4	$2.8	$3.5
Drugs and drug sundries	$6.7	$9.3	$9.9	$11.3	$13.2
Eyeglasses and appliances	$1.8	$2.9	$3.0	$3.9	$4.4
Nursing home care	$2.9	$4.8	$5.3	$6.1	$7.5
Other health services [4]	$2.5	$4.1	$4.5	$5.1	$6.0
Prepayment and administration	$2.1	$2.7	$2.8	$3.3	$3.7

[1] Tables 1 and 4. Population: 207,300,000; gross national product (GNP): $956,200,000,000.

[2] Social Security Administration projections by Rice and McGee, cited below. Populations 1975 and 1980: 217,600,000 and 232,400,000; GNP 1975 and 1980: $1,398,400,000,000 and $1,935,000,000,000.

[3] Includes all expenditures for health services and supplies other than Government public health and related activities, expenditures of private voluntary agencies for other health services, medical research, and medical facilities construction.

[4] For the projections, the same proportion as in 1969-70 (86 percent) of the estimated total for the category was included here as expenditures for personal health care services.

Source: "Actual, 1969–70," from source cited in tables 1 and 4; "Projections" of national health expenditures, 1975 and 1980," by Dorothy P. Rice and Mary F. McGee. Research and Statistics Note, No. 18, 1970, October 30, 1970 (Office of R. & S. SSA, DHEW).

On the basis of recent experience and the stated assumptions, these "SSA" projections indicate that total national health expenditures would be expected to rise from about $67 billion in 1969–70 to $111 to $120 billion in 1975 and to $156 to $189 billion in 1980. These imply increases of 11.8–14.3 percent a year for the period between 1969–70 and 1975, and of 12.5–17.3 percent a year between 1969–70 and 1980. Taking into account growth of population, annual *per capita* costs would be rising from $324 in the benchmark year to $509–$552 in 1975

and to $670–$815 in 1980. Though the gross national product (GNP) is estimated to increase from $956 billion in 1969–70 to $1,398 billion in 1975 and $1,935 in 1980, the health care expenditures—increasing at a higher rate than expansion of the national economy—would rise from 7.0 percent to 7.9–8.6 percent in 1975 and to 8.0–9.8 percent in 1980. In other words, health care which involved one dollar in fourteen of the national economy in the year 1969–70 would be moving toward accounting for one in twelve of a larger economy expected by 1975, and toward one in eleven or one in ten in the still larger economy assumed for 1980.

Since our special interest here is in the *personal health care services*, the expenditures for these categories in the "SSA" projections are also shown in Table 7. Their aggregate amount is estimated to increase from about $60 billion in 1969–70 toward $103 to $111 billion in 1975 and toward $147 to $178 billion in 1980. These are equivalent to increases in annual *per capita* costs from $290 in the table's base year 1969–70 to $473–$512 in 1975 and to $630–$766 in 1980. In relation to the increasing GNP, the personal health care expenditures would be rising from 6.3 percent to 7.4–8.0 percent in 1975 and to 7.6–9.2 percent in 1980. Thus, *personal health care*, responsible for one dollar in sixteen in the whole economy, would be tending toward utilizing one in fourteen, twelve or even ten.

Increase in aggregate expenditures for the personal health care services results from increases in all categories of service though at different rates of change, *most steeply for hospital care, physicians' services and nursing-home care.* Since the expenditures for these services are expected to increase at a higher annual rate of change than the communitywide and other non-personal services, the personal services would be becoming an increasingly large proportion of all health care expenditures: They accounted for about 89 percent of the total in 1969–70 and would be expected to rise to about 93 percent in 1975 and to about 94 percent in 1980.

Adjusted Projections

The "SSA" projections of national health expenditures to 1975 and 1980 in effect indicate what may be expected to come about if trends of the recent past continue, if there are no major changes in health care or in the financing programs, and if there are no substantial interventions to moderate the escalation of health care costs and expenditures. However, even without such interventions through formal and extensive national health-care programs, many steps are being taken and various measures are being invoked to moderate the upward sweep of health care costs. These are in large measure responses to public objections and resentments against escalations far steeper for health care than for essentials of living generally and steeper than the rise in real income. Some new restraints on cost increases for health services are being introduced by public authorities (by Congress and the Federal administrative agencies for Medicare and Medicaid, by state legislatures and their administrative, planning and regulatory agencies for Medicaid and for private insurance or prepayment contracts); cost control injunctions are being advocated by the Blue Cross and Blue Shield Plans and by hospitals, medical associations and others representing providers of care; and diverse utilization and cost control measures are being introduced.

Increasingly strong resistances against rising medical-care costs are being offered by consumers and employers. Less expensive ambulatory services are being substituted for much more expensive inpatient hospital services. The advantages of group practice plans for economical delivery of care are being made widely known, established plans are expanding, new plans are coming into operation, and new supports are appearing to accelerate further expansions and inaugurations.

The pressures for such restraints on cost escalations will no doubt persist; and, as health care expenditures continue to rise steeply, the measures that are taken may be expected to intensify. These counter-measures against rising costs have apparently already begun to have some effect on the cost escalations. More may reasonably be expected in the next few years, especially with respect to expenditures for hospital care and physicians' services. We should take these developments into account.

In addition to these measures that are directed specifically at the steep escalations of medical-care costs, a temporary (90-day) national program was initiated by the President in mid-August 1971 to control—or, at least, to moderate—increases in prices, wages, rents, etc., generally throughout the national economy. What may be done after the temporary price "freeze" period is not known at this writing. However, since such national undertakings—temporary or longer term—apply to various health service costs, they may substantially reinforce the cost-containment efforts being made within the health care "industry."

The estimates which emerged in the "SSA" projections may quite correctly reflect the outlook for 1975 and 1980 from the trend data of 1960–68 and from the non-interventional assumptions. We believe, however, that those estimates are unduly high and are unacceptable as a basis for prospective program cost estimates because the substantially total non-intervention assumptions are becoming unrealistic. This is to say that the steep escalations of the recent past which were projeced do not try to anticipate the moderations that are to be expected from such counter-efforts as have already begun to appear. Moreover, if cost escalations were to continue, unabated, as indicated in "SSA" projections, we would surely have to expect successively stronger and stronger countervailing measures to moderate if not actually to contain the steep upward movement of costs, prices and expenditures for health care services. Indeed, we are inclined to believe that these projections could be expected to prove to be realistic only if they were to obtain in an envrionment and economy with characteristics approaching those of a general runaway inflation. In any other circumstances the continued escalations would breed their own remedy from public outcry and resistance and from interventions to be expected before 1975 or 1980.

We have therefore adjusted the "SSA" projections by modest reductions in the rate of expected increases in the estimated expenditures for hospital care and physicians' services over the next few years. These two categories were selected because they involve the largest items of expenditure, they are the principal objects of outcries against cost escalations, and they are the main targets of current interventions to restrain cost increases. These delimited downward adjustments may be less than is already warranted.

Our estimates of personal health care expenditures for fiscal years 1973–74 and 1974–75 are based, in the first instance, on the "SSA" projections—using their "low" series in which the rate of escalation still exceeds the average rate for the pre- and post-Medicare period 1960–68. Their rates of escalation have been moderated by reducing the rate of change for hospital care to approximately the 10.9 percent rate which actually prevailed in the base period 1960–68 (i.e., reduced from 12.8 percent to the rate of 11.0 percent a year which our own studies had suggested) : and for physicians' services by reducing the rate by about 0.7 percent (i.e., reduced from 9.7 percent to our own estimate of 9.0 percent a year).[3] Fiscal year estimates were prepared from calendar year data for the individual years 1973–1975 furnished by the Social Security Administration.

The results of our studies are summarized in Tables 8 and 8A; and, as in Table 7, the prospective expenditures are shown in comparison with the actual expenditures in the benchmark fiscal year 1969–70. The expenditures for personal health care services are expected to increase from $60.1 billion in fiscal year 1969–70 to $85.1 billion in 1973–74 and to $92.8 billion in 1974–75. These reflect increases of 42 and 54 percent, respectively, above the expenditure level of the benchmark year for the four-year and five-year interim periods. These are generous increases—slightly more than an average of 10 percent a year. The *per capita* expenditure figures, taking account of population growth, would rise from $290 to $397 and to $428; and the portion of the enlarging gross national product utilized for personal health care services would have gone from 6.3 to 6.7 and to 6.9 percent.

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[3] No moderations were made in the rates of change applicable to other categories of service—though some may soon be indicated (as for nursing home care).

TABLE 8.—ACTUAL EXPENDITURES IN 1969-70 AND ADJUSTED PROJECTIONS TO FISCAL YEARS 1974 AND 1975 FOR PERSONAL HEALTH CARE SERVICES

[National dollar amounts in billions]

National expenditures	Actual fiscal year 1969-70 [1]	Adjusted projections [2]	
		Fiscal year 1974	Fiscal year 1975
Total (amount)	60.1	85.1	92.8
Per capita	$290.0	$397.0	$128.0
Percent of GNP	6.3	6.7	6.9
Hospital care	25.6	36.9	40.9
Physicians' services	12.9	18.6	20.3
Dentists' services	4.2	5.9	6.4
Other professional services	1.4	2.0	2.2
Drugs and drug sundries	6.7	8.6	9.0
Eyeglasses and appliances	1.8	2.6	2.8
Nursing home care	2.9	4.2	4.6
Other health services	2.5	3.8	4.0
Prepayment and administration	2.1	2.5	2.6

[1] From tables 1, 4 and 7.
[2] Adjusted from the "SSA" projections in table 7 (see the text).

Note: Corresponding further projections would give totals of $101.2 billions for fiscal year 1976 and $110.4 billions for fiscal year 1977.

TABLE 8A.—ACTUAL EXPENDITURES IN 1969-70 AND ADJUSTED PROJECTIONS TO FISCAL YEARS 1974 AND 1975 FOR PERSONAL HEALTH CARE SERVICES BY SOURCE OF FUNDS

[National dollar amounts in billions]

National expenditures by source of funds	Actual fiscal year 1969-70 [1]	Adjusted projections [2]	
		Fiscal year 1974	Fiscal year 1975
All	$60.1	$85.1	$92.8
Private	39.3	55.5	60.6
Governmental	+20.8	29.6	32.2
Federal	13.9	19.7	21.4
General revenues	[3] 8.4	11.9	13.0
Other	[4] 5.5	7.8	8.4
State and local	7.0	9.9	10.8

[1] From table 2.
[2] Source of funds according to proportions in 1969-70 (table 3).
[3] See page 5.
[4] Medicare payroll taxes and premiums (table 17).

Table 8A shows the projections by source of funds, on the assumption that the proportionate allocations in the prospective years would remain as they were in the benchmark year. On this basis, the private expenditures would increase from $39.3 billion in 1969–70 to $60.0 billion in 1974–75; and the governmental from $20.8+ billion to $32.2 billion.

These tables, though based on relatively moderate projections, show large increases in expenditures which would bring great difficulties for the health care system and for the population needing and expecting health care; and they would generate strong resistances against such trends and their consequences. Steeper upward trends and higher expenditure expectations seem to us to be unrealistic, and even these which we propose to use for our further analyses may be too high for periods only four and five years ahead.

We are not unmindful that the escalation of health and medical care costs at rates faster than for other costs of living has been going on for decades. It has been very steep in recent years and has become one of the most acutely disturbing aspects of the current "medical care crisis." The projections reflect that, unless there is massive program intervention, there is no end to these cost escalations in sight. But this is an unacceptable perspective, since society cannot view with equanimity increases in health service costs toward absorbing an endlessly increasing share of earnings, disposable personal income, and the national economy, especially in the face of increasing disatisfactions with the adequacy of medical care for large and apparently expanding proportions of the population. Program intervention is unavoidable.

The steep annual increases in the expenditures for the health and medical services compound annually. Consequently, the longer the program intervention to deal with these costs is delayed, the higher the costs that will have to be built into whatever program pattern will then have to be undertaken. Conversely, the costs aspects of an improved program for health care will be more easily manageable the sooner such a program is brought into operation. Effective program intervention is therefore urgent.

IV. THE HEALTH SECURITY PROGRAM

The Committee for National Health Insurance was organized in 1968 to undertake the design of a program to meet urgent national needs for improvement of medical care. From its beginnings, the Committee recognized duality in its general objectives: to encourage and facilitate the development of adequate resources and organization for the availability and delivery of medical care; and to design a system for the sufficient and assured financing of medical care services. The Program Principles adopted by the Committee, which are included in Appendix A, became the guidelines when its Technical Subcommittee proceeded to develop specifications for a program.

The Technical Subcommittee, assisted by many consultants, formulated the following more specific objectives as a framework for proposed specifications—

1. The whole population should be eligible for all the benefits of the program, according to the need for health care and without financial tests or barriers.
2. The program should undertake to assure the availability of all useful and promising medical care services within the spectrum of its benefits.
3. The desired organizational pattern and delivery system should, as a practical matter, be achieved on an evolutionary course which starts with acceptance of current patterns and practices, and with provider incentives and supports for developments toward the declared goals.
4. The national economy as a whole should be the underlying source of financing, both for the development of needed resources for the provision of services, and for adequate and assured support of continuing functional performances.
5. To be acceptable as well as viable, the program design should be based on a partnership of—(a) national public financing, and (b) private provision of medical care services, through self-selected diversities among providers of services, their location, organization, professional and fiscal operations, and participation in planning and administration.
6. Continuing financial supports should be assured through—(a) taxes which are earmarked for medical care and which automatically adjust to the state of the national economy, (b) matching or supporting appropriations from general revenues, made as nearly automatic as possible, and (c) utilization of the total yield through a trust fund permanently available for the support of the program, minimizing the uncertainties of annual appropriations.
7. The program's fiscal operations should rest on prospective annual budgets for the support and compensation of providers of medical care services and goods, in order to bulwark planning and to contain costs within levels determined by national decisions.
8. To assure the worth of services supported by public funds, the design of the program should provide for standards of quality and the administration should be required to implement all practical measures for the observance of such standards.

9. Administration of the program should involve not only the public authority but also the participation of representatives of consumers as well as providers of services.

10. There should be mandatory provisions for public accounting of program operations and performances.

The specifications which were developed by the Subcommittee are given in some detail in Appendix B in the form in which they were subsequently elaborated for inclusion in a bill introduced in Congress (S. 3 and H.R. 22, 92nd Congress, January 25, 1971). Their general scope and content for benefits and administration may be summarized here.[4]

The population coverage of the proposal extends to substantially all persons resident in the United States, and all would be eligible for benefits without either contribution histories or means tests. The benefits to be available include all needed personal health services from all available qualified providers, including services for prevention and early detection of disease, diagnostic and treatment care, and rehabilitation services, from physicians and other qualified individual providers, and from hospitals and other institutions, inpatient and ambulatory. With a few exceptions, there would be no arbitrary cutoff dates for services, and there would be no deductibles and no copayments required from persons served. Four exceptions to unlimited care according to need are with respect to: dental care (surrounded initially by age limitations, the benefits are to be broadened as rapidly as feasible); skilled nursing home care (limited as to duration); psychiatric consultations (limited to twenty consultations in a benefit period not an element of organized comprehensive care or provided by a participating institution) and psychiatric hospitalization (limited to active treatment up to forty-five inpatient days in a general or psychiatric hospital); and prescribed medicines, which are not covered unless provided through a hospital organized care program or required for treatment of chronic disease or conditions for which drug therapy is costly.

Specifications for qualifying providers, indivdual and institutional, are patterned after those developed under Medicare but go further in providing for requirements as to continuing education and in permitting interstate personnel mobility for the federal program despite state requirements of licensure. Payments to individual providers may be made through alternative methods (fee-for-service, capitation, stipends, and so forth); to hospitals and institutional providers on the basis of approved prospective budgets; to comprehensive organizations and to professional foundations (which meet prescribed qualifications) on the basis of capitation amounts (or through alternative negotiated methods); and to other providers (for services, medicines, or appliances) on adaptive bases.

Broad policies and diverse specific guidelines are laid down for the planning and implementation of resources development—to improve the supply and distribution of health service personnel and the location of facilities and for the organization and delivery of health services, with participation by health planning agencies in the states. The guidelines extend to fiscal and technical supports for education and training of needed personnel, with special supports for members of minority groups; incentives for the development of comprehensive health service organizations; provisions for coordination and linkages among institutional providers; and supports for services needed in underserved urban and rural areas.

Restrictive state laws that would obstruct program developments are declared inoperative in relation to provision of benefits under this program. This applies to interstate movement of professional practitioners and to the functions permitted to various categories of ancillary personnel (subject, in both cases, to meeting national standards), and to corporate practice of medicine in hospitals and comprehensive health service organizations. If a comprehensive organization cannot be incorporated in a state for various specified reasons, it may be given national incorporation and authorization to function under the proposed program.

The guidelines for resources development specify that the undertakings under this program shall supplement and not absorb or supersede existing programs

[4] Adapted from a summary by I. S. Falk in *Law and Contemporary Problems*, Duke University School of Law, September 1971.

in this field. The Secretary of HEW is directed and authorized to coordinate established programs with the new undertakings to be developed under this program.

Administration is assigned to public authorities: a full-time national Board (under the Secretary of HEW), which is to function with a statutory national Advisory Council and with professional and technical advisory committees and to operate through regional and local offices, assisted by advisory councils with consumer and professional representatives. Provisions are made for hearings and judicial review; for a comprehensive series of prospective studies; and for special studies with respect to such matters as benefit provisions for U.S. citizens when abroad, needs for long-term care, coordination with other federal health benefit programs, and malpractice liabilities.

The Medicare and Federal employee health benefit programs would be absorbed into the health security program and would be repealed. Federal aid for Medicaid, vocational rehabilitation, and maternal and child health services would be phased out except as the proposed health security program does not take over their service provisions.

Even at the risk of repetition, we would recapitulate the principal points which are especially important for our focus on costs and their financing—

1. Eligibility of substantially all persons resident in the U.S.A. for all the personal health care benefits of the program;

2. Eligibility of all qualified practitioners and institutions to participate;

3. Services to be available without arbitrary limitations, except for four categories (dental, nursing home, psychiatric, and medicines and appliances);

4. Compensation to individual providers by various methods of their choice; and to institutional providers through approved prospective budgets;

5. Diverse incentives and supports to encourage: development of organized arrangements for the availability of comprehensive services, economy in operations, and observance of quality standards; and

6. Reliance on a budget pattern to determine the expenditures which may be incurred annually.

With these specifications and emphases as a basis, we proceed to consider the prospective direct costs of the health security program and how those costs may be financed.

V. ESTIMATES OF EXPENDITURES UNDER THE HEALTH SECURITY PROGRAM

Definitive estimates for expenditures under the proposed national system of health security must reflect many detailed decisions about the benefits to be provided, assumptions and estimates about volumes of services, costs, prices, income levels for those who furnish services, and other factors applicable to the prospective operational years of the program. Benchmark estimates which will indicate the approximate level of the cost figures may be developed by using current expenditures in the last year for which detailed data are available at this time, fiscal year 1969–70. In effect, such estimates serve the purpose of indicating what the costs would have been if the proposed system of national health security had been functioning in that benchmark year.

Benchmark Cost Estimates, 1969–70

The estimates were developed by inspecting the current (1969–70) levels of expenditures and arriving at estimates of the expenditures that would have been incurred under the health security program in that year. These estimates took account of the specifications for the proposed program, data available from many sources on service utilizations and expenditure patterns, and the expectations and opinions of those who had worked on the design of the specifications.

Our procedure was to examine private expenditures by type of expenditure and expenditures under public programs according to program, object of expenditure, and source of funds. For each category, a coverage percentage was estimated on the basis of all applicable considerations and the data available to us.

For those categories in which the proposed benefits would be delimited under the health security program, available data on expenditures were used to guide the estimates. For example, *for dental care*, estimates were developed by the Subcommittee and by a special task force on proportionate services (and expendi-

tures) for dental care of children and young persons in the current patterns, and estimates of what might reasonably be expected under the proposed benefit specifications; *for psychiatric services,* estimates were made of approximate proportionate expenditures for active medical care as distinguished from custodial and maintenance care in 1969–70, and estimates were developed for what might be expected under the proposed program in light of reviews by a special task force; *for nursing home care,* estimates were made for proportionate distributions and expenditures for which probably would not qualify for benefits under our proposed specifications, and for occupancies extending beyond those intended to be covered by the program, having special regard for experiences since the enactment of Medicare and Medicaid; *for medicines,* estimates of noninstitutional expenditures for medicines prescribed for various broad categories of disease made allowances for expected impacts of the proposed specifications and having regard for experiences under private insurance programs and under domestic and foreign (public) programs; and *for prescribed appliances,* the estimates were based on the program specifications and the intent to contain costs within a fixed maximum percentage of total benefit expenditures.

For categories in which the benefits would not be delimited, patterns of current private expenditure were inspected for relations to the proposed specifications. *For hospital care,* separate estimates were developed for general and special short-term and for psychiatric and other long-term hospitals. For the short-term hospitals, the coverage estimate (95 percent) excluded only estimates for flagrantly unwarranted operating costs (for unnecessary services and medically unjustified admissions) and for expenditures (like gift shops, visitors' dining rooms, etc.) not directly chargeable as medical care costs; for the long-term institutions, the coverage estimate (10 percent) attempted to approximate a portion of the total costs chargeable to active medical care within the meaning of the proposed benefits. *For physicians' services,* the exclusion of 5 percent of current expenditures from the coverage estimate reflected an approximation of expenditures clearly unwarranted because reflecting exorbitant fees, excessive surgery or ancillary services, performances by practitioners who do not meet qualifications in the proposed benefit specifications, services that would be excluded by referral requirements, etc., *net* of expected increases from increased service utilizations to be expected under the proposed program. For the categories "*other professional services*" and "*other health services*" in Table 9, the coverage estimates (80 percent and 15 percent, respectively) reflect composite estimates for the inclusion only of expenditures to practitioners of various kinds who would qualify as participating providers in the program, or with respect to services or commodities that would be covered as benefits.

For the current expenditures *under public programs,* the estimates (shown in Table 10) were developed by corresponding inspections, having regard for the characteristics of each program—objectives, population eligibilities, scope of services, sources of funds, etc.—and for the large volume of available data on patterns of operations.

Expenses for administration were estimated on the basis of position papers presenting various alternative designs for administration of the proposed program, and from estimates of manpower needed for administration, of expenditures for pre-payment under private insurance, for the administration of public programs (national, Federal-state, and state-local). *Resources for development* were fixed as percentages of program obligations on the basis of needs and the probable costs of meeting them, with regard for the maximum amounts which it may be feasible to expend usefully and effectively in successive years in light of recent experiences under privately initiated undertakings and under programs providing public incentives and supports.

We would emphasize that the coverage percentages shown in Tables 9 and 10 indicate the proportion of current total expenditures, by category of expenditure, estimated as potentially included within the health security program if it had ben operational in 1969-70. These percentages do *not* imply limitations in the program's 100 percent coverage of costs for covered services furnished to persons receiving benefits under the program, because there would be neither deductibles nor co-payments for covered services provided to the population eligible for the benefits.

TABLE 9.—ESTIMATES OF PERSONAL HEALTH CARE EXPENDITURES POTENTIALLY INCLUDED INITIALLY IN A NATIONAL HEALTH SECURITY PROGRAM, AS OF FISCAL YEAR 1969–70

Object of epxnediture	Private expenditures			Expenditures under public programs [1]			All expenditures		
		Potentially included			Potentially included			Potentially included	
	Total (millions)	Amount (millions)	Percent	Total (millions)	Amount (millions)	Percent	Total (millions)	Amount (millions)	Percent
Total	$39,253	$27,204	69	$20,846	$11,866	57	$60,099	$39,850	66
Hospital care	13,292	12,277	[2]	12,333	7,157	58	25,625	19,434	76
Physicians' services	9,655	9,172	95	3,275	2,510	77	12,930	11,682	90
Dentists' services	3,906	781	20	241	172	71	4,147	953	23
Other professional services	1,186	949	80	248	197	79	1,434	1,146	80
Drugs and drug sundries	6,297	1,700	27	444	331	75	6,741	2,031	30
Eyeglasses and appliances	1,742	697	40	60	23	38	1,802	720	40
Nursing home care	1,068	267	25	1,776	581	33	2,844	848	30
Other health services	439	66	15	2,087	529	25	2,526	595	24
Expenses for prepayment	1,667						1,667		
Expenses for ad ministration		[3] 1,295		383	366	96	383	[4] 1,661	[4]
Resources development								[5] 780	[5]

[1] Includes Federal and State-local public programs. (See footnote in table 10, and supplementary note below.)
[2] Including: For general hospitals 95 percent, and for psychiatric hospitals 10 percent.
[3] 5 percent of aggregate expenditures for potentially included amounts.
[4] Equal to 4.4 percent of aggregate expenditures for potentially included amounts.
[5] 2 percent of the amount available for obligation during the year.

Source: Basic data (totals) from "National Health Expenditures, 1929–70," by Dorothy P. Rice and Barbara S. Cooper. Social Security Bulletin, January 1971, 34:1, table 2.

Supplementary note: If the possible revisions for expenditures under public programs indicated in the footnote on table 10 were accepted, the totals for potentially included expenditures shown here would become: under public programs $12,453,000,000 (plus $587,000,000) (60 percent of the total), and for all expenditures under the NHSP $40,437,000,000 (67 percent of the total). Account will be taken of these possible revisions in subsequent text.

TABLE 10.—EXPENDITURES UNDER PUBLIC PROGRAMS, FISCAL YEAR 1969–70, AND ESTIMATES OF AMOUNTS INCLUDED AND EXCLUDED IN THE POTENTIAL INITIAL COSTS OF A NATIONAL HEALTH SECURITY PROGRAM (NHSP)

[In millions]

Type of expenditure	Total 1969–70			Included in NHSP			Excluded from NHSP		
	Total	Federal	State and local	Total	Federal	State and local	Total	Federal	State and local
All	$24,982	$16,667	$8,315	$11,866	$9,317	$2,549	$13,116	$7,350	$5,766
Health and medical services	22,274	14,502	7,772	11,866	9,317	2,549	10,408	5,185	5,223
Health insurance for the aged	7,149	7,149		7,149	7,149				
Workmen's compensation (medical only)	790	19	951				970	19	951
PA (vendor medical payments)	5,042	2,515	2,527	2 913	1,430	1,453	2,129	1,055	1,074
Mental hospitals	413	207	206	70	35	35	343	172	171
Nursing homes	1,432	714	718	286	150	136	1,146	564	582
Other	3,197	1,594	1,603	2,557	1,275	1,282	640	319	321
General hospital and medical care	3,132	216	2,916	[1] 1,063	165	[1] 898	[1] 2,069	51	[1] 2,018
DOD hospital and medical care	1,650	1,650					1,650	1,650	
Military departments medical care	250	250		[1] 180	[1] 180		[1] 70	[1] 70	
Maternal and child health services	429	214	215	200	100	100	229	114	115
Other public health	1,429	627	802				1,429	627	802
VA hospitals and medical care	1,599	1,599					1,599	1,599	
Medical vocational rehabilitation	152	114	38	152	114	38			
OEO health and medical care	149	149		149	149				
Temporary disability insurance (medical benefits)	60		60	60		60			
School health (educational agencies)	263		263	[1] (?)		[1] (?)	[1] 263		[1] 263
Medical research	1,695	1,622	73				1,695	1,622	73
Medical facilities construction	1,013	543	470				+ 1,013	543	470

[1] A review performed after completion of tables 9 and 10 suggests various possible revisions in the estimates shown here: The amount "included in NHSP" from State and local expenditures for "general hospital and medical care" may be too low by about $385,000,000 and may be estimated as $1,283,000,000 (44 percent) instead of $898,000,000 (31 percent) of the total $2,916,000,000; the total Federal expenditure for "military departments medical care," $250,000,000 may be included in NHSP; and a substantial though indeterminate share of State and local "School health (educational agencies)" expenditures may be absorbed into NHSP. If these revisions were accepted (including transfer from "excluded" to "included" of ½ the school health expenditures), they would increase the "total" potentially included amount for health and medical services to $12,453,000,000 (plus $587,000,000)—$9,387 Federal (plus $70,000,000) and $3,066,000,000 State and local (plus $517,000,000). Account will be taken of these possible revisions in subsequent text.

Source: Basic data ("total 1969–70" columns) from: "National Health Expenditures, 1929–70," by Dorothy P. Rice and Barbara S. Cooper. Social Security Bulletin, January 1971, 34:1, pp. 3–18; and subdivisions for PA (vendor medical payments) and Department of Defense expenditures, from the Social Security Administration, DHEW.

The results of these inspections of expenditures in 1969–70 are shown in Table 9 by category of service (i.e., by object of expenditure), according as the expenditure in the benchmark year was private or under a public program, and for private and public expenditures combined. The detail with respect to the expenditures under public programs is given in Table 10, showing for each such program the amount estimated to be absorbed within or excluded from the coverage of the health security program. The data may be summarized as follows:

COST ESTIMATES FOR HEALTH SECURITY PROGRAM COVERAGE, AS OF FISCAL YEAR 1969-70

Expenditures	All personal care (billions)	Potentially covered by the health security program				
		Total (billions)	Percent	Percent of all	Per capita	Percent of GNP
All	$60.1	$39.9	100	66	$192	4.2
Private	39.3	27.2	68	69	131	2.8
Public	20.8	11.9	30	57	57	1.2
Resources development		.8	2		4	.1

Thus, if the proposed program of health security had been functional in fiscal year 1969–70, substantially at the then current levels of costs for the categories of service intended to be covered by the program, it would have involved (Table 9) expenditures of about $39.9 billion, equivalent to about two-thirds of the expenditures actually made during that year for all personal health care services. It would have paid for something approximating comprehensive care, except for the specifically limited or non-covered services, for substantially the entire population at a cost of about $192 *per capita*. It would have absorbed about 69 percent of all *private* expenditures, leaving about 31 percent still to have been met privately—whether under existing insurance programs or by out-of-pocket payments. It would have taken over about 57 percent of all expenditures made that year for personal health care services under *public programs* (Table 9), relieving the Federal Government of $9.3 billion of expenditures mainly for Medicare and Medicaid, and the state and local governments of more than $2.5 billion of expenditures mainly for Medicaid and for general hospital and medical care (Table 10). The proposed program would have utilized about 4.2 percent of gross national product.[5]

These estimates may be summarized in another way. In 1969–70, the population spent in the aggregate, through private and governmental expenditures, about $60 billion for personl health care services—amounting to $290 *per capita* (Table 7). If the proposed health security program had been fully operational that year, it would have involved about $40 billion or $192 *per capita*. For this amount, which is about $100 *per capita* less than the actual total expenditures of that year, the population could have had all needed physician, hospital and other health services that could have been available to them under the program that year, without having to satisfy the eligibility or premium requirements of private insurances, without having to meet "barrier" payments in the form of deductibles or co-insurances—and all this while the program was paying for the services at the current cost or price levels of that year. This assumes, of course, that the health security program had become operational that year after the preparatory improvements in the medical care system intended in the "tooling-up" period and that the covered services were available under the operational patterns contemplated by the program.

Validity of the Benchmark Cost Estimates

As we proceed to utilize these benchmark estimates as a basis for anticipating the costs of the national health security program in future years we have to keep in mind that they were based on a hypothetical application of the health security program to the fiscal year 1969–70. And we have to be clear about the assumptions, explicit and implicit, bearing on the question whether—and to what

[5] Possible revisions for estimated expenditure under *public* programs (Table 10, footnote [1]) would increase the potentially covered dollar figure from $39.9 billion to $40.4 billion (67 percent of the total in Table 9), and the amounts absorbed from Federal expenditures by an additional $70 million and from state-local public expenditures by an additional $517 million.

extent—the availability of the propsed program would have invited and led to changes in the expenditures.

Initially, one effect of such availability as was postulated should have been an increase in the utilization of health services, a consequence of removing economic barriers and of dealing with some of the deficiencies in the arrangements for delivery of care which stand in the way of receiving needed services; and an increase in utilization usually means an increase in cost and expenditure. Such an increase in medical care cost and expenditure might, however, have reflected not only an increase in volume of utilization but also an escalation of prices because of larger effective demand on the available resources. We have seen just such increases in utilization, in prices, and in expenditures following first the initial enactment and then the operation of Medicare, apparently because that program provided new resources for payment of costs incurred for persons 65 years of age and over while effecting no substantial changes in resources, organization or procedures for delivery of care. Thus, if a national health security program effected only the removal of financial barriers to the receipt of health services, increase in utilization and in expenditures would have had to be expected. We must emphasize, however, that increases in utilization would occur only gradually and not all at once; and—despite the expression of fears from various quarters—experiences with newly instituted medical care programs have been showing for decades that, even if there are no substantial controls, new demands for services are initially only a small fraction of services alreday being provided. This was most recently evidenced when Medicare benefits first became available. The capacity of service providing resources do not change greatly when a new program becomes available, and neither do public perspectives and effective demands for service.

On this basis, and if there were no countervailing effects, the benchmark cost estimates derived above—based on actual expenditures in fiscal year 1969–1970—would have had to be increased by (say) 5 or 10 percent even for the program's initial operational year, and prob bly by further increa es later. In view of the already unacceptable strains on various resources for health care, and in light of the steeply escalating costs of recent years, a health insurance program which did no more than make more money available to convert health service "need" into "effective demand" could have invited unmanageable strains on the resources for service and even disastrous escalations of prices, costs, and expenditures.

However, a sensible national health program anticipates these potential consequences. It undertakes to assure—as far as possible—that even its initial years' fiscal resources are used only for needed services, that the costs for producing and delivering the services are restrained, and that the services are provided through professionally and economically sensible organizational arrangements. Such a program therefore expects to invite increase in utilizations, but only in truly needed utilizations and without substantial increase in unit prices or even in total expenditures. The opportunities to contro wasteful practices, to minimize extravagant expenditures, to discourage excessive services, and to encourage more efficient use of health manpower facilities are very large. Consequently, the health security program with which we are concerned here—with its provisions for controls—could anticipate reduced expenditures as logically as expecting increased expenditures for the year in which it becomes operational.

We have built into the health security program a wide variety of specifications to provide not only for the availability of the covered services without financial barriers but also—and at the same time—for improvements in the efficiency and economy of the medical care system of delivery. We expect increases in needed medical care utilizations, and for them to occur gradually; and we expect reductions in unwarranted services and increases in productivity of the resources for medical care, and for them to be effected more rapidly. We therefore regard it as sound to assume that *increases* in costs resulting from larger utilizations of services which have been medically insufficient and inadequate and which can be quickly improved would be offset by *reductions* in costs resulting from even a substantial beginning in the control of over-utilizations, inefficiencies in provision of care, and other wasteful or extravagant practices. We therefore use the cost estimates adapted from fiscal year 1969–70 expenditure levels as benchmark data without further arbitrary increases for the initial years of the national health security system.

Higher Cost Estimates for Future Years

The specifications for the health security program propose that the health services of the program should become available on July 1 of the second calendar year after the year in which the program is enacted. If enacted in 1971, the first "benefit year" would be the fiscal year 1973–74; and if in 1972, it would be the fiscal year 1974–75. Thus, at least four and possibly five years would have elapsed between the benchmark year 1969–70 and the first "benefit year." We have to assume that in this interim the annual national expenditures for health care will be rising—presumably according to the pattern indicated by our adjusted projections summarized in Table 8.[6]

Estimates for expenditures under the health security program in fiscal years 1973–74 and 1974–75 are shown in Table 11. They were developed by applying to the estimated national health care expenditures (Table 8) the estimated coverage percentages, by category of service, in Table 9. Thus, if first fully effective in 1973–74, the program would be expected to have obligations of about $56.7 billion, and if first effective in 1974–75, of about $62.5 billion—including in each case the costs of administration and resources development.

We must expect that, beyond an initial operational year, the costs to be incurred by the proposed program would need to increase, especially if the program starts with the several benefit delimitations which had to be incorporated in the specifications. This reflects not only the outlook for continuing growth of population and the expectation of certain larger utilizations gradually, but also the broadening of the benefit services delimited initially and of needed supports for undertakings to improve the resources for medical care and the arrangements for improved delivery of care. Thus, even if prices remain—or are held—moderately stable, the costs would need to increase; and they may require a somewhat larger share of the GNP of the future years. Instead of needing somewhat more than 4.0 percent of GNP by 1969–70 standards (page 24), the costs of the program may need to go to 5.0 or even 6.0 percent of GNP—or even higher—when resources for health services have become more rationally organized as well as more adequate. Such a progression would depend, however, not only on what happens to the health service system but also on the course of the economy as a whole.

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[6] Enactment in 1971 is now impossible. Nevertheless, fiscal year 1973–74 was retained in this report as a first possible benefit year because this is the pattern in bills (S. 3: H.R. 22, 23, etc.) currently before the Congress and fiscal year 1973–74 is being widely used for cost estimates applicable to the health security program and to various national health insurance proposals.

TABLE 11.—EXPENDITURES UNDER THE HEALTH SECURITY PROGRAM ESTIMATED FOR ITS 1ST BENEFIT YEAR AS OF FISCAL YEARS 1973-74 AND 1974-75[1]

[National dollar amounts in billions]

Object of expenditure	Fiscal year 1973–74	Fiscal year 1974–75
Total	$56.7	$62 5
Percent of all[2]	67.0	67.0
Per capita	$264.0	$289.0
Percent of GNP[3]	4.5	4.6
Hospital care	$28.0	$31.1
Physicians' services	16.7	18.3
Dentists' services	1.4	1.5
Other professional services	1.6	1.8
Drugs and drug sundries	2.6	2.7
Eyeglasses and appliances	1.0	1.1
Nursing home care	1.3	1.4
Other health services	.9	1.0
Administration[4]	2.1	2.4
Resources development[5]	1.1	1.2

[1] Estimated by applying to the adjusted projections in table 8 the coverage percentages (by object of expenditure) in table 9. Some possible revisions noted in tables 9 and 10 would not change these figures substantially, adding as a maximum about $86,000,000 for 1973–74 and about $90,000,000 for 1974–75.

[2] Percent of expenditures for all personal health services shown in table 8. The percent is slightly higher here (67) than in table 9 (66) because a larger proportion of the total here is for categories (like hospital care and physicians' services) with very high program coverage.

[3] Estimated gross national product fiscal year 1974 and fiscal year 1975: $1,265,000,000 and $1,352,500,000,000.

[4] Estimated as 4 percent of expenditures for benefits.

[5] 2 percent of the amount available for obligation.

Beyond the beginning of the first full program benefit year, whether this proves to be mid-1973 or mid-1974, or even beyond January 1 of the first year in which the health security taxes become payable, we have assumed that the system-improvement provisions built into the program would have begun to exercise restraining effects on the rate of escalation in medical care costs. These provisions should moderate the annual rates of increase after the program becomes operational from approximately 9–10 percent per annum *toward* the level of *6 percent per annum*—the combined rate for assumed population growth and price escalation of the general economy. We have therefore assumed annual rates of increase of *6 percent* for the subsequent functional years to which our projection of costs might extend.

System Improvement

The health security program includes—in addition to the operations of a national health insurance—many explicit provisions to stimulate and support improvement in the resources for the availability of medical care and for its delivery. After extensive review of needs, of potential undertakings, and of expenditures which may be profitably incurred, provision was made for (a) an interim program for system improvement to be carried forward vigorously during the "tooling up" period between enactment of the legislation and the effective date for the availability of covered services, and (b) a definitive continuing program of system improvement to take over after the effective date for the availability of benefits.

The specifications provide that the interim program should be financed, separately, by appropriations from Federal general revenues—authorizing the appropriation of $200 million for the fiscal year beginning in the year of enactment and $400 million for the next fiscal year.[7] These amounts do not enter into our estimates of costs beginning with the fiscal year 1973–74 or 1974–75.

For the definitive and continuing program proposed to begin July 1, 1973, or July 1, 1974, it is intended that these important undertakings for system improvement should be financed through portions of the fiscal resources in the program's permanent Trust Fund. The specifications provide for the transfer into a Health Resources Development Account of amounts equal to 2 percent of the global costs for reach of the first two benefit years, 3 percent for each of the next two fiscal years, and further increases by 1 percent for each two succeeding fiscal years, these transfers leveling off at 5 percent beginning with the seventh fiscal year.[8]

It will be noted that we have increased the cost estimates for the program operational years by the percentages required to finance this special Account. This may be an excessive allowance because in part the system improvement expenditures will finance services already budgeted in the estimates for the costs of covered services, and because in part it should be possible to meet these expenditures from within the escalated estimates through the cost-containment provisions built into the specifications for the operational program.

Summary of Program Expenditure Estimates

Our reviews and assumptions therefore lead to the following estimates for the expenditures under the health security program, including the national health insurance and the system improvement undertakings.[9] [10]

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[7] Section 101(b) in S. 3 and in H.R. 22, 23, etc., 92d Congress, 1971.
[8] Section 63(b) in S. 3 and in H.R. 22, 23, etc., 92d Congress, 1971.
[9] Exclusive of the appropriations from general revenue for the system improvement undertakings in the two fiscal years between enactment and benefit provision.
[10] These projections do not include any explicit provisions for increases in costs by reason of changes in the specifications for delimited benefits (e.g., for dental care, certain medicines and appliances, skilled nursing home care, or for psychiatric services).

Estimated expenditures for the program[1]

INITIAL BENEFIT YEAR, 1973–74

Fiscal year:	*Billions*	Calendar year:	*Billions*
1973–74	$56.7	1973	[2] $28.4
1974–75	60.1	1974	58.4
1975–76	63.7	1975	61.9
		1976	65.6

See footnotes at end of table, p. 544.

INITIAL BENEFIT YEAR, 1974–75

Fiscal year:	*Billions*	Calendar year:	*Billions*
1974–75	$62.5	1974	[2] $31.3
1975–76	66.3	1975	64.4
1976–77	70.2	1976	68.3
		1977	72.3

[1] Benchmark year, 1969–70: $39,900,000,000.
[2] Expenditures for one-half year.

These estimates for the health security program rise from $39.9 billion (applicable to the price, utilization and expenditure levels of fiscal year 1969–70) to $56.7 billion for the first fiscal year of program operations if in 1973–74 and to $62.5 billion if in 1974–75. Thereafter, the figures rise by 6 percent a year, our assumed rate for expansion of benefits, growth of population, general increase in prices, etc., net of system improvements and economies.

It should be clear, however, that the increase in the estimates between the year 1969–70 and 1973–74, or between 1969–70 and 1974–75, reflects not the operation of the health security program but, on the contrary, the increase in medical care costs which has already occurred since June 30, 1970, and the expected increases ahead before the health security program can become operational.

VI. FINANCING THE PROGRAM

The estimates developed above indicate that, at fiscal year 1969–70 utilization and expenditure levels, the initial total expenditures for the health security program would have been about $39.9 billion, 4.2 percent of the GNP of that fiscal year (page 22). We would emphasize, again, that those costs would not have been new expenditures for personal health care, but only a re-routing—through the proposed national system—of expenditures already being made in that year through private and public channels.

Primary Allocation of Costs between Federal General Revenues and Special Taxes

Of that total cost of about $40 billion in 1969–70, about 30 percent of the health security program expenditures would have been incurred for services which in that year were actually incurred under public (i.e., governmental) programs. From that pattern of expenditure, we reasoned that even with no increase in the direct government share of the cost approximately one-third of the total expenditures for the health security program would have been funded from and through public (tax and related) funds. Our Technical Subcommittee was unanimous in concluding that we should subscribe to assured unitary *national* financing of the proposed national program, as in the well-established and generally accepted national system of social insurance (OASDHI). The case for this view was strongly reinforced by arguments for reducing the continuing burdens of State and local governments that result from financing the costs of personal health services under Medicaid and other Federal-State, State, State-local, or local programs. Accordingly, the Subcommittee recommended that all financing of the health security program should be effected by the Federal Government, with at least a major share of the costs financed through Federal general revenues.

The subcommittee was also mindful of two other important fiscal objectives:

(*a*) to shift more of the current costs of personal health care services from individual to national fiscal resources, especially to reduce the load of medical care costs which fall on lower income groups, and

(*b*) to provide for costs incurred for persons who cannot be reached, adequately or at all, by taxes related to income.

When arriving at these conclusions, we were well aware that the expenditures made by public agencies are funded in various ways and from diverse sources—from Federal general revenues, from Federal compulsory payroll taxes and supplementary premiums for Medicare, and from State and local funds raised through many kinds of taxes (including payroll taxes for medical benefits under temporary disability insurance programs).[11] A distinguishing characteristic of these governmental expenditures is that they are made for services which our

[11] Expenditures under workmen's compensation programs are not included in the health security program data.

society has already decided are endowed with a public interest sufficiently strong and pervasive to warrant governmental intervention. Our Subcommittee was therefore of the opinion that however the funding patterns for these expenditures came about historically, they should now begin to be made rational and equitable in relation to the current and prospective characteristics of the economy. Rational financing, it seemed to us, should minimize the regressivity of the underlying funding processes; should maximize the progressivity of that financing—especially for the indigent, the medically indigent, the aged and other disadvantaged groups; and should give relief to State and local governments and to the taxpayers of those jurisdictions from burdensome expenditures under Medicaid and related medical care programs for the poor and near-poor. Rational financing under programs sponsored by government should also serve toward minimizing the unevenness of fiscal burdens left upon employers as a result of differences in community medical care needs and programs, and the large differences among employers in the impacts of diverse provisions under collective bargaining.

The Subcommittee therefore concluded that at least one-third and indeed a larger share of the total costs of the health security program should be allocated to Federal general revenue sources. The Subcommittee made various analyses of the economic and fiscal implications of a decision on this point. After considering various alternatives and their consequences, it reached a consensus to recommend that 50 percent of the direct program costs should be financed from Federal general revenues, and that the "residual" 50 percent should be financed through taxes specifically identified with the financing of the health security program and its benefits.

Accordingly, if the health security program had been initially functional in 1969–70 the estimated expenditures of about $40 billion should have been allocated as follows for that year:

From Federal general revenues: Percent of total, 50; amount (billions), $20.
From health security taxes: Percent of total, 50; amount (billions), $20.

Allocation of the Tax-Supported Costs

The Subcommittee then undertook a series of studies to determine, with respect to the costs not allocated to general revenues, the potential impact of these "residual" costs on the economy in general and on various sectors of the economy which might serve as bases for financing. The inspections extended to the relation of the estimated costs to: gross national product; total national income; personal income; earnings covered under the national social security program; current practices in management-labor agreements on the payment of medical care costs; provisions under current and prospective public assistance and other public welfare programs; policies with respect to federal, state and local governmental expenditures for health and related programs; etc. Account was taken of various possible tax patterns with exemption of income or earnings above or below selected levels, and with the exemption of persons with low earnings at selected levels. Account was also taken of impacts with respect to current patterns in paying for medical care through private arrangements and under public programs, equity in bearing the costs, ability to pay, administrative feasibilities, etc.

As a result of its deliberations, the Subcommittee concluded its studies with the following general recommendations for the financing of the health security program—

	Recommended allocations (percent)
1. A basic portion of the cost should be met by appropriations from Federal general revenues	50
2. The remaining costs should be met through Federal health security taxes	50
(*a*) from employers, through a tax applicable to total payroll without "ceiling"	37½
(*b*) from individuals, through taxes applicable to income under $15,000 a year, whether from current earnings or from other sources	12½

When these recommendations are applied to the estimates of prospective expenditures summarized earlier, they yield the allocations shown on Table 12.[12] As before, the estimates apply respectively to the alternative start-up dates for the program—according as the first *benefit* year would be July 1, 1973–June 30, 1974 or July 1, 1974–June 30, 1975. For each start-up date series, the expenditures in successive years increase by 6 percent; and the second start-up *benefit* year series begins with expenditures which are 10+ percent higher than for the first start-up series, having escalated one year longer between 1969–70 and 1974–75. The figures in Table 12 provide the targets for calculations of health security tax rates—as well as indicating the approximate amounts to be financed from Federal general revenues—in relation to the start-up year and the proportion of total expenditure allocated to each source.

TABLE 12.—ALLOCATION OF EXPENDITURES UNDER THE HEALTH SECURITY PROGRAM IN CALENDAR YEARS 1973-76

[Dollars in billions]

Allocation	1973	1974	1975	1976
INITIAL BENEFIT YEAR FISCAL YEAR 1973-74				
Total expenditures	[1] $28.4	$58.4	$61.9	$65.6
50 percent from Federal general revenues	14.2	29.2	31.0	32.8
50 percent from health security taxes	14.2	29.2	30.9	32.8
37½ percent through employer taxes	10.7	21.9	23.2	24.6
12½ percent through taxes on individuals	3.5	7.3	7.7	8.2
INITIAL BENEFIT YEAR FISCAL YEAR 1974-75				
Total expenditures		[1] $31.3	$64.4	$68.3
50 percent from Federal general revenues		15.7	32.2	34.2
50 percent from health security taxes		15.6	32.2	34.1
37½ percent through employer taxes		11.7	24.2	25.6
12½ percent through taxes on individuals		3.9	8.0	8.5

[1] One-half benefit year within the calendar year.

Health Security Tax Rates

As a first approximation, the tax rates that would be required to finance the direct expenditures under the proposed health security program were calculated in accordance with the specifications shown in the upper part of Table 12. These calculations use only the assumption that the initial benefit year would be the fiscal year 1973–74 and that the health security taxes would become effective beginning with January 1, 1973; application to the second assumption—that the initial benefit year would be 1974–75 and that the taxes would become effective January 1, 1974—will appear later (in Table 15). Table 13 gives the results for the recommended financing pattern.

It should be noted in Table 13 that the tax base for the tax on *employers* excludes the payrolls of state and local governments, because of serious doubt that a Federal tax could constitutionally be applied to those governments as employers. There is no such exclusion, however, in the tax base for the tax on *individuals*, since this is permissible and those individuals are eligible for the benefits of the program.

It will be seen in Table 13 that, with 50 percent of the program expenditures to be derived from Federal general revenues, the recommended allocations of residential costs (37½ percent to employers and 12½ percent to individuals) suggest tax rates of approximately 3.5 percent on employers' total payrolls and of approximately 1.0 percent on individuals' income, earned and non-earned, under $15,000 a year.

Using these first approximations as guidelines, our Subcommittee inspected the allocations further and recommended the following tax rates:

[12] The estimated expenditures and their allocations are presented for the sequence of *Calendar* years in order to relate these figures later to the estimated yields from taxes on a calendar year basis.

TABLE 13.—HEALTH SECURITY TAX RATES, FIRST APPROXIMATIONS, ASSUMING INITIAL BENEFIT YEAR 1973–74 AND 50 PERCENT OF EXPENDITURES FROM FEDERAL GENERAL REVENUES, CALENDAR YEARS 1973–1976 [1]

[Dollar amounts in billions]

Tax bases and rates	1973 [2]	1974	1975	1976 [3]
For employers:				
Total wage and salary payments	$701	$754	$809	$870
Less State and local government payrolls	92	101	110	121
Less the Armed Forces	13	14	15	16
Net tax base	596	639	684	733
37½ percent of total expenditure	21.3	21.9	23.2	24.6
Tax rate, percent	3.57	3.43	3.39	3.36
For individuals:				
Total wage and salary receipts, under $15,000	$645	$687	$728	$772
Less the Armed Forces, under $15,000	13	14	15	16
Net wage and salary receipts	632	673	713	756
Add other income, under $15,000	80	84	87	91
(a) from self-employment	40	41	42	43
(b) nonearned income [4]	40	43	45	48
Net tax base	712	757	800	847
12½ percent of total expenditure	7.1	7.3	7.7	8.2
Tax rate, percent	1.00	0.96	0.97	0.97

[1] Tax base data were provided by the Social Security Administration, DHEW. These estimates are based on the fisca year 1972 budget projections.
[2] Using total annual data.
[3] Tax base data estimated by percentage escalations from the preceding years.
[4] Estimated as 6 percent of total earned income under $15,000.

Recommended health security tax schedule

Assuming 50 percent from Federal general revenues:	*Percent*
(*a*) On employers' total payrolls	3.5
(*b*) On wage and salary receipts, up to $15,000 a year	1.0
(*c*) On self-employment income, up to $15,000 a year	2.5
(*d*) On non-earned income, up to $15,000 a year	1.0

This tax schedule has arbitrary elements; but it attempts to arrive at reasonably valid results having regard for the diverse considerations involved in trying to effect relations that are equitable with respect to health services, their utilizations and costs. When these tax rates are applied to the estimated tax bases of Table 13, they lead to the tax obligations shown in Table 14.

In Table 15 we have brought together the yields from the tax schedule and the estimates of program "residual" expenditures intended to be financed by these tax yields (i.e., the total expenditures exclusive of the 50 percent "matching" amount to be derived from Federal general revenues). The balance is shown for the initial years of program operation under the recommended tax schedule program in relation to the two alternative start-up years 1973 and 1974.

TABLE 14.—ESTIMATED HEALTH SECURITY TAX YIELDS, CALENDAR YEARS 1973–76

Tax base	Tax rate (percent)	Estimated tax obligations [1] (billions) 1973	1974	1975	1976
Employers' payrolls	3.5	$20.9	$22.4	$23.9	$25.7
Individuals' incomes, up to $15,000 a year		7.7	8.1	8.7	9.2
(a) Wage and salary receipts	1.0	6.3	6.7	7.1	7.6
(b) Self-employment income	2.5	1.0	1.0	1.1	1.1
(c) Nonearned income	1.0	.4	.4	.5	.5
Total		2.86	30.5	32.6	34.9

[1] Tax obligations were calculated by applying the tax rates shown here to the tax bases in table 13.

Note: 50 percent of expenditures from Federal general revenues.

It will be seen in Table 15 that the program tax schedule would produce more than the amount estimated as required to fund the "residual" expenditures for either start-up year. And since the tax schedule would start (January 1) one-half year before benefits would become available (July 1) in the initial benefit year, a reserve would be built up from the excess of the tax yield over the estimated "residual" program expenditures, amounting initially to $14.4–$14.9 billion. If this amount is supplemented by the formula "matching" appropriations from Federal general revenues, it becomes $28.8–$29.8 billion, of which amounts approximately one-half (one-quarter's taxes) would have been collected before the benefit year begins. Since there would be excesses of tax yield over "residual" program expenditures in each succeeding year, the reserve has the potential of increasing; but since these excesses are relatively small, they indicate that the tax schedule is very closely balanced against the expected program expenditures.

Table 15 shows the progress of the balance sheet for three or four calendar years and for two or three fiscal years, depending on the start-up year. This reflects the number of years for which the tax base estimate data are available. For the longer run, the balance between income and expenditure would depend on the comparative rates at which the tax base and the expenditures change, and on other developments. Under the assumptions used in this analysis, the close balance would tend to persist because (a) the budget system for health care expenditures relates those expenditures to the growth of population and the general escalation of the economy, and (b) the tax bases may be expected to change at (roughly) the same pace. If these assumptions were to prove valid, change in the program expenditures, and needed revision in the tax rates and their yields, would depend on various other factors—operational experience under the program, the rate at which benefits are delimited initially can be made more comprehensive, changes in the technology of the personal health services, the future course of medical care volume—as well as depending on changes in prices, costs and the behavior of the national economy.

TABLE 15—BALANCE OF HEALTH SECURITY EXPENDITURES AND TAX YIELDS, CALENDAR YEARS 1973-76 AND FISCAL YEARS 1974-76 [1]

[In billions of dollars]

Balance items	Calendar years—				Fiscal years—		
	1973	1974	1975	1976	1973-74	1974-75	1975-76
Tax obligations [2]	$28.6	$30.5	$32.6	$34.9	$29.6	$31.6	$33.8
50 percent of program expenditures:							
Initial tax year 1973 [3]	14.2	29.2	31.0	32.8	28.4	30.1	31.9
Excess of tax yield	14.4	1.3	1.6	2.1	1.2	1.5	1.9
Initial tax year 1974 [4]		15.6	32.2	34.1		31.3	33.2
Excess of tax yield		14.9	.4	.8		.3	.6

[1] Assumes that 50 percent of program expenditures are financed from Federal general revenues.
[2] Amounts from table 14.
[3] Initial benefit year 1973-74.
[4] Initial benefit year 1974-75.

VII. SOME EFFECTS OF THE PROPOSED HEALTH SECURITY FINANCING ON THE PATTERNS OF EXPENDITURE

Re-allocation of Governmental Financing

The recommended pattern for the financing of the health security program would result in important changes in the sharing of medical care costs by government. As a first step in inspecting the changes, we recapitulate in Table 16 the estimates presented earlier for the benchmark fiscal year 1969–70.

The health security program would have taken over, in 1969–70, somewhat more than 65 percent of expenditures for all personal health services. In addition to absorbing 69 percent of all private expenditures for these services, it would have covered 57 percent of the costs incurred under public programs—67 percent of the Federal and 37 percent of the state-local. Expressed another way, the program would have involved expenditures of $39.9 billion, it would have absorbed in that year $27.2 billion of expenditures from the private sector, and it would have taken over $9.3 billion of then current Federal expenditures and $2.6 billion of state-local expenditures.[13]

TABLE 16.—PRIVATE AND PUBLIC EXPENDITURES FOR PERSONAL HEALTH SERVICES, FISCAL YEAR 1969–70

[In billions of dollars]

Sources	All personal care	Health security program— Included [1] Amount	Included [1] Percent	Not included [1] Amount	Not included [1] Percent
All	$60.1	[2] $39.1	65.1	[3] $21.0	34.9
Private	39.3	27.2	69.2	12.1	30.8
Public	[3] 20.8	11.9	57.2	9.0	43.3
Federal	13.9	9.3	66.9	4.6	33.1
State-local	7.0	2.6	37.1	4.4	62.9
Resources development		.8			

[1] See footnote 1 in table 10. If the possible revisions cited there were made, the "included" total would increase from $39,100,000,000 to $39,700,000,000 (plus $800,000,000 for resources development): $27,200,000,000 private; and $12,500,000,000 public (including $9,400,000,000 Federal and $3,100,000,000 State-local). The "not included" total would decrease correspondingly.

[2] Excluding the amount introduced for resources development.

[3] Discrepancy in the total is due to the effects of rounding.

The public program expenditures of $11.9 (or possibly $12.5) billion which would have been absorbed by the health security program in 1969–70 are summarized in Table 17. The largest single item to be absorbed is Medicare ($7.1 billion). It is an unusual mixture of funds—derived from social insurance (OASDHI) contributions and general revenues for the hospital insurance component (Title 18, Part A, of the Social Security Act) and from an approximately even mixture of (a) individual contributions (premiums) and (b) matching funds from Federal general revenues for the supplementary medical insurance component (Title 18, Part B). All other Federal expenditures shown here are from Federal general revenues. Thus, of the total $9.3–$9.4 billion of Federal expenditures listed in Table 17, $3.8–$3.9 billion were derived from Federal general revenues. The $2.6–$3.1 billion of state and local expenditures in this summarization of programs derive from various public funds—general revenues, various earmarked taxes, etc.—and the medical care benefits under temporary disability insurance programs are financed from legally required contributions (state payroll taxes).

The miscellany of personal health service expenditures under public programs *not* included in these cost estimates for the health security program are also summarized here, in Table 18, so that it will be equally evident what has *not* been included in our cost estimates for the health security program.

[13] Slightly higher figures, based on possible revisions in Table 10, are also shown in the table.

TABLE 17.—EXPENDITURES FOR PERSONAL HEALTH SERVICES UNDER PUBLIC PROGRAMS, FISCAL YEAR 1969-70, INCLUDED WITHIN THE HEALTH SECURITY PROGRAM COSTS [1]

[Dollar amounts in billions]

Programs	Public program expenditures					
	Federal		State-local		Both	
All	$9.3	($9.4)	$2.6	($3.1)	$11.9	($12.5)
Medicare	[2] 7.1				7.1	
Medicaid, etc	1.5		1.5		3.0	
General hospital and medical care	0.2		0.9	(1.3)	1.1	(1.5)
Military dependents	0.2	(0.3)			0.2	(0.3)
Maternal and child health services	0.1		0.1		0.2	
Medical vocational rehabilitation	0.1		0.0	+	0.1	+
OEO health and medical care	0.1				0.1	
Temporary disability insurance (medical benefits)			0.1		0.1	
School health (educational agencies)				(0.1)		(0.1)

[1] For more detailed figures, see tables 9 and 10. The figures in ( ) indicate the effect of possible revisions cited in Table 10.
[2] Includes $1,660 from general revenues, as follows:

	Millions
Total medicare	$7,149
For hospital insurance	4,953
From payroll taxes	4,379
From general revenues	574
For supplementary medical insurance	2,196
From premiums	1,086
From general revenues	1,110

TABLE 18.—EXPENDITURES FOR PERSONAL HEALTH SERVICES UNDER PUBLIC PROGRAMS, FISCAL YEAR 1969-70, EXCLUDED FROM THE HEALTH SECURITY PROGRAM COSTS [1]

[Dollar amounts in billions]

Programs	Public program expenditures		
	Federal	State-local	Both
All	$4.5	$4.5($4.0)	$9.0($8.5)
Medicaid	1.0+	1.1	2.1+
General hospital and medical care	0.0+	2.0(1.6)	2.1
Department of Defense, hospital and medical care	1.7—		1.7
Military dependents	0.1—		0.1—
VA hospital and medical care	1.6		1.6
Workmen's compensation medical only	0.0+	1.0	1.0
School health (educational agencies)		0.3(0.1)	0.3
Maternal-child health services, community-wide	0.1	0.1	0.2

[1] For more detailed figures, see tables 9 and 10. The figures in ( ) indicate the effect of possible revisions cited in table 10.

Thus, considering the proposed inclusions within the health security program, the existing public programs would have been relieved of the following expenditures for personal health services (at the 1969–70 level)—

	Billion	
Federal public programs	[1] $9.30	($9.37)
From general revenues	3.83	(3.90)
From payroll taxes	4.38	
From premiums	1.09	
State and local public programs	2.55	(3.07)
Total public programs	11.85	(12.44)

[1] The figures in ( ) reflect possible adjustments cited in Table 10.

We have submitted a financing schedule intending that 50 percent of the expected direct expenditures of the health security program should be financed from Federal general revenues. At the 1969–70 level, this would have meant 50 percent of $39.9 billion or $20 billion from this source—about $8 billion more than was met by all governmental expenditures in that year. The proposed *additional* funding from Federal general revenues would have meant $16 billion above the amount ($3.83–$3.90 billion) spent in 1969–70 for personal health services and financed from that source. A portion of the additional amount from Federal general revenues for the health security program at the 1969–70 level would have reflected $2.55–$3.07 billion of relief for state and local governments from expenditures they were making in that year for personal health services from their tax funds.

Here, as elsewhere in our analyses, we are dealing only with direct program expenditures and their financing; and we are making no adjustments for impacts in the form of changes in the payment of income, excise or other taxes which depend on the details of other legislation subject to unrelated as well as related considerations.

For later years, when the health security program could become operational, we can only speculate as to the amounts or proportions of Federal and state-local expenditures under public programs that would be taken over by the prospective health security program. If we may assume that the public programs will be escalating at the same rates as the personal health services in general, and that their *distribution* of expenditures and their *sources* of funds would be much as they were in 1969–70, the expenditures for personal health services in fiscal years 1973–74 and 1974–75 *without new program intervention* would be about $85.1 and $92.8 billions, respectively; and the governmental programs would involve about $29.6 and $32.2 billions in those years (Table 8A). The health security program would involve $56.7 billion in fiscal year 1973–74 and $62.5 billion in 1974–75 (Table 11). The following tabulation summarizes the comparison, with respect to the estimated sources of the funds for personal health care services.

Here it is evident that the health security program would require $28.4 and $31.3 billion from Federal general revenues in these alternative initial fiscal years. It would be absorbing $16.9 and $18.2 billions of expenditures otherwise expected to be incurred in those years under governmental programs and financed, variously, from Federal general revenues, payroll taxes and premiums for Medicare, and from state-local funds.

[Dollars in billions]

Source of funds	Fiscal year 1974	Fiscal year 1975
A. Assuming no new major program interventions:		
Total expenditures	$85.1	$92.8
Private sources	55.5	60.6
Governmental sources	29.6	32.2
Federal	19.7	21.4
General revenues	11.9	13.0
Other sources	7.8	8.4
State and local	9.9	10.8
Governmental expenditures within the scope of the health security program:		
Total expenditures	16.9	18.2
Federal general revenues	5.4	5.9
Other Federal	7.8	8.4
State and local	3.7	4.0
B. Assuming operation of the health security program (for alternative initial fiscal years):		
Total expenditures under the program	56.7	62.5
Federal general revenues (50 percent)	28.4	31.3
Health security taxes	28.3	31.2

Re-allocation of Costs for Employers

The recommended pattern for financing the proposed program would also affect substantial changes in the impacts of medical care costs in the private sector.

In fiscal year 1969–70, employers provided—apart from their payments toward the general revenues of Federal, state and local governments—the following amounts toward the direct financing health services of the categories included in the health security program:

	Million
Private insurance payments	$8,405
Medicare payroll taxes	2,190
Total	10,595

If the recommended program had been operational in that year, they would have been relieved of the Medicare taxes and most if not all of the obligations they met through private insurance contracts and related provisions for their employees, and for temporary disability insurance (medical care benefits) under state programs.[14] [15] Instead, they would have been required under the recommended tax schedule to pay health security program taxes of $14.94 billion (37½ percent of the $39.85 billion cost of the program). Thus, the net effect would have been an increased cost obligation of about $4.35 billion—*plus* a relatively small residual cost required under their insurance contracts and related obligations but not replaced by health security benefits. The final impacts of such additional cost obligation on employers—as a business operational cost—would have been variously distributed, as is the case now for costs met through direct employer private expenditures and for payments to governments used to finance the costs of medical care incurred on behalf of employees.

For future years, the health security program costs to be met through employer payments would be larger than what they actually met in the benchmark year; but whether larger or smaller than employer costs that will result from a continuation of current patterns would depend upon escalation rates for privately purchased insurance, self-insurance, Medicare costs, and taxes for the general revenues of all levels of government. Estimates of those prospective costs have to expect that, with continuing steep escalation of medical care costs, the pressures will increase to make both private insurance and Medicare benefits much more comprehensive and to have at least the private insurance costs wholly met by employers for both employees and dependents. On this basis it is likely that employers will have no larger—and they may have smaller—costs with than without the health security program, while also being progressively relieved of responsibilities for negotiating and effecting health insurance provisions.

Reallocation of Costs for Employees and Other Individuals

In the benchmark year 1969–70, individuals and families made expenditures of about $26.14 billion for services in the categories included within the proposed benefits of the health security program, as follows:

	Million
Private insurance premiums	[1] $7,075
Medicare, Part A, payroll taxes	2,190
Medicare, Part B, supplementary premiums	1,086
Direct payments as patients	[2] 15,784
Total	26,135

[1] Including about $3.6 billion for group and about $3.5 billion for individual health insurance contracts.

[2] Estimated as 68.9 percent of direct payments in Table 2, based on the ratio of included expenditures (excluding expenses for administration) to total private expenditures (excluding expenses for prepayment) in Table 9.

In that year, the proposed health security program taxes on individuals would have required under the recommended tax schedule aggregate payments from them of $4.98 billion (12½ percent of $39.85 billion), a reduction of $21.16 billion—less some residual cost for group and individual private insurance cover-

[14] Only a very small portion of the total expended for health insurance through purchased insurance, health and welfare funds, self-insurance, etc., is used to pay for services which are excluded from the initial health security program (e.g., dental services for adults, long-term psychiatric care, medicines for extra-hospital use, appliances, etc.).

[15] Since the recommended benefits do *Not* embrace medical care services under workmen's compensation programs, the figures given here do *not* include employer insurance payments or expenditures under those programs.

age not completely encompassed by the health security program.[16] This change would have meant a *reduction* in the direct impact of medical care costs on individuals and families equivalent to (say) about $102 *per capita* or about $408 for a family of four with respect to services covered by the health security program.

For future years, reductions in the direct impact of medical care costs on individuals and families would be very large indeed. If the proportionate distributions of costs which obtained in 1969–70 persist, and a health security program is *not* established, employees and other individuals would have to provide directly about $37.0 billion in 1973–74 and about $40.3 billion in 1974–75 for personal health care services in those years.[17] If, on the contrary, the health security program were instituted, their direct tax obligations would be very much less: $7.1 billion in 1973–74 or $7.8 billion in 1974–75. They would still have expenditures to make for services and commodities not covered as health security benefits. How much is highly speculative, but it certainly would be very much less than the difference between these proposed tax obligations and the expenditure they would have to incur if the proposed program has not intervened.

Reductions in the total prospective expenditures of employees and other individuals would reflect the cost-containments effected by the health security program for the services it would provide as benefits. In addition, reductions would also be effected with respect to expenditures that would not be made for services that are not included as benefits.

Some of the expected reductions would be offset by the impacts on individuals and families from health security program costs to be met from Federal general revenues and through employer health security program payroll taxes. The net effect is difficult to evaluate; but it is not unreasonable to expect that the aggregate effects of the payroll and income taxes on individuals, of the relatively progressive taxes that would be financing the Federal general revenue support of the health security program, and of the diversely distributed payroll taxes on employers, would be much more progressive than the expenditures by individuals and families which those taxes would replace.

Nearly all elements in the current medical care expenditure patterns of individuals and families are relatively regressive in their fiscal impacts, taking proportionately larger tolls the lower the family income level. It is therefore quite certain that the continuance of current patterns of expenditures are likely to become more rather than less regressive; and that the health security program pattern of financing promises improved progressivity in the allocation of costs to individuals and families.

VIII. BUDGETING AND ALLOTMENT OF FUNDS

The steep escalation of medical care costs in recent years is one of the main reasons for dissatisfaction with the medical care "system" as a whole and particularly with its finances. The escalation reflects various characteristics of the system, but not least its "open-end" fiscal behavior.

Fees for the services provided by personal providers, and the operating costs and charges—or cost reimbursements—for hospitals and other institutional providers, have reflected demand for services, production costs, income expectations of providers, resources for service, and other factors. By and large, the fees, charges, costs have been "what the traffic would bear," and they have been strongly supported by the benefit patterns and the payment practices of private insurance. These practices have been further encouraged and supported by the cost of charge reimbursement guarantees from public funds under some important public programs (Medicare, Medicaid, maternal and child health, vocational rehabilitation, etc.). These guarantees have been substantially without ceilings on governmental obligations to the individual and institutional providers, and without effective restraints or controls through fiscal standards or administrative practices. Such public guarantees have extended to the payment of each practitioner's customary charges, within the range of charges prevailing in the

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[16] As noted earlier for employers, only very small portions of these private insurance expenditures are with respect to the costs of services excluded from the initial health security program.

[17] These figures result from applying 43.5 percent (the 1968–70 proportion of employee and individual expenditures toward the total of $60.1 billion for personal health services) to the expected expenditures shown in Table 8.

community, whatever those customary and prevailing charges are or become.[18] These guarantees have also extended to the reimbursement of the charges, or to the full-cost reimbursement for operating costs, of hospitals and other institutions, without ceiling or limitations through approved prospective budgets.

The studies of our Technical Subcommittee have been proceeding on the assumptions that these fiscal and administrative practices cannot continue, and that a rational system of financing for a health security program should function on a "budget" basis. Accordingly, we explored the design of a pattern for the budgeting of the costs nationally, and for the rational allotment of nationally budgeted funds for the financing of the program's services throughout the country.

As indicated earlier, our studies started with the resources we have, how they function and are utilized, and our fiscal analyses proceeded from the levels of current expenditures for the services being received. Our estimates for the costs of a health security program and their financing were therefore based in the first instance on current expenditures. We made upward allowances for expenditures to meet desirable and expected increases in utilization, and offsetting downward adjustments for the expenditures actually incurred for services to be excluded from the initial financial obligations of the program. We then projected the estimates from a current level to the initial years of program operation, and these are summarized in Tables 9, 10, and 11.

Budget, Tax Rates and Reserves

Assuming reasonably accurate estimates for the initial costs of the health security program, the financing mechanisms should provide to a proposed "Health Security Trust Fund" a total annual income from all tax sources equal to the expected expenditures *plus* a marginal additional sum to serve as a contingency reserve amount. However, since benefits which are of limited scope initially are intended to be broadened in successive years, such reserves should also be provided so as to permit authorized expansion of benefits without requiring annual or frequent revision of tax sources or change of tax rates. Alternatively, changes in the taxes or their rates would have to be programmed to provide the funds expected to be needed for benefit expansions. The uncertainties that have to be expected in the latter course for the taxes led us to suggest the accumulation of an initial reserve equal to (say) 25–50 percent of an initial year's budget estimate, whether through appropriation to the Trust Fund from general revenues or through collection of health security taxes for a brief period in advance of benefit availability.[19] The Secretary of DHEW or the administering Board should be authorized to certify benefit expenditures against such reserve funds, perhaps with annual ceiling on this authority at a level of permissible annual increase of (say) 5–10 percent of the annual expenditure budget for each of (say) the first five years of operations. For various contingent uses of the proposed reserve suggested in implementing legislation, see Appendix B.

The starting point for the national health security budget of expected annual expenditures is therefore an estimate of the total amount to be available for expenditure, prepared by the Health Security Board with the advice of a broadly constituted Advisory Council. Our estimates and projections indicate that the initial fiscal year's global amount would be approximately $56.7 billion (page 30). The Board should then earmark and set aside portions of the *initial* global budget for the costs of administration in accordance with the appropriations at first estimated and later approved by Congress (*circa* 5 percent), for systems improvement activities (2 percent), and for contingent national allotments (up to 5 percent). The remaining 88–90 percent of the national annual health security budget should then be allotted among the (ten) administrative Regions of the Department of Health, Education, and Welfare, with the advice of an Advisory Council.

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[18] As noted earlier, some limitations were recently introduced in Medicare, Medicaid and other Federal and Federal-State programs to dampen fee increases and to moderate volumes of utilization.

[19] In the financing section of this report the tax rates and estimated yields were designed on the second alternative: the tax obligations would begin one-half year in advance of benefit availability, and the initial reserve is developed from this source and from the appropriations from general revenues related by formula to the yields from the health security taxes.

Allotment Procedures

Two alternative patterns were considered at length by our Technical Subcommittee and its consultants for the first steps in the allotment procedures. One would propose that the administering Health Security Board should—with the advice of an Advisory Council—fix a national *per capita* amount to be available for each major category of service, and thus a total *per capita* amount for all health security services. These *per capita* amounts should take into account recent national expenditure levels, adequacies and inadequacies in services and expenditures, health security program objectives to support or to change current practices, etc. These amounts would then be assigned to each of the (ten) Reions, after adjustments for regional differences with respect to various factors: e.g., current expenditure levels; medical care price indexes; indexes of "risk" such as age and sex composition of the population; personnel and institutional resources for medical care, etc. And the resulting (adjusted) *per capita* amounts for each Region would then be allotted to sub-Regional areas similarly.

This procedural pattern lends itself to national determination of total national expenditure levels, and provides opportunity for decisions to change levels of expenditure downward as well as upward in relation to recent trends in prices, utilizations and costs. It is the pattern of choice if the health security program is authorized and expected to pursue from the outset a strong policy of expenditure controls, even to the point of attempting to reverse some recent trends. However, because of the difficulty of devising specifications for legislative guidelines, the discretionary authority which this pattern would vest in the Board might prove to be unacceptably broad.

An alternative procedural pattern takes as the starting point not administratively determined expenditure levels, nationally and for the Regions, but the *status quo* when program operations begin as reflected in current prices, costs, utilizations and expenditures in the several Regions; and it undertakes to effect both supports and adjustments in the Regions over the course of succeeding years. On this pattern, the allotments to the Regions should then be reasonably in accord with the most recently available data on expenditures for personal health services in the several Regions, having regard for the scope of the health security program benefits.[20] Such allotments would therefore reflect the financial needs of the Regions for the expected costs of the health security benefits.

This second pattern more or less automatically takes into account for each Region such factors as (a) size of population, and (b) risk factors (age, sex, morbidity and need for service), medical care resources, medical care price levels, hospital and other institutional cost levels—*to the extent that all of these factors are reflected in utilization, costs and expenditure practices in the last year to which the underlying expenditure data apply.* The resulting allotments, if unadjusted, in effect would accept initially the very large regional differences in *per capita* expenditure patterns. The Board should have authority to moderate in the course of time the differences in the resources for medical care and the receipt of care—so that these differences do not continue endlessly to preserve the wide regional and sub-regional variations in the amounts and costs of medical care above and below the national averages. Such an adjustment procedure should tend to contain future increases in costs where they have already grown to the highest *per capita* levels, and to provide funds more generously where resources, utilization and expenditures have been unusually low. The importance of some such adjustments is indicated by the very wide ranges in the levels of expenditures among the states, shown in Appendix C with respect to *per capita* expenditures—for non-Federal hospital care, for physicians' and for dentists' services—for which data are available for 1968. Unless the patterns of medical care expenditure change greatly between 1971 and 1973–74, the health security program will have to pursue a policy of gradualism in moderating expenditure differences which range, roughly, from nearly as low as one-half to nearly as high as twice the national averages among the states.

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[20] The Subcommittee was aware that this assumes the availability of annual or fiscal year expenditure data state by state (by services or object of expenditure, and by sources of funds). Such data have not been prepared hitherto on a comprehensive national basis, but we were advised that they are in preparation in the Social Security Administration (DHEW) and can be expected to become available in the near future. The Subcommittee was also aware of the need to elaborate the available data for smaller areas (counties, medical market areas, etc.).

The *per capita* allotments for the several Regions would then be subdivided among service categories, having regard for the expenditure levels in each Region. The categories may be greatly subdivided or they may be grouped—as for: hospitals and skilled nursing homes; physicians; dental services; medicines and appliances; other professional and technical services. The *per capita* allotments to categories of services would then require further allotment to states and to smaller sub-Regional ("medical market") areas.

After the initial year(s), the budgeting and allotment procedures should then follow the same pattern except for adjustments in the national global and *per capita* amounts on the basis of operating experience, trends in the economy with respect to earnings and prices, and health security program objectives to improve the organization of medical care services and to increase or decrease supports for various categories of service. On this general pattern, though the initial allotments of national funds would be close to the then current levels of expenditures, the course of post-initial practices would be determined in part by expenditure patterns from years antedating the program operations and in part by actual health security program experiences and by national policies applicable to the program.[21]

IX. SUMMARY AND CONCLUSIONS

1. The design of the National Health Security Program was undertaken in order to meet urgent national need to improve the availability and delivery of good medical care to all of the population and to assure adequate financing of the services without controllable wastes and extravagances. The urgency of the need reflects inadequacies in the availability of needed services for many people, uneveness in the quality of care, and cost escalations which have been pricing medical care beyond the means of millions in the population and even beyond acceptable demands on the national economy. Thus, the Program udertakes to develop a basis for improvement of resources for medical services and of their availability and delivery; and for the financing of the costs, utilizing the leverage of the financing pattern to provide incentives and supports for resources development.

2. National expenditures for health care in general and for personal health care services in particular have been escalating steeply, absorbing a steadily increasing share of national economic resources and of the spendable income of families. In 1969–70, the last fiscal year for which detailed data are available at this time, expenditures for all health care reached $67 billion, and for personal health care services $60 billion, having been increasing by about 12 percent a year. Hospital care, physicians' services, and nursing home care have been among the most steeply escalating categories.

There are diverse reasons for the escalations in these categories and in others. There have been not only rising expectations and demands for service, technological developments, health manpower shortages, catch-up in some wage and salary levels, etc., but also inefficiencies in the ways in which the resources are made available and are utilized, and invitations to excessive utilizations, prices and costs from the prevailing methods of paying for services. Not the least of the incentives for rising expenditures are the assurances of payments through the prevalent patterns of private insurance and the largely uncontrolled guarantees under public programs to pay charges determined by individual providers of core and to reimburse costs incurred by hospitals and other institutions.

3. If expenditures for health care continue to rise at rates experienced in recent years, they threaten to attain frightening levels. Projections published by the Social Security Administration in October 1970, and assuming substantially the continuance of recent trends, carry the national expenditures for *all* health care from $67 billion in FY 1969–70 to $111–120 billion in 1975 and to about 40–60 percent more in 1980; and those projections indicate (Table 7) increase of the national expenditures for *personal health care services* from $60 billion to $103–$111 billion in 1975 and to correspondingly higher figures in 1980. Since those projections increase faster than the gross national product, health care would be absorbing larger and larger shares of the national economy.

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[21] A more detailed description of the budgeting and allotment procedures will be found in Appendix B (Part D—Trust Fund; allocation of funds for services).

4. The "SSA" projections, however validly reflecting the stated assumptions which accompany them, have seemed to us to reach unacceptable expenditure levels, principally because—admittedly—they do not take into account countervailing measures to moderate the current rates of escalation. Some such measures have already been taken and many more are in course of application. We have therefore developed an "adjusted" model of projected expenditure levels to 1975, moderating somewhat the expected rates of annual increase in expenditures for hospital care and physicians' services. In our model (Table 8), expenditures for personal health care services would increase from $60 billion in FY 1970 to $85 billion in FY 1974 and to $93 billion in FY 1975. Even this model emphasizes the urgency of instituting adequate program measures to further moderate—if not to contain—the escalation of medical care costs. It also emphasizes that the longer the needed program intervention is delayed, the higher the expenditure level at which any new functional program would have to take over.

5. The health security program proposes a national system of public financing, based on national resources, and the continuance of private provision of health care services with many built-in safeguards for the professional status and the quality performances of the providers.

6. The health security program proposes that the national system of financing should pay for needed services available to substantially all persons resident in the U.S., from all qualified personal and institutional providers, without payments by patients for covered services and with eligibility determined by medical care need—without requiring a contribution history or a means test.

Arbitrary limitations on the benefits are specified for only four categories of service: for dental care (by age) because of inadequacies in resources for care; for psychiatric care in order to delimit the system's obligations to actual medical care, to take account of current shortage of qualified personnel, and to exclude payments for domiciliary or custodial care; for nursing home care for similar reasons and to wait on development of improved methods of needed control; and for medicines and appliances so that the system avoids many problems of administration and utilization control, pays only for services and goods which justify public expenditures, and protects patients against budensome costs. The benefit specifications also include many provisions to control potentially excessive utilizations and other wastes, to assure observance of quality standards, to encourage efficient use of health manpower and facilities, and to emphasize preventive care and ambulatory (as against unwarranted more expensive inpatient hospital) services—all toward economy without sacrifice of quality and toward having barriers to unjustified and not truly needed care.

7. Personal providers of care under the proposed program could continue to choose their place and pattern of practice, and could elect the method of payment among various alternatives (fee-for-service, capitation, stipends, etc.); institutional providers would be compensated on the basis of approved prospective budgets. The payment procedures would reflect the intention of having operating costs that are compatible with annual budgeting for the system as a whole and for its major service categories.

8. Extensive incentives are proposed in the program to encourage and support the development of organized provisions for comprehensive care, whether through group practice or through "foundation" type plans. Various provisions are also made to support other resource developments for health manpower expected to be needed for the program, to encourage location of providers where there are acute deficiencies, to finance new undertakings which promise more effective use of resources, etc. Thus, the specifications emphasize system improvement as well as financing of services.

9. Estimate of expenditures under the health security program were developed first by hypothecating its operation in fiscal year 1969–70. Each category of expenditure in that year, private or under public programs, was inspected for the potential degree of inclusion under the health security program specifications. It developed that about 69 perecnt of private and about 57 percent of public program expenditures would have been covered if the program had been in operation at that time—about 66 percent for both. Thus (Tables 9 and 10), of $60 billion of expenditure actually incurred for personal health services in that year, about $40 billion would have been covered by the proposed program (including the cost of resources development activities). This reflects the conviction that savings effect-

ed by avoiding wastes and extravagances would have offset increases in costs for justifiably higher utilizations of needed services which could have been provided through the resources available that year.

10. Our studies based on 1969–70 data were then applied to our model for expenditure levels to be expected in future years when the health security program could become operational. This led to estimates that the program would involve direct expenditures of $56.7 billion if first operational in 1973–74 and of $62.5 billion if in 1974–75. In subsequent years, the operational costs should be expected to escalate by about 6 percent a year, having regard for population growth, general price increase in the economy as a whole, etc., but without taking account of potential benefit changes.

We would emphasize that these cost estimates for the health security program involve no new total expenditures for medical care by reason of the new program itself. The estimates are the amounts that would be re-routed from the current to the proposed pathways of expenditure.

We would also emphasize that the increase in operating cost from the $40 billion estimate for 1969–70 to the higher estimates for 1973–74 and 1974–75 reflects not inherent higher costs for the health security program but only the higher level of national expenditures expected to result from delay in implementing the proposal.

11. We proposed that the health security program should be financed nationally (as for the Social Security program) and that 50 percent of the costs of the program should be met from Federal general revenues; and that the "residual" fiscal need, 50 percent of the total, should be financed through earmarked health security taxes levied on employer payrolls and on the incomes of individuals. Many alternative allocations were considered and inspected. The Technical Subcommittee finally recommended that, with 50 percent from Federal general revenues, employers' payrolls should provide 37½ percent and individual incomes 12½ percent of the "residual" amount.

The recommended allocations lead to the following tax rates:

With 50 percent from Federal general revenues—	*Percent*
Employers' payrolls (with no ceiling)	3.5
Individuals' incomes (up to $15,000 a year):	
On wage and salary receipts	1.0
On self-employment income	2.5
On non-earned income	1.0

If the program became functional in 1973 or in 1974, we estimated (Table 15) that these allocations and tax rates would yield amounts that would meet the estimated expenditure levels for calendar years 1973–1976 and for fiscal years 1974–1976. An adequate contingent reserve—to minimize need for changes in tax rates in the initial years of program operation—could be achieved either by having the tax obligations start one-half year before benefits become available and these tax yields supplemented by formula appropriations from general revenues (as recommended), or by credit appropriations from general revenues.

12. The program specifications and the proposed financing would effect important changes in the impacts of medical care costs on governments. The absorption of Medicare, of substantial parts of Medicaid, and of various other obligations under Federal and state-local public programs means (Table 17) that the health security program would relieve governments of expenditures which in 1969–70 amounted to $11.9–$12.5 billion ($9.3–$9.4 billion Federal and $2.6–$3.1 billion state and local). The transfers in a future year, when the proposed program could be operational are speculative because of uncertainties about the expenditure escalations of public programs. One set of estimates indicates that in 1973–74 the program might absorb about $17 billion of expenditures that would otherwise be under public programs ($13.2 billion Federal and $3.7 billion state-local) while requiring appropriation of $28 billion from Federal general revenues.

13. In 1969–70, employers provided about $10.6 billion for the financing of personal health services through private insurance and Medicare payroll taxes. The health security program would have relieved them of these expenditures, while the recommended pattern of financing would have required them to pay $15 billion in health security taxes—an increase of about $4.4 billion. For future years, the impact on them could be higher or lower, depending on whether the costs of private insurance and Medicare under current programs escalate more steeply

or less steeply than medical care costs under the proposed program. If current medical care costs continue to escalate steeply, employers may expect to be pressed to provide increasingly comprehensive insurance and to meet the whole cost. The health security program may then cost them less, while also, progressively relieving them of responsibility for health insurance.

14. In 1969–70, employees and other individuals spent about $26.1 billion for personal health services that would have been covered by the health security program. That program would have required them to provide $5 billion through health security taxes—and they would have been left with some residual costs not covered by the program and would have paid shares of employer and Federal supports to the program. There can be no doubt, however, that then or in future years the health security program financing would greatly reduce the regressivity of medical care costs on individuals and families, aiding especially those in lower and middle income brackets.

15. The health security program undertakes to move toward a "budget" basis for the financing of medical care costs, beginning to substitute national budgeting for the open-end escalation of expenditures according to what "the traffic will bear." Starting with the then current levels of expenditures when the program becomes functional. the proposed financing would provide to a Trust Fund the amounts needed to make reasonably adequate payments for the covered services at then current prices and costs. The national administrative agency (assisted by a broadly constituted advisory council) would allot the available budget funds, regionally, initially in relation to regional levels of medical care expenditures; and then would break down the allotments by categories of service and for subregional areas. For future years, the budgeted amounts would change in relation to needs and trends in the economy; and allotments would attempt to reduce regional disparities—moderating the escalations where they have been steepest and strengthening the resources where they have been weakest. The objective is national operation of the national program toward national equality in the availability and delivery of good medical care.

16. The medical care system in the United States is admittedly in crisis, and it is not healing itself. Measures being taken to deal with the causes of crisis are grossly insufficient, and an adequate national undertaking is required. The need for action is urgent, especially because the steep escalations of medical care costs and expenditures continue to enlarge the problems that have to be solved. The health security program proposed by our Committee has the promise of meeting the major needs and of providing the basis for a durable system for both the availability of good medical care and its financing. We recommend that the program be instituted as quickly as practical.

Appendix A

The Program Principles Adopted by the Committee for National Health Insurance

1. All persons resident in the United States should have available, as a matter of right, comprehensive personal health care services, with equal opportunity of access to the available services throughout the country.

2. Personal health care services should be provided under arrangements that, to the maximum extent practicable and within a framework of improved provisions for service, make full use of existing personnel and facilities and are acceptable to the people to be served and to those who provide the services.

3. The availability of personal health services should be assured through a national health insurance program.

4. The national health insurance program should be an integral part of the national social insurance system. The program should be financed by contributions from employers, employees, self-employed persons—preserving present provisions which permit employer assumption of all or part of employee contributions—and from Federal general tax revenues.

5. The benefits of the program should extend to the entire range of services required for the maintenance of personal health, including services for the prevention and early detection of disease, for the care and treatment of illness, and for medical rehabilitation when needed.

6. Payments for the services provided as benefits of the program should assure full financial protection for the consumers and should be fair to the providers of the services.

7. The national health insurance program should include provisions designed to contribute toward safeguarding the quantity, quality, effectiveness, continuity and economy of the family health care services it finances.

8. The administrative arrangements and the finances of the national health insurance program should be designed so as to encourage the organization of professional, technical and supporting personnel into health teams and groups capable of providing comprehensive health care for families and individuals efficiently and effectively, with compensation through comprehensive *per capita* payments as an alternative to the prevailing fee-for-service method of payment.

9. There should be public control of the basic policies governing the program, and full public accountability for its financial and operational activities.

10. There should be appropriate provisions for effective participation by consumers and providers both in the development of the national health insurance program and on the advisory councils assisting in its continuing public administration.

11. The national health insurance program should be so structured and have such inter-agency relationships as to enable it to influence substantially the accelerated development of needed health manpower and facilities and their availability, and to this end shall contribute substantial and assured continuing financial support toward the national development of adequate manpower, facilities and organization needed for the effective delivery of comprehensive personal health care services in all parts of the country.

12. Although primarily directed to the development and support of comprehensive personal health care services, the national health insurance program should also have concern for the development of effective community health and welfare programs at the national, state, regional and local levels through comprehensive community health planning.

13. The national health insurance program should provide for studies and demonstrations which give promise for continuing adjustment of the health services so as to serve the changing needs of people in the most efficient and effective manner consistent with sound professional goals and standards and so as to utilize expanding medical knowledge and skill.

14. The national health insurance program should be designed and developed in accordance with these principles and policies so that it shall function not merely to increase national expenditures for health services but also to contribute to the control and elimination of present wastes and extravagances and toward maximum practical effectiveness and efficiency in the delivery of and payment for comprehensive health services of good quality commensurate with our need and potential.

Appendix B

Section-by-Section Summary of The Health Security Act, S. 3 and H.R. 22, 92nd Congress [1]

SECTION-BY-SECTION ANALYSIS OF THE HEALTH SECURITY ACT

TITLE I

Part A—Eligibility for benefits

(Sections 11–12.) Every resident of the U.S. (and every non-resident citizen when in the U.S.) will be eligible for covered services. Reciprocal and "buy-in" agreements will permit the coverage of groups of non-resident aliens, and in some cases benefits to U.S. residents when visiting in other countries.

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[1] Excerpted from the Congressional Record of Jan. 25, 1971 (Vol. 117, pages 23–30). Introduced in the Senate by Senators Kennedy, Cooper, Saxbe, Bayh, Case Cranston, Gravel, Harris, Hart, Hughes, Humphrey, Inouye, Javits, Magnuson, McGee, McGovern, Metcalf, Mondale, Moss, Muskie, Pastore, Pell, Randolph, Stevenson, and Tunney; and in the House of Representatives by Representatives Griffiths, Corman, and others.

Part B—Nature and scope of benefits: Covered services

(Section 21.) Every eligible person is entitled to have payments made by the Board for covered services provided within the United States by a participating provider.

(Section 22.) All necessary professional services of physicians, wherever furnished, are covered, including preventive care, with two important restrictions:

(1) Major surgery, and other specialist services designated in regulations, are covered only when performed by a qualified specialist—except in emergency situations—and generally only on referral from a primary physician. This is intended to protect the public from inadequately trained practitioners and to restore the primary or family practitioner to the role of the manager of health services.

(2) Psychiatric services to an ambulatory patient are covered only for active preventive, diagnostic, therapeutic or rehabilitative service with respect to mental illness. If the patient seeks care in the organized setting of a comprehensive health service organization, or a hospital out-patient clinic, or other comprehensive mental health clinic, there is no limit on the number of consultations. In these kinds of organized settings, peer review and budgetary controls can be expected to curtail unnecessary utilization. If the patient is consulting a solo practitioner, there is a limit of 20 consultations per benefit period. In communities where psychiatric services are in especially short supply the Board may prescribe referral or other non-financial conditions to give persons most in need of services a priority of access to solo practitioners.

(Section 23.) Comprehensive dental services (exclusive of most orthodontia) are covered for children under age 15, with the covered age group increasing by two years each year until all those under age 25 are covered. This benefit is limited initially because, even with full use of dental auxiliaries, there is insufficient manpower to provide dental benefits for the entire population. Persons once covered for dental services remain covered throughout their lives, and it is the declared intention to extend dental benefits to persons initially excluded, as rapidly as this becomes feasible.

(Section 24.) Inpatient and outpatient hospital services and services of a home health agency are covered without arbitrary limitation. Pathology and radiology services are specifically included as parts of institutional services, thus reversing the practice of Medicare. Domiciliary or custodial care is specifically excluded in any institution, thus necessitating the two important restrictions on payments for institutional care:

(1) Payment for skilled nursing home care is limited to 120 days per benefit period except that this limit may be increased when the nursing home is owned or manager by a hospital and payment for care is made through the hospital's budget. It is not practical to assume that the majority of nursing homes and extended care facilities in the country will be able to implement effective utilization review and control plans in the first years of Health Security. The demand for essentially domiciliary or custodial care in nursing homes is so overwhelming that an initial arbitrary limit on days of coverage is necessary. Extension of the benefit is authorized when this becomes feasible.

(2) Many state hospitals do not provide optimal active treatment to their psychiatric patients but rather maintain them in a maintenance or custodial setting. If Health Security provided unlimited coverage for patients in these hospitals, it might tend to freeze the level of care instead of stimulating these institutions to upgrade their medical-care performance. Therefore the psychiatric hospital benefit is limited to 45 consecutive days of *active treatment* during a benefit period.

(Section 25.) The bill provides coverage for two categories of drug use: prescribed medicines administered to inpatients or outpatients within participating hospitals, or to enrollees of comprehensive health service organizations, and drugs necessary for the treatment of specified chronic illnesses or conditions requiring long or expensive drug therapy. This will provide coverage of most drug costs for individuals who require costly drug therapy.

The bill requires the Board and the Secretary of HEW to establish two lists of approved drugs, taking into account the safety, efficacy and cost of each drug. There will be a broad list of approved medicines available for use in institutions and by comprehensive health service organizations and a more restricted list which is available for use outside such organized settings. The restricted list shall stipulate which drugs on it shall be available for treatment of each of the specified chronic diseases. No such restrictions shall be placed upon drug therapy within an institutional setting.

Use of the restricted list will meet the most costly needs for drug therapy while restraining unnecessary utilization. The benefit is more liberal where adequate control mechanisms exist.

(Section 26.) The appliances benefit is similar in concept and operation to the drug benefit, subject to a limitation on aggregate cost. The Board shall prepare lists of approved devices, appliances or equipment which it finds are important for the maintenance or restoration of health, employability or self-management (taking into consideration the reliability and cost of each item). The Board will also specify the circumstances or the frequency with which the item may be prescribed at the cost of the Health Security program.

(Section 27.) The professional services of optometrists and podiatrists are covered, subject to regulations, as are diagnostic or therapeutic services. The care of a psychiatric patient in a mental health day care service is covered for up to 60 days (day care benefits are unlimited if furnished by a comprehensive health service organization or by a community mental health center). Ambulance and other emergency transportation services are covered, as well as non-emergency services where (as in some sparsely settled areas) transportation is essential to overcome special difficulty of access to covered services.

Supporting services such as psychological, physiotherapy, nutrition, social work and health education are covered if they are part of institutional services or are furnished by a comprehensive health service organization. This establishes the important principle that these and other supporting services should be provided as part of a coordinated program of health maintenance and care. Psychologists, physical therapists, social workers, etc. will not be permitted to establish independent practices and bill the program on a fee-for-service basis. This is intended to assure that whenever services of this nature are provided they are under appropriate medical supervision and are germane to the over-all care of the patient.

(Section 28.) Health services furnished or paid for under a workmen's compensation law are not covered. Reimbursement for loss of earnings is so closely interlocked with the health services aspects of workmen's compensation that absorption of the health services portion of workmen's compensation by Health Security could have the effect of delaying findings of eligibility for income payments.

School health services are covered only to the extent provided in regulations.

The Board may exclude from coverage medical or surgical procedures which are essentially experimental in nature. The Board may exclude coverage of specified nonemergency surgical procedures unless an appropriately qualified specialist has been consulted and has recommended surgery. Individuals who enroll in a comprehensive health service organization or enroll themselves with a primary practitioner accepting capitation payments are not entitled to seek covered services from other providers of services (except as specified in regulations). Surgery primarily for cosmetic purposes is excluded from coverage.

The services of a professional practitioner are not covered if they are furnished in a hospital which is not a participating provider. This is intended to discourage physicians from admitting patients to hospitals which cannot or will not meet standards for participation in the program.

Part C—Participating providers of services

(Section 41.) Participating providers are required by subsection (a) to meet standards established in this title or by the Board. In addition, they must agree to provide services without discrimination, to make no charge to the patient for any covered service, and to furnish data necessary for utilization review by professional peers, statistical studies by the Board, and verification of information for payments.

Under subsection (b) the Board may, for those surgical procedures for which advance consultation is required under section 28, require pathology reports on tissue removed and clinical abstracts or discharge reports of the cases.

(Section 42(a).) Professional practitioners licensed when the program begins are eligible to practice in the State where they are licensed. All newly licensed applicants for participation must meet national standards established by the Board in addition to those required by their State. While stopping short of creating a Federal licensure system for health professionals, this will guarantee minimum national standards. A state-licensed practitioner who meets national standards will be qualified to provide Health Security covered services in any other state. (See also Section 56(a)(1)).

(b) For purposes of this title a doctor of osteopathy is a physician, as is a dentist when performing procedures which, in generally accepted medical practice, may be performed by either a physician or a dentist.

(c) Participating professional providers shall be required to meet continuing education requirements established by the Board (in consultation with appropriate professional organizations).

(d) Major surgery and certain other specialty services shall be covered only when provided by a board certified or board eligible physician (except in emergency circumstances). Physicians who do not meet these standards but who are providing such services as a substantial part of their practice when the program begins may be found qualified if they meet standards established by the Board and, where appropriate, if recommended by a participating hospital.

(Section 43.) This section establishes conditions of participation for general hospitals similar to those required by Medicare. Two requirements not found in the Medicare program are: (1) that the hospital must not discriminate in granting staff privileges on any grounds unrelated to professional qualifications; (2) that the hospital establish a pharmacy and drug therapeutics committee for supervision of hospital drug therapy. Medicare allows any hospital accredited by the Joint Commission on the Accreditation of Hospitals (if it provides utilization review) to participate in the program, thus in effect delegating to the Commission the determination whether the standards are met. This title requires all participating hospitals to meet standards established by the Board.

(Section 44.) Psychiatric hospitals will be eligible to participate only if the Board finds that the hospital (or a distinct part of the hospital) is engaged in furnishing *active* diagnostic, therapeutic and rehabilitative services to mentally ill patients. Psychiatric hospitals are required to meet the same standards as those prescribed for general hospitals in Section 43, and such other conditions as the Board finds necessary to demonstrate that the institution is providing active treatment to its patients. These standards will exclude costs incurred by state mental institutions to the extent they serve domiciliary or custodial functions. In addition, psychiatric hospitals must be accredited by the Joint Commission on the Accreditation of Hospitals. (As in Medicare, accreditation is an *additional* requirement in the case of psychiatric hospitals, as further assurance that they meet the requirements of an active treatment program.)

(Sections 45 and 46.) Section 45 establishes conditions of participation for skilled nursing homes similar to those established for extended care facilities under Medicare. Important differences, however, are the requirement for affiliation with a participating hospital or comprehensive health service organization (see Section 52(b)), and changes in the requirements for utilization review (see Section 51). Under section 46 participation by home health agencies will be limited to public agencies and non-profit private organizations—proprietary home health agencies are specifically excluded.

(Section 47.) Subsection (a) describes a comprehensive health service organization which undertakes to provide an enrolled population either with complete health care or, at the least, with complete Health Security services (other than institutional services, mental health or dental services) for the maintenance of health and the care of ambulatory patients. The bill, in its aim to improve the methods of delivery of health services, places much emphasis on the development of new organizations of this kind and the enlargement of old ones.

The section is designed to accommodate forms of organization typical of existing prepaid group practice plans, but also to be flexible enough to permit experimentation with somewhat different forms. In some urban or rural areas, for example, it may be impracticable to bring all of the various services together in one place, and the section has been designed to encompass what has been described as "comprehensive group practice without walls"; the basic essential is the assumption of responsibility for a reasonably comprehensive range of services (including health maintenance) on a continuing and coordinated basis

to a group of persons who have chosen to receive all or nearly all their health care from the organization.

Other requirements are spelled out in this section: The organization must furnish services through the prepaid group practice of medicine, or as near an approximation to prepaid group practice as is feasible. It must be a nonprofit organization, or if several providers share in the furnishing of services the prime contractor with the Board must be nonprofit. All persons living in or near a specified service area will be eligible to enroll, subject to the capacity of the organization to furnish care and subject to minimal underwriting protections. Services must be reasonably accessible to persons living within the specified service area. Periodic consultation with representatives of enrollees is required. Professional policies and their effectuation, including monitoring the quality of services and their utilization, are to be the responsibility of a committee or committees of physicians. Health education and the use of preventive services must be stressed, and lay persons are to be employed so far as is consistent with good medical practice. Charges for any services not covered by Health Security must be reasonable. Finally, the organization must agree to pay for services furnished by other providers in emergencies, either within the service area of the organization or elsewhere, but may meet this requirement to the extent feasible through reciprocal service arrangements with other organizations of like kind.

Subsection (b) makes clear that the organization, or professionals furnishing services for it, may also serve non-enrollees, with payment to be made to the organization, or, at its request, to such professionals.

(Section 48.) This section permits a foundation sponsored by a city, county, or State medical or dental society, by agreement with the Board, to participate as a provider of services. The foundation's general policies must be developed, and reviewed periodically, by the society or a committee selected by it, and it must establish a professional group to review the quality and utilization of services. Generally, the foundation must furnish all covered medical or dental services, and may furnish other covered or non-covered services if the Board approves; it must accept for enrollment any resident of the area it serves, subject to the same limitations as appear in section 47(a). It must permit any practitioner who needs its professional qualifications to participate in furnishing services, whether or not he is a member of the sponsoring society. The foundation must agree to pay for emergency services to its enrollees in or outside its area, and must make no more than reasonable charges for any services not covered by Health Security. Finally, it must meet requirements for continuing education and other requirements, which the Board may specify.

(Section 49.) This section deals with several classes of health organizations that vary widely, even within a single class. In their structure and in the scope of the services which they offer. Because statutory specifications cannot well be tailored to so many variables, the section sets forth only a general statement of the kinds of organizations to which it relates and leaves participation of each organization to a case-by-case decision of the Board.

Subsection 49(a)(1) permits the participation of community health centers or the like which though furnishing services as comprehensive as are required by section 47(a), do not serve an enrolled or otherwise predetermined population and may not meet some other requirements of section 47(a). Subsection (a)(2) authorizes the Board to deal separately with the primary care portion of a system of comprehensive care where it is necessary to rely on arrangements with other providers, rather than on a unified structure, to round out the other elements of the system. Where organizations meeting the extensive requirements of section 47(a) are not available, those two subsections will give the Board flexibility in furthering one of the bill's prime objectives, the development and broad availability of comprehensive services furnished on a coordinated basis.

Because of the extent to which mental health services are separated from other health care, subsection (a)(3) permits the Board to contract directly with public or other nonprofit mental health centers and mental health day care services.

If a State or local public health agency is providing preventive or diagnostic services, such as immunization or laboratory tests, the Board may under subsection (a)(4) contract with it for the continuance of these services. Subsection (a)(5) permits the Board to contract with nonprofit health prepayment or insurance organizations which provide substantially comprehensive services to ambu-

latory patients, on terms similar to those specified in section 48 for professional foundations.

In the field of private practice, physicians or dentists or other practitioners may group themselves in a clinic, nonprofit or proprietary, or in any number of other ways, and it may be more convenient both to them and to the Board to regard them as an entity than to deal with each practitioner separately. Subsection (a)(6) permits this. The Board will have wide discretion in contracting with such entities subject only to the limitation that, like other organizations described in section 49(a), the entity may not (under section 88(a)) be paid on a fee-for-service basis. Practitioners who elect that method of payment may of course pool their bills ofr submission to the Board, but there is no reason to contract with a unit for the payment of fees to it.

Subsection (d) sets forth the Board's authority to specify terms and conditions or agreements under this section. Subsection (c) makes clear that agreements with the Board under section 48 or 49 shall not (unless expressly so stipulated) preclude practitioners furnishing services under the agreements from furnishing other services as independent providers.

(Section 50.) This section specifies the broad and general conditions under which independent pathology laboratories, independent radiological services, providers of drugs, devices, appliances, equipment, or ambulance services may qualify as providers under Health Security. As under Medicare, a Christian Science Sanatorium qualifies if operated, or listed and certified, by the First Church of Christ, Scientist, Boston.

(Section 51.) The requirements of utilization review in hospitals and skilled nursing homes are in the main similar to those which Medicare has, since 1966, imposed with respect to services to aged patients. In Health Security the requirements will of course apply to the entire patient population. As in Medicare, the review is designed to serve a dual purpose: identification of certain specific misuses of the institutional services with a view to their termination, and a focusing of continuing attention and concern of the medical staff on the necessity for efficient utilization of institutional resources. Section 51(a) strengthens the educational aspect of the process by requiring specifically that records of reviews be maintained and statistical summaries of them be reported periodically to the institution and its medical staff (and, on request, to the Board). As under Medicare, the review committee will consist of two or more physicians, with or without other professional participation; and in the case of hospitals, will normally be drawn from the medical staff unless for some reason an outside group is required. For skilled nursing homes, on the other hand, section 51(c) departs from Medicare by permitting as an alternative that the Committee be established by the State or local public health agency under contract with the Board, or failing that, by the Board. If the nursing home operates under a consolidated budget with a hospital, the review will be made by the hospital committee. Like Medicare, section 51(d) calls for review of specific long-stay cases as required by regulations, and section 51(e) for notice to the institution, the attending physician, and the patient when a decision adverse to further institutional service is made.

(Section 52.) Subsection (a) of Section 52 is also like Medicare in requiring a participating skilled nursing home to have in effect an agreement with at least one participating hospital for the transfer of patients and medical and other information as medically appropriate. Subsection (b) introduces a requirement, applicable two years after the effective date of health benefits to both skilled nursing homes and home health services agencies, of affiliation with a participating hospital or comprehensive health service organization. Unless the medical staff of the hospital or organization undertakes to furnish the professional services in the nursing home or the professional services of the home health service agency, that medical staff or a committee of it must assume responsibility for these services. Subsection (c) allows the Board to waive the application of either of these requirements to a skilled nursing home or a home health agency which the Board finds essential to the provision of adequate services, if (but only for as long as) lack of a suitable hospital or organization within a reasonable distance makes a transfer or an affiliation agreement impracticable.

(Section 53.) If the construction or substantial enlargement of a hospital or skilled nursing home has been undertaken after December 31, of the year of enactment, without prior approval by a planning agency designated by the gov-

ernor of the state or the Board, section 53 precludes the institution from participating in the Health Security program. This should greatly strengthen state and local planning authorities.

(Section 54.) Subsection (a) requires the Board in fixing, for institutional and other providers, standards beyond those specified in the statute, to take into consideration criteria established or recommended by appropriate professional organizations. The Board is given authority under subsection (b) to require upgrading in staffing patterns and personnel standards of participating institutional providers that fall below standards recommended by such organizations.

(Section 55.) Institutions of the Department of Defense and the Veterans Administration, and institutions of the Department of Health, Education, and Welfare serving merchant seamen or Indians or Alaskan natives, are excluded by section 55 from serving as participating providers, as is also any employee of these institutions when he is acting as an employee. The Board will, however, provide reimbursement for any services furnished (in emergencies, for example) by these institutions or agences to eligible persons who are not a part of their normal clientele. It will also provide reimbursement for services furnished by the Public Health Service under the recently enacted Emergency Health Personnel Act of 1970.

(Section 56.) This section overrides, for purposes of the Health Security program, State laws of several kinds which inhibit the utilization or the mobility of health personnel, cloud the legality of so-called "corporate practice" of health professions, or restrict the creation of group practice organizations. The authority of Congress to do this, in conjunction with a program of Federal expenditure to provide for the general welfare, flows from the Supremacy Clause of the Constitution and seems now to be clearly established. (*Ivanhoe Irrigation District v. McCracken*, 357 U.S. 275 (1958) ; *King v. Smith*, 392 U.S. 309 (1968)).

The first three paragraphs of subsection (a), while stopping short of creating a system of Federal licensure for health personnel, will greatly facilitate both the interstate mobility of State licensees and the effective use of ancillary personnel in the furnishing of health care. The dispensations contained in these paragraphs will be available to persons who meet national standards established by the Board.

Paragraph (1) permits a physician, dentist, optometrist, or podiatrist, licensed in one State and meeting the national standards, to furnish Health Security benefits in any other state, the scope of his permissible practice being governed by the law of the State in which he is practicing. This paragraph obviates the difficulty and cost which a practitioner may encounter, especially where reciprocity of licensure is not available, in taking up practice in a State in which he has not been licensed.

Paragraph (2) grants a similar authority to other health professional and nonprofessional personnel. For occupations such as pharmacy and professional nursing, which are subject to licensure in all States, a person can avail himself of this paragraph only if he is licensed in one State and meets the national standards; in other cases, where licensure is not universally required, compliance with national standards is sufficient. Here again, impediments to mobility created by existing licensure laws will be removed.

The restrictions which many professional practice acts impose on the use of lay assistants, and the legal uncertainties which often deter such use, discourage practices that can increase greatly, without sacrifice of safety, the volume of services which professionals can render. Accordingly, paragraph (3) of subsection (a) enables the Board to permit physicians and dentists, participating in public or nonpublic hospitals and comprehensive health service organizations, to use ancillary health personnel, acting under professional supervision and responsibility, to assist in furnishing Health Security benefits. Such assistants may do only things which the Board has specified, and may be used only in the context of an organized medical staff or medical group. Persons employed as assistants must not only meet national standards for their respective occupations, but must also satisfy special qualifications that the Board may set for particular acts or procedures.

In the interest of encouraging salaried practice and the integration of professional practitioners into well-structured organizations for the delivery of health services, paragraph (4) of subsection (a) does away with the "corporate practice" rule insofar as concerns participating public or other nonprofit hospitals and comprehensive health service organizations. These institutions may employ

physicians or make other arrangements for their services, unless in the unlikely event that lay interference with professional acts or judgments should be threatened. No conflict of interest results from such arrangements; in the nonprofit setting loyalty to employer and loyalty to patient run parallel.

Some of the state laws place restrictions of one kind or another on the incorporation of group practice organizations. When these restrictions prevent the State incorporation of an organization meeting the strict requirements of the Health Security Act, section 56 (b) empowers the Secretary to incorporate it for purposes of the Act. Except for the special restrictions, State law will govern the corporation.

Part D—Trust fund; allocation of funds for services

(Section 61.) This section establishes the Health Security Trust Fund, to receive the net assets of existing (Medicare) funds taken over by the Health Security program, the yield of the Health Security taxes, and the Government's contribution from general revenues amounting to 100% of the yield from these taxes.

Accordingly, this section amends the Social Security Act to convert the present Hospital Insurance Trust Fund (Medicare, Title XVIII, Part A) into the Health Security Trust Fund, and to provide that the appropriations that would have gone into the former (increased by the new tax provisions) shall go into the latter. In addition, on the effective date of benefits the assets and liabilities of the Federal Supplementary Medical Insurance Trust Fund (Medicare, Title XVIII, Part B) will be transferred to the Health Security Trust Fund. Also, a Government contribution to the new Trust Fund is authorized to be appropriated, equal to 100% of the aggregate yield from the payroll taxes on employees and employers and the taxes on self-employment and unearned income, imposed for Health Security under Title II of this Act. The Fund will also receive recoveries of overpayments, and receipts from loans and other agreements. To implement the role of the Trust Fund, the Managing Trustee (the Secretary of the Treasury) will make payments from the Trust Fund provided for under Title I, as the Board certifies, and with respect to administrative expenses as authorized annually by the Congress.

(Section 62.) The Health Security program is intended to operate on a budget basis overall. Accordingly, subsection (a) requires the Board to determine for each fiscal year the maximum amount which may be available for obligation from the Trust Fund. The amount so determined in advance (by March 1 preceding each fiscal year) shall not exceed the smaller of two stated limitations. The first limit is fixed at 200% of the expected net receipts from all the Health Security taxes (i.e., the tax receipts augmented by 100% thereof, to be appropriated into the Fund from general revenues of the Government). The second limit, applicable to each fiscal year after the first year of benefit operation, (i.e. after a year's availability of covered services), is an amount equal to the estimated obligations of the current year (within which the estimate is being made), subject to certain adjustments. Such adjustments will reflect changes expected in: (A) the price of goods and services; (B) the number of eligible persons; (C) the number of participating professional providers, or the number or capacity of institutional or other participating providers so far as such changes are not readily adequately reflected; and (D) the expected cost of program administration.

In the interest of prudent fiscal management, subsection (b) requires the Board to restrict its estimate of the amount available for obligation in the next fiscal year (in accordance with subsection (a)) if the Board estimates that the amount in the Trust Fund at the beginning of the next fiscal year will be less than one-quarter of the total obligations to be incurred for the current year, and that such restriction will not impair the adequacy or quality of the services to be provided. Also, the Board is required to reduce its alternative estimate of the maximum amount to be available if it finds that the aggregate cost to be expected has been reduced (or an expected increase has been lessened) through improvement in organization and delivery of service or through utilization control.

Subsection (c) provides against various contingencies which may result in increase or decrease in the estimate of the maximum amount to be available for obligation in the next fiscal year. The amount may be modified before or during the fiscal year: if the Secretary of the Treasury finds that the expected Health Security tax receipts will differ by 1 percent or more from the estimate used under

subsection (a); or if the Board finds that either its factors of expected change or the cost of administration is expected to differ from the estimate by 5 percent or more; or if an epidemic, disaster or other occurrence compels higher expenditure than had been expected. If, as a result, the maximum estimate has to be increased (rather than being decreased), the Board (through the Secretary) shall promptly report its action to the Congress with its reasons.

(Section 63.) Subsection (a) provides that three separate accounts shall be established in the Health Security Trust Fund—a Health Services Account, a Health Resources Development Account, and an Administration Account, as well as a residual General Account. Subsection (b) provides that in each of the first two years of program operation, 2% of the Trust Fund shall be set aside for the Health Resources Development Fund; and the allocation shall increase by 1% at two-year intervals to 5% within the next 6 years. The money in this account will be used exclusively for the planning and system improvement purposes described in part F.

(c) (d) After deducting the amount appropriated by the Congress into the Administration Account, the remainder of the monies shall be allocated to the Health Services Account, and shall be used exclusively for making payment for services in accordance with part E.

(Section 64.) This section provides for allocation of the Health Services account among the regions of the country. (a) The allocation to each region shall be based on the aggregate sum expended during the most recent 12-month period for covered services (with appropriate modification for estimated changes in the price of goods and services, the expected number of eligible beneficiaries, and the number of participating providers). (b) In allocating funds to the regions the Board shall seek to reduce, and over the years gradually eliminate, existing differences among the regions in the average per capita amount expended upon covered health services (except when these reflect differences in the price of goods and services). To accomplish this, the Board will curtail increases in allocations to high expenditure regions and stimulate an increase in the availability and utilization of services in regions in which the per capita cost is lower than the national average. (c) A contingency reserve of up to 5% may be withheld from allocation. If the remaining funds available are inadequate, allocations will be reduced pro rata. (d) Allocations may be modified before or during a fiscal year if the Board finds this is necessary.

(Section 65.) The Board will divide the allocation to each region into funds available to pay for: institutional services; physician services; dental services; furnishing of drugs; furnishing of devices, appliances and equipment; and other professional and supporting services, including subfunds for optometrists, podiatrists, independent pathology laboratories, independent radiology services, and other items. The percent allocated to each category of service may vary from region to region. In determining the allocation to these funds, it will be guided by the previous year's expenditures for each category of service but also take into account trends in the utilization of services and the desirability of stimulating improved utilization of resources. It will encourage a shift from heavy reliance on institutional care to better utilization of preventive and ambulatory services.

(Section 66.) These regional funds will be subdivided among the health service areas in each region, primarily upon the basis of the previous year's experience for each kind of service. Again, the Board will gradually attempt to achieve the equalization of services within each region by restraining the increase of expenditures in high cost areas and channeling funds into health service areas with a low level of expenditures.

(Section 67.) Before or during a fiscal year, the division of regional funds by classes of service or the allotments to health service areas may be modified if necessary or if indicated by newly acquired information.

Part E—Payment to providers of services

(Section 81.) Payments for covered services provided to eligible persons by participating providers will be made from the Health Services Account in the Trust Fund.

(Section 82.) This section delineates methods of paying professional practitioners. Every independent practitioner (physician, dentist, podiatrist, or optometrist) shall be entitled to be paid by the fee-for-service method (subsection (a)). the amounts paid being in accordance with relative value scales prescribed after consultation with the professions (subsection (g)). Each physician engaged

in general or family practice of medicine in independent practice may elect to be paid by the capitation method if he agrees to furnish individuals enrolled on his ist with all necessary and appropriate primary services, make arrangements for referral of patients to specialists or institutions when necessary, and maintain records required for medical audit; and independent dentist practitioners may elect to capitation method of payment similarly (subsection (b)).

These requirements in connection with capitation payments are intended to assure that the physician (or dentist) provides to his patients all professional services within the range of his undertaking and secures other needed services by referral. Through regular medical audits, the Board will monitor the level and quality of care provided.

When necessary to assure the availability of services in a given area, subsection (c) permits paying an independent practitioner a full-time or part-time stipend in lieu of or as a supplement to other methods of compensation. This method of payment will be used selectively by the Board, mainly to encourage the location of practitioners in remote or deprived areas. Practitioners may also be reimbursed for the special costs of continuing education required by the Board and for maintaining linkages with other providers—for example, communication costs. Incentives operative under this provision will encourage physicians to improve the quality and continuity of patient care, even if the physician does not participate in a group practice. The Board may pay for specialized medical services on a per session, or per case basis, or may use a combination of methods authorized by this section.

Subsection (d) defines the capitation method of payment.

Subsection (e) of this section describes the method to be used in applying, as between practitioners electing the various methods of payment the monies available in each health service area for payment to each category of professional providers. From the amount allocated to each service area, the Board will earmark funds sufficient to pay practitioners receiving stipends and for the professional services component of institutional budgets, such as hospitals. The remainder of the money will be divided to compute the amount available per capita in the eligible population of the area for each category of service (i.e. physicians, dentists, podiatrists, optometrists). This per capita amount in each category will fix the capitation payments to organizations that undertake to provide the full range of services in that category to enrolled individuals. Lesser amounts will be fixed for more limited services. For example, if the per capita amounts available for physician, dental and optometric services are $65, $25 and $5 respectively, primary physicians accepting capitation payments will receive the percentage of that $65 which is allocated for primary services, a medical society sponsored foundation would receive the entire $65 for physician services, a dental society foundation would receive the $25 allocated for dental service, and organizations which undertake to provide all physician, dental and optometric services to enrolled individuals will receive $95 for each enrolled individual.

The budgeted per capita amount for each type of covered service (physician, dental, etc.) will be divided between the categories of providers of service according to the number of individuals who elect to receive care from those providers. For example, in a city of 100,000 people, 25,000 may enroll in a comprehensive health service organization. Using the figures cited in the example above, the Board will pay the comprehensive health service organization $1,625,000 ($65 x 25,000) for physician services. The other 75,000 individuals elect to receive their physician services from solo, fee-for-service practitioners. The Board will create a fund of $4,875,000 ($65 x 75,000) to pay all fee-for-service bills submitted by the physicians in that community, in accordance with relative value scales and unit values fixed by the Board. The fund for fee payments will be augmented to the extent that some capitation payments have been lowered because they cover only primary services, and may be augmented further where a substantial volume of services is furnished, on a fee basis, to nonresidents of the area.

Subsection (h) authorizes the Board to experiment with other methods of reimbursement so long as the experimental method does not increase the cost of service or lead to overutilization or underutilization of services.

(Section 83.) Hospitals will be paid on the basis of a predetermined annual budget covering their approved costs. To facilitate review of these budgets, the

Board will institute a national uniform accounting system. Subsection (b) stipulates that the costs recognized for purposes of the budget will be those incurred in furnishing the normal services of the institution except as changed by agreement, or by order of the Board under section 134. This will enable the Board, on the basis of State and local planning, to eliminate gradually any wasteful or duplicative services, and also to provide for an orderly expansion of hospital services where needed.

Physicians and other professional practitioners whose services are held out as available to patients generally (such as pathologists and radiologists) will be compensated through the institutional budget, whatever the method of compensation of such practitioners and whether or not they are employees of the hospital. This departs from the practice in Medicare which allowed independent billing by such physicians. The institution's budget may also be increased to reflect the cost of owning or operating an affiliated skilled nursing home, or home health service agency. Hospital budgets will be reviewed by the Board, locally or regionally, which may permit participation by representatives of the hospitals in each region. Budgets may be modified before, during, or after the fiscal year if change occur will make modification necessary.

(Section 84.) If an entire psychiatric hospital is found by the Board to be providing active treatment to its patients, and the institution is therefore primarily engaged in providing covered services to eligible beneficaries, it will be paid on the same basis as a general hospital (on the basis of an approved annual budget.) Otherwise the Board will negotiate a patient-day rate to be paid for each day of covered service provided to an eligible beneficiary.

(Section 85.) This section provides that skilled nursing homes and home health agencies will be paid in the same manner as a general hospital (on an approved annual budget basis). The Board may specify use of nationally uniform systems of accounting and may prescribe by regulation the items to be used in determining approved costs and the services which will be recognized in budgets.

(Section 86.) Reimbursement for drugs will be made to the dispensing agent on the basis of an official "product price" for each drug on the approved list plus a dispensing fee. The official product price will be set at a level which will encourage the pharmacy to purchase substantial quantities of the drugs (this should result in significant reductions in the unit cost of each drug). The official price may be modified regionally to reflect differences in costs of acquiring drugs. The Board will establish dispensing fee schedules for reimbursing independent pharmacies. These schedules will take into account regional differences in costs of operation, differences in volume, level of services provided and other factors.

(Section 87.) A comprehensive health service organization or professional foundation will be paid for other than hospital or skilled nursing home services, on the basis of a fixed capitation rate multiplied by the number of eligible enrollees. The amount of the capitation rate will be determined by the per capita amounts available for the several professional services in the area, and a rate fixed by the Board as the average reasonable and necessary cost per enrollee for such other covered services as the organization or foundation undertakes to provide (exclusive of hospital and skilled nursing home services) such as physical therapy, nutrition, etc.

A comprehensive health service organization or foundation which undertakes to provide for hospital or skilled nursing home services for its enrollees may be paid on an approved annual budget basis or on a capitation basis. An organization or foundation which arranges for such services through other providers may be reimbursed on the basis of patient days of service utilized by enrollees. The organization or foundation will also be entitled to share in up to 75% of any savings which are achieved by lesser utilization of such institutional services. Entitlement to such savings is conditional upon a finding by the Board that the services of the organization or foundation have been of high quality and adequate to the needs of its enrollees, and that the average utilization of hospital or skilled nursing services by enrollees of the comprehensive health service organization or foundation is less than use of such services by comparable population groups under comparable circumstances. This money may be used by the comprehensive health service organization or professional foundation for any of its purposes, including the provision of services which are not covered under the Health Security Program.

(Section 88.) Subsection (a) provides that organizations or agencies with which the Board has entered into an agreement under section 49 (such as a neighborhood health center, a nonprofit mental health center, a nonprofit prepayment insurance agency, or local health agency furnishing preventive or diagnostic services) may be paid by any method agreed upon other than fee-for-service.

Subsection (b) provides that independent pathology or radiology services may be paid on the basis of an approved budget or such other methods as may be specified in regulations.

Subsection (c) leaves the method of payment for other types of supporting services to be specified in regulations.

(Section 89.) All participating providers will be paid from the Health Services Account in the Trust Fund at such time or times as the Board finds appropriate (but not less often than monthly). The Board may make advance payment to supply providers with working funds when it deems advisable.

Part F—Planning; funds to improve services and to alleviate shortages of facilities and personnel

(Section 101.) This section sets forth the general purposes of Part F and authorizes appropriations, and subsequently expenditure from the Trust Fund, for these purposes. The part envisages a substantial strengthening of the health planning process throughout the country with an eye, first, to the special needs for personnel, facilities, and organization which inauguration of the Health Security program will entail, and thereafter, to continuing improvement of the capabilities for effective delivery of health services. Beyond this, the part enables the Board, through selective financial assistance, to stimulate and assist in the deevlopment of comprehensive health services, the education and training of health personnel who are in especially short supply, and the betterment of the organization and efficiency of the health delivery system. For the two-year "tooling-up" period, appropriations of $200 and $400 million are authorized for financial assistance. Beginning with the effective date of health benefits, percentages of the Trust Fund expenditures will be earmarked for such assistance (section 63). From that date on, the leverage of these expanding funds will supplement and reinforce the incentives, which are built into the normal operation of the Health Security program, for improvement of the organization and methods of delivery of health services.

(Section 102.) This section directs the Secretary, in collaboration with State comprehensive health planning agencies, regional medical programs, and other planning agencies, to institute a continuous process of health service planning. Prior to the effective date of health benefits, the planning process must give first consideration to the most acute shortages and needs for delivery of covered services under this Act. Thereafter, planning shall be focused on maximizing continuing capability for delivery of these services.

This section places primarily on the State agencies the responsibility for coordinating the work of the many health planning agencies within the States, and for coordination with interstate agencies and with agencies planning in other fields related to health, but charges the Secretary with this function in any State that fails to meet the responsibility. The section amends the Public Health Service Act to increase the authorized appropriations for State and for local health planning to extend them to 1978, and to condition grants upon collaboration for these national purposes. Thus the section, strengthening State planning agencies, focuses in them a responsibility, visualized in the "partnership-for-health" legislation but in many States not yet an operating reality, for pulling together all health planning efforts within their territories. The task will not be easy, but it is one that is lent new urgency by the Health Security program. It belongs more properly to the States than to the national Government, but if any State proves unequal to the task it must and will be assumed by the Secretary.

(Section 103.) In administering part F, this section stipulates, the Board will give priority to improving comprehensive health services for ambulatory patients through the development or expansion of organizatoins furnishing such services, the recruitment and training of personnel, and the strengthening of coordination among providers of services. Financial assistance will be dispensed, so far as possible, in accordance with recommendations of the approriate health planning agencies. Funds will not be used to replace other Federal

financial assistance, and may supplement other assistance only to meet specific needs of the Health Security program. Other Federal assistance programs are to be administered when possible to further the objectives of part F, and the Board may provide loans or interest subsidies to help the beneficiaries of other programs to meet the requirements for non-Federal funds.

(Section 104.) Help of several kinds will be available under this section for the creation or the enlargement of organizations and agencies providing comprehensive care to ambulatory patients—either organizations to serve an enrolled population on a capitation basis, or agencies such as neighborhood health centers which need not require enrollment in advance. Grants may be made to any public or other nonprofit organization (which need not be a health organization) to help meet the cost, other than construction cost of establishing such a health service organization, and to existing health service organizations to help meet the cost of expansion: the maximum grants being, in the former case 90 percent of the cost, in the latter 80 percent. The Board may also provide technical assistance for these purposes. Loans may be made for the cost of necessary construction, subject to the same 90 and 80 percent limitations on amount. Finally, start-up costs of operation of these organizations may be underwritten, for five years in the case of organizations which must build up an enrollment to assure operating income, and in other cases until the Health Security program begins payment for services in the first year of entitlement to benefits. The effect of these several provisions is to reduce sharply, if not eliminate, the financial obstacles which have heretofore impeded the growth of comprehensive group practice organizations.

(Section 105.) This section contains a series of provisions to assist in the recruitment, education, and training of health personnel. The Board will establish priorities to meet the most urgent needs of the Health Security system, but the priorities will be flexible both as between different regions and from time to time. Professional practitioners will be recruited for service in shortage areas, both urban and rural, and in comprehensive health service organizations, and such practitioners may be given income guarantees. Other Federal assistance for health education and training will be availed of, but the Board may supplement the other assistance if the Board believes it inadequate to the needs, until Congress has had opportunity to review its adequacy. The training authorized includes the development of new kinds of health personnel to assist in furnishing comprehensive services, and the training of area residents to participate in personal health education and to serve liaison functions and serve as representatives of the community in dealing with health organizations. Grants may be made to test the utility of such personnel, and to assist in their employment before the effective date of health benefits. Education and training are to be carried out through contracts with appropriate institutions and agencies, and suitable stipends to students and trainees are authorized. Physicians will be recruited and trained to serve as hospital medical directors. Finally, special assistance may be given, both to institutions and to students, to meet the additional costs of training persons disadvantaged by poverty, membership in minority groups, or other cause.

(Section 106.) This section authorizes special improvement grants: first, to any public or other nonprofit health agency or institution to establish improved coordination and linkages with other providers of services; and, second, to organizations providing comprehensive ambulatory care, to improve their utilization review, budget, statistical, or records and information retrieval systems to acquire equipment needed for those purposes, or to acquire equipment useful for mass screening or for other diagnostic or therapeutic purposes.

(Section 107.) This section provides that loans under Part F are to bear 3 percent interest and to be repayable in not more than 20 years. Other terms and conditions are discretionary with the Board, except for required compliance with the Davis-Bacon Act and related laws. Repayment of loans made from general appropriations will go to the general fund of the Treasury; repayment of later loans will revert to the Health Resources Development Account in the Trust Fund.

(Section 108.) This section specifies that payments under Part F shall be in addition to, and not in lieu of, payments to providers under Part F.

Part G—Administration

This part of the bill creates an administrative structure within the Department of Health, Education, and Welfare with exclusive responsibility for administra-

tion of the Health Security program. Program policy will be made by a five-member Board serving under the Secretary of HEW. The Board will be assisted by a National Health Security Advisory Council which will recommend policy and evaluate operation of the program, and an Executive Director who will serve as Secretary to the Board and chief administrative officer for the program. Administration of the program will be greatly decentralized among the HEW Regional Offices. Regional and local health services advisory councils will advise on all aspects of the program in their regions and local areas. The Board may also appoint such professional or technical committees as it may deem necessary.

(Section 405.) This section authorizes appropriations for the conduct of studies under this title and confers authority to employ consultants and to contract for services in making the studies.

(Section 121.) This section establishes a five-member full-time Health Security Board serving under the Secretary of Health, Education, and Welfare. Board members will be appointed by the President with the advice and consent of the Senate, for five-year overlapping terms. Not more than three of the five appointees may be members of the same political party. A member who has served two consecutive terms will not be eligible for reappointment until two years after the expiration of his second term. One member of the Board shall serve as chairman at the pleasure of the President.

(Section 122.) This section charges the Secretary of HEW and the Board with responsibility for performing the duties imposed by this title. The Board shall issue regulations with the approval of the Secretary. It is required to engage in the continuous study of operation of the Health Security program; and, with the approval of the Secretary, to make recommendations on legislation and matters of administrative policy, and to report to the Congress annually on administration and operations of the program. The report will include an evaluation of adequacy and quality of services, costs of services and the effectiveness of measures to restrain the costs. The Secretary of HEW is instructed to coordinate the administration of other health-related programs under his jurisdiction with the administration of Health Security, and to include in his annual report to the Congress a report on his discharge of this responsibility.

The Civil Service Commission is instructed to make every effort to facilitate recruitment and employment, to work in the Health Security Administration, of persons experienced in private health insurance administration and other pertinent fields.

(Section 123.) This section creates the position of an Executive Director, appointed by the Board with the approval of the Secretary. The Executive Director will serve as secretary to the Board and shall perform such duties in administration of the program as the Board assigns to him. The Board is authorized to delegate to the Executive Director or other employees of HEW any of its functions or duties except the issuance of regulations and the determination of the availability of funds and their allocations to the regions.

(Section 124.) This section provides that the program will be administered through the regional offices of the Department of HEW. It also requires the establishment of local health service area offices and local offices.

The health service areas will in most instances be a State or a part of a State except where patterns in the organization of health services and the flow of patients indicate that an interstate area would provide a more practical administrative unit. One of the responsibilities of local offices will be to investigate complaints about the administration of the program.

(Section 125.) Subsection (a) establishes a National Health Security Advisory Council, with the Chairman of the Board serving as the Council's Chairman and 20 additional members not in the employ of the Federal Government. A majority of the appointed members will be consumers who are not engaged in providing and have no financial interest in the provision of health services. Members of the Council representing providers of care will be persons who are outstanding in fields related to medical, hospital or other health activities or who are representatives of organizations or professional associations. Members will be appointed to four-year over-lapping terms by the Secretary upon recommendation by the Board.

Subsection (b) authorizes the Advisory Council to appoint professional or technical committees to assist in its functions. The Board will make available to the Council all necessary secretarial and clerical assistance. The Council will meet as frequently as the Board deems necessary, or whenever requested by seven or more members, but not less than four times each year.

Subsection (c) provides that the Advisory Council will advise the Board on matters of general policy in the administration of the program, the formulation of regulations and the allocation of funds for services. The Council is charged with responsibility for studying the operation of the program and utilization of services under it, with a view to recommending changes in administration or in statutory provisions. They are to report annually to the Board on the performance of their functions. The Board, through the Secretary, will transmit the Council's report to the Congress together with a report by the Board on any administrative recommendations of the Council which have not been followed, and a report by the Secretary of his views with respect to any legislative recommendations of the Council.

(Section 126.) To further provide for participation of the community, the Board will appoint an advisory council for each region and local area. Each such Council would have a composition parallel to that of the National Council; and each will have the function of advising the regional or local representative of the Board on all matters directly relating to the administration of the program.

(Section 127.) The Board is authorized to appoint standing committees to advise on the professional and technical aspects of administration with respect to services, payments, evaluations, etc. These committees will consist of experts drawn from the health professions, medical schools or other health educational institutions, providers of services, etc. The Board is also authorized to appoint temporary committees to advise on special problems. The committees will report to the Board and copies of their reports are to be made available to the National Advisory Council.

(Section 128.) Subsection (a) requires the Board to consult with appropriate State health and planning agencies to assure the coordination of the Health Security program with State and local activities in the fields of environmental health, licensure and inspection, health education, etc.

Subsection (b) requires the Board, whenever possible, to contract with States to survey and certify providers (other than professional practitioners) for participation in the program. This is similar to Medicare except that the Board is given authority to establish the qualifications required of persons making the inspections.

Subsection (c) authorizes the Board to contract with State agencies to undertake health education activities, supervision of utilization review programs, and programs to improve the quality and coordination of available services in that State.

Subsection (d) requires the Board to reimburse States for the reasonable cost of performing such contract activities and authorizes the Board to pay all or part of the cost of training State inspectors to meet the qualifications established by the Board.

(Section 129.) The Board is authorized to provide technical assistance either directly or through contract with a State to skilled nursing homes and home health agencies to supplement the skills of their permanent staff in regard to social services, dietetics, etc.

(Section 130.) Subsection (a) charges the Board with responsibility for informing the public and providers about the administration and operation of the Health Security program. This will include informing the public about entitlement to eligibility, nature, scope, and availability of services. Providers would be informed of the conditions of participation, methods and amounts of compensation, and administrative policies. In support of the program's effort to improve drug therapy, the Board is authorized, with the approval of the Secretary, to furnish all professional practitioners with information concerning the safety and efficacy of drugs appearing on either of the approved lists (Section 25), indications for their use and contraindications. Information of this nature is not now always available to practitioners.

Subsection (b) requires the Board to make a continuing study and evaluation of the program, including adequacy, quality and costs of services. Subsection (c) authorizes the Board directly or by contract to make detailed statistical and other studies on a national, regional, or local basis of any aspect of the title, to develop and test incentive systems for improving quality of care, methods of peer review of drug utilization and of other service performances, systems of information retrieval, budget programs, instrumentation for multiphasic screening or patient services, reimbursement systems for drugs, and other studies which

it considers would improve the quality of services or administration of the program.

(Section 131.) This section authorizes the Board to enter into agreements with providers to experiment with alternative methods of reimbursement which offer promise of improving the coordination of services, their quality or accessibility.

(Section 132.) This section grants authority to the Board, in accordance with regulations, to make determinations of who are participating providers of service, determinations of eligibility, of whether services are covered, and the amount to be paid to providers. The Board is granted authority to terminate participation of a provider who is not in compliance with qualifying requirements, agreements or regulations. But unless the safety of eligible individuals is endangered, the provider shall be entitled to a hearing before the termination becomes effective.

(Section 133.) This section establishes procedures for appeals similar to those under the Social Security Act.

(Section 134.) This section has one of the bill's most important provisions with respect to achieving improvement in coordination, availability, and quality of services. It greatly strengthens state and local planning agencies and gives the Board authority to curtail inefficient administration of participating institutional providers.

The Board is authorized to issue a direction to any participating provider (other than an individual professional practitioner) that, as a condition of participation, the provider add or discontinue one or more covered services. For example, if two community hospitals are operating maternity wards at low occupancy rates, the Board may require that one hospital cease to provide such service. A provider may be required to provide services in a new location, enter into arrangements for the transfer of patients and medical records, or establish such other coordination or linkages of covered services as the Board finds appropriate.

In addition, if the Board finds that services furnished by a provider are not necessary to the availability of adequate services, under this title, that their continuance is unreasonably costly, or that the services are furnished inefficiently (and that efforts to correct such inefficiency have proved unavailing) the Board may terminate participation of the provider.

No direction shall be issued under this section except upon the recommendation of, or after consultation with, the appropriate state health planning agency. And no direction shall be issued under this section unless the Board finds that it can be practicably carried out by the provider to whom it is addressed. The Board is required to give due notice and to establish and observe appropriate procedures or hearings and appeals, and judicial review is provided.

(Section 135.) Subsection (a) creates the positions of Deputy Secretary of Health, Education, and Welfare and Under Secretary for Health and Science in the Dept. of Health, Education, and Welfare.

Subsection (b) fixes the levels of compensation in the Executive pay rates scale for the Deputy Secretary (level II), the Under Secretary for Health and Science (level III), the Health Security Board chairman (level III), Board Members (level IV), and the Exec. Director (level V).

Part H—Miscellaneous provisions

(Section 141.) This section contains definitions of certain terms used in the title.

(Section 142.) This section stipulates that the effective date for entitlement for benefits will be July 1, of the second calendar year following enactment.

(Section 143.) Subsection (a) provides that an employer will not be relieved, by the enactment of the Health Security Act, of any existing contractural or other non-statutory obligation to provide or pay for health services to his present or former employees and their families. Subsection (b) expresses the sense of Congress that if, nevertheless, inauguration of the Health Security Program lessens the cost of an employer's aggregate obligations for health services to such persons, the savings should, at least for the period of any coitract subsisting on the effective date of benefits, be applied to the payment of the employees' health security taxes, to wage increases, or to other employee benefits.

TITLE II

Part A—Payroll taxes

(Section 201.) Effective on January 1 of the second year after enactment, subsections (a) and (b) convert the existing Medicare hospital insurance payroll taxes into Health Security taxes, and raise the rates to 1 percent on employees and 3.5 percent on employers. Subsection (c) raises the wage base for the employee tax from the present $7,800 to $15,000 with subsequent further increase if wage levels rise, eliminates the wage ceiling from the employer tax, and broadens the definitions of covered employment to include foreign agricultural workers, employees of the U.S. and its instrumentalities (other than members of the armed forces, and the President, Vice-President, and Members of Congress), employees of charitable and similar organizations, railroad employees, and (for the employee tax only) employees of States and their political subdivisions and instrumentalities. This subsection also provides the mechanism for increasing the wage base, by $600 intervals, in proportion to future increases in average wage levels.

(Section 202.) Section 202 makes a number of conforming and technical amendments. Chief among these are provisions for refund of excess taxes collected from an employee, who has held two or more jobs, on wages aggregating in a year more than the amount of the new wage base; exclusion of Health Security contributions from agreements with State governments for the social security coverage of State and municipal employees (since these employees will contribute to Health Security through payroll taxes); and exclusion of Health Security contributions from agreements for the coverage of United States citizens employed by foreign subsidiaries of United States corporations (since these employees will not benefit directly from Health Security in its present form).

(Section 203.) This section excludes from the gross income of employees, for income tax purposes, payment by their employers of part or all of the Health Security taxes on the employees.

(Section 204.) This section spells out the precise effective dates of the new payroll tax provisions.

Part B—Taxes on self-employment income and unearned income

(Section 211.) Effective at the beginning of the second calendar year after enactment, this section converts the existing Medicare self-employment tax into a Health Security self-employment tax, raises the rate to 2.5 percent, and raises the maximum taxable self-employment income from $7,800 to $15,000 (with the same upward adjustment as in the employee tax for subsequent rises in average wage levels).

(Section 212.) Effective on the same date, this section adds a new 1 percent Health Security tax on unearned income (unless such income is less than $400 a year), subject to the same maximum on taxable income as is applicable to the employee and self-employment taxes. Taxable unearned income is adjusted gross income up to the stated maximum, minus wages and self-employment income already taxed for Health Security purposes (excluding certain items of income specifically excluded from the other taxes).

(Section 213.) This section makes appropriate changes in nomenclature and in the requirements of tax returns, including reports of estimated tax liability under the new tax on unearned income.

(Section 214.) This section details the specific effective dates of the taxes imposed by this part.

TITLE III

(Section 301.) Subsection (a) repeals Medicare on the date benefits become effective but stipulates that this shall not affect any right or obligation incurred prior to that date.

(Section 302). This section requires that after the effective date of benefits, no State shall be required to furnish any service covered under Health Security as a part of its State plan for participation under Medicaid, and that the Federal government will have no responsibility to reimburse any State for the cost of providing a service which is covered under Health Security. After the effective date of benefits, the Secretary of HEW shall prescribe by regulation the

new minimum scope of services required as a condition of State participation under Title XIX. To the extent the Secretary finds practicable, the new minimum benefits will be designed to supplement Health Security—especially with respect to skilled nursing home services, dental services and the furnishing of drugs.

(Section 303.) This section provides that funds available under the Vocational Rehabilitation Act or the Maternal and Child Health title of the Social Security Act shall not be used to pay for personal health services after the effective date of benefits, except (to the extent prescribed in regulations by the Secretary of HEW) to pay for services which are more extensive than those covered under Health Security.

TITLE IV

(Section 401.) This section authorizes the Secretary of Health, Education, and Welfare in consultation with the Secretary of State and the Secreary of the Treasury to study the coverage of health services for U.S. residents in other countries.

(Section 402.) Subsection (a) sets forth Congressional findings concerning the shortage of appropriate services and facilities for the long-term care of the aged or chronically sick. It notes that the shortage is in large measure due to the inadequacy and fragmentation of public programs, and that the shortage of appropriate services results in a severe hardship to the elderly and disabled, and causes much improper use of hospitals and skilled nursing homes. Subsection (b) directs the Secretary to make a comprehensive study of the need for additional social, homemaker and other services for persons described in subsection (a) and the most equitable and appropriate means of financing such services. The Secretary is required to report his findings together with recommendations of legislation to the Congress within two years of the enactment of this title.

(Section 403.) Subsection (a) directs the Secretary of HEW to study the feasibility and desirability of coordinating the federal health benefit programs for merchant seamen, and Indians and Alaskan natives with the health security benefit program. The Secretary and the Administrator of Veterans Affairs shall conduct a similar joint study of the desirability and feasibility of coordinating veterans health care programs with the health security benefits program. Reports to the Congress and any legislative recommendations arising from the studies are required within three years after the enactment of this title.

Subsection (b) requires the Secretary and Administrator to consult with representatives of the affected beneficiary groups and include a summary of their views in the reports to Congress.

With respect to the joint study to determine the most effective method of coordinating the Veterans Administration Health Program with the Health Security Program established under this bill, it is important to understand that there is no intention to require either the integration of the VA program into the Health Security Program, or even the consideration of such integration. Rather, the section recognizes that any national health security or health insurance program would be so pervasive as to require other federal health programs such as those of the Veterans Administration to be effectively coordinated with them. Through such coordination, needless duplication and expenditures should be avoided.

(Section 404.) Subsection (a) sets forth Congressional findings concerning medical malpractice, and the methods of determining liability and assessing damages, are unsatisfactory, it notes that the cost of malpractice insurance is a significant element in the mounting cost of health care, and points to increasing evidence that the cost, together with the limited availability of insurance, may tend to discourage desirable medical procedures and have a detrimental effect on the use of health services. It concludes that better mechanisms must be found to determine and award fair compensation in appropriate cases to patients who have been injured in the course of the receipt of health services.

Subsection (b) directs the Secretary to make a comprehensive study of the problem, including the most approriate criterion of compensable injury, means of adjudication, and means of financing the payment of compensation. The Secretary is required to make to the Congress an interim report within one year, and a final report and recommendations for legislation within two years of enactment of this title.

Appendix C

PER CAPITA EXPENDITURES[1] FOR NON-FEDERAL HOSPITAL CARE, PHYSICIANS' SERVICES AND DENTISTS' SERVICES, 1968

Geographic division	Non-Federal hospital care	Physicians' services	Dentists' services
United States, all	$78.84	$57.85	$18.07
New England	103.29	51.17	21.48
Middle Atlantic	95.52	60.80	21.14
East North Central	79.09	58.59	17.16
West North Central	79.17	51.30	14.30
South Atlantic	63.92	46.26	15.80
East South Central	59.51	43.07	12.08
West South Central	61.30	52.05	12.07
Mountain	71.12	62.71	15.12
Pacific	86.14	83.52	27.04

[1] Based on data furnished by the Social Security Administration (Office of Research and Statistics), DHEW.

Lowest and highest states[1]—Non-Federal general hospital care, U.S. average $78.84 per capita

3 LOWEST STATES		3 HIGHEST STATES	
Mississippi	$44.84	Rhode Island	$104.05
South Carolina	45.27	New York	114.33
Arkansas	47.83	Massachusetts	123.66

[1] Excluding Alaska (with unusually extensive Federal facilities whose expenditures are not included in these figures) and the District of Columbia (with expenditures allocable to Maryland and Virginia).

Physicians' services, U.S. average $57.85 per capita

3 LOWEST STATES		3 HIGHEST STATES	
South Carolina	$32.73	Colorado	$80.52
South Dakota	33.23	Oregon	85.81
Maine	35.14	California	89.11

Dentists' services, U.S. average $18.07 per capita

3 LOWEST STATES		4 HIGHEST STATES	
Louisiana	$7.95	Hawaii; New York	$25.93
New Mexico	9.69	California	27.49
Mississippi	9.71	Oregon	31.66

Mr. WOODCOCK. Thank you, Mr. Chairman.

If the Health Security Act had been operational for fiscal year 1970 the expenditures required would have been $40 billion, which is about two-thirds of all the personal health service expenditures made in that year.

I emphasize this is not a new $40 billion. It is a rechanneling of existing expenditures. Health services absorbs 69 percent of the private expenditures and 57 percent of the public expenditures.

The $9.3 billion spent for medicare and medicaid in fiscal 1970 would have been replaced and more than $2½ billion spent by State and local governments would have been absorbed.

The later the time of new program initiation, the greater the costs because of the strong inflation operating in this field. In 1973–74 the $40 billion would rise to $56.7 billion; a year later, fiscal year 1974–75.

to $62.5 billion, all of these figures including the cost of administration and resource development.

Beyond the first year, the study assumes that cost controls are taking hold and would begin to moderate the 10 percent annual inflationary factor down toward 6 percent, but still including the cost of expanding services, population growth and price increases.

So we start from the same base but future costs would be relatively diminished because any other program before this committee has no provision whatsoever for any control of future costs.

Under Health Security all the American people would move toward health protection for less than is now being totally paid for a fragmented system for some Americans.

The benefits embrace the entire range of personal health services. They include prevention, early detection of disease, treatment of illness, and rehabilitation.

There are no restrictions on needed services, no cut-off points, no coinsurance, no deductibles, no waiting periods, except for four modest limitations in the areas of dental care, skilled nursing home care, psychiatric care, and drugs, which are spelled out in detail the statement. There is complete coverage for physician services, hospital services, optometry, podiatry, and specified prescribed devices, appliances and equipment.

A notable feature of the program and of the bill is the resource development fund, reaching a level of $3 billion by 1975, for strengthening professional and supporting personnel resources and upgrading delivery systems.

The program is grounded on freedom of choice for the physician in practice, with incentives to encourage more efficient systems in an evolutionary way. There is freedom of choice for individuals who are for the most part now more concerned about access to decent care then to choosing.

We urge the sympathetic study by this committee of H.R. 22.

Last February when we first heard of the administration's health strategy we supported much of what was in the President's message; the expansion of training, MEDEX, the endorsement of the Emergency Health Personnel Act, the promise of new funds for medical education and for research programs.

We were particularly pleased with strong emphasis placed on the development of health maintenance organizations, the HMO's. Unfortunately implementation has lagged and HMO's now appear headed for the profitmaking sector.

Last week our growing disappointment was magnified when before this committee the administration backed off from the promise to require Federal regulation to the health insurance industry. They propose to continue to leave it to the States, with a large chunk of business mandated by Federal authority. This large chunk of mandated business, $30 billion to begin with and which would sharply escalate, is part of a crazy quilt of classes and coverage and lack of coverage, with millions of people left out.

This is an offense to the consumer and we believe an administrative nightmare. The only cost controls considered are to make the con-

sumer "cost-conscious" through tough coinsurance payments and deductibles.

I submit, Mr. Chairman, a sick child is not discretionary spending like a Chevrolet. It will work against preventive medicine and make sure we keep sickness insurance and not health care insurance.

We pray this committee will consider the primacy of the health of the American people which should be our prime natural asset and not the profitability of the health insurance industry which has failed its mission after 30 years.

For these 30 years we have tinkered and patched. The time has come to get a progressive reform of the health care system through evolution, while protecting the freedom of the professions and the patients. H.R. 22 we submit, Mr. Chairman, does exactly that.

Mr. ULLMAN. Does that conclude your statement, Mr. Woodcock?

Mr. WOODCOCK. It does, yes, sir.

Mr. ULLMAN. Let me just ask one question with respect to the cost estimates.

I haven't had a chance to thoroughly look at them. It would be most helpful if we could have something in graph form that might put this in perspective. We should really know what Dr. Falk's estimate of the total health care costs might be as projected in the future under existing health programing and then under your program, and then broken down into components.

Would the total national expenditures be larger, and I presume they would, under H.R. 22 because of the availability of more health services for more people. To what extent would they be larger under H.R. 22 than they would be under existing circumstances?

Mr. WOODCOCK. We agree this is a critical question, Mr. Chairman. We believe that in fact they would be less although the availability of service would be total and would be universal.

I would like to have Dr. Falk comment on the question if I may.

Mr. ULLMAN. Yes, Dr. Falk.

We would be glad to hear from you.

Mr. FALK. Thank you, Mr. Chairman.

Perhaps I might first give you an answer in very brief and capsule form and then see to what extent it may need expansion and explanation.

On the basis of the available data, the estimates for the years ahead, and I gather your question focuses on that, if we assume no new major program interventions and merely assume the continuance of the trends from recent years, the present expenditures for all personal health services, which are of the order of magnitude of $70 billion to $75 billion for 1971, would according to the model which has been used by the actuary of the Department of Health, Education, and Welfare go up to approximately $103 billion in calendar year 1975 and to $146 billion in calendar year 1980. May I say parenthetically the phrase "personal health services" is important here because that excludes expenditures for biomedical research and for the construction of facilities, et cetera.

That is one set of projections based upon studies which were conducted in the HEW, primarily in the Social Security Administration.

As Mr. Woodcock indicated, we think that the model which was used by the HEW actuary and which goes toward the figures I have

just cited is an unduly high and generous model because it does not take into account interventions of modest intensity and proportions which are already ocurring in some measure under governmental auspices as has been the case in the work of this committee in dealing with H.R. 1, other governmental activities by administrative decisions and actions with respect to medicare and medicaid, some modest but well intended undertakings by the Blue Cross and Blue Shield plans, by professional associations and others.

So that, taking all of these interventions which are already occurring, we had developed our own model. As a matter of fact we had developed it before the Social Security Administration model become available.

On the basis of the model we have used if there are no major new program interventions, the present scene leads, using recent trends, to costs which would go up to $85.5 billion in fiscal 1974, and moves up to $93 billion in fiscal 1975. It then crosses $100 billion, reaching $100.2 billion in fiscal 1976 and $110 billion in fiscal 1977.

Those are the projections if we assume no new major program undertakings and interventions in this scene and merely the continuance of what we can observe in the present scene. These are to most people threatening, even frightening, figures of what is ahead because they mean unquestionably very extensive extension of costs to a point where medical care becomes increasingly beyond the reach of many, many people in the country.

Mr. ULLMAN. Dr. Falk, do you have those broken down into who pays those amounts?

Dr. FALK. Yes, sir. Our estimates are derived by projections by type of service for which the expenditures are incurred, so much for hospital care et cetera, and also by the sources of funds, on the assumption that for the projection periods in the years ahead, the proportions of the funds that would come from the various sources are the same as the proportions which applied in the last fiscal year for which we have detailed data, which was fiscal 1970.

Mr. GIBBONS. Will the gentleman yield for a repeat of some of this information? I didn't catch some of it.

Mr. ULLMAN. Yes.

Mr. GIBBONS. Is the $84 billion 1974 figure H.R. 22 or present health costs?

Dr. FALK. No, sir. That is the projection if you make the assumption of no new major program interventions.

Mr. GIBBONS. That is leaving things as it is right now. That is $84 billion?

Dr. FALK. $85 billion.

Mr. GIBBONS. Versus HEW's $105 billion, is that right?

Dr. FALK. I haven't a strict comparison in front of me because the figures I used from the Social Security Administration are on a calendar year basis. Their calendar 1975 would lead to $103 billion.

Excuse me, I think I do have that comparable figure. The calendar year 1975, their model would lead to approximately $103 billion; and the model we have used would give us for calendar year 1975, $97 billion. These are figures which are based on model projections, assuming no new major program intervention.

Mr. ULLMAN. Is that material in your paper, in terms you have been giving us orally, not on any of the tables in the prepared material?

Dr. FALK. The figures up to and including 1975 are in that document. The projections beyond that are not included in that document, but are easily made available for the record if you wish to have them, Mr. Chairman.

Mr. ULLMAN. Would that be table 7 on page 7A?

Dr. FALK. Table 7 is the projections based upon the model developed by the Social Security Administration, and that is the model used by the actuary of the HEW.

Mr. ULLMAN. Where is your comparable figure?

Dr. FALK. In table 8.

Mr. ULLMAN. Is that page 12A?

Dr. FALK. Yes; page 12A. I am sorry, I am fumbling a little, but I didn't develop this on the basis of the same typing as the document you have. It is page 12A.

Mr. ULLMAN. That gives adjusted projections for fiscal 1974 and 1975?

Dr. FALK. Yes, sir.

Mr. ULLMAN. As against 1969 and 1970?

Mr. Burke, I will yield.

Mr. BURKE. Mr. Chairman, is this entire statement of Dr. Falk going to appear in the record?

Mr. ULLMAN. It has already been placed in the record; yes.

Now, as against those projections continuing, what is your estimate of H.R. 22?

Dr. FALK. Assuming the enactment of H.R. 22 in 1972, and we have to fix a date because this, in turn, vxes the date to which the program operations will apply——

Mr. ULLMAN. Yes; surely.

Dr. FALK (continuing). In fiscal 1975, the program costs, including the costs of administration and resources development et cetera, which are new elements in the picture, the figures would be $62.5 billion. It moves up then by 6 percent per annum. The corresponding figure for the calendar years, in order to be comparable with the other figures which are on a calendar year basis, in calendar year 1975 would be $64.4 billion; calendar 1976, $68.3 billion; and 1977, $72.3 billion.

Mr. ULLMAN. What you are sayinig is that the total cost would be considerably less under H.R. 22 than a projection of the existing circumstances?

Dr. FALK. May I answer the question, Mr. Chairman, in two respects? I think the answer is yes, but the figures I just cited with respect to the costs expected under H.R. 22 are the costs under that program.

Mr. ULLMAN. The Federal costs.

Dr. FALK. No, sir; the total costs of operating the program under H.R. 22. Those figures do not include any costs that would be being incurred for personal health services not included within or covered by the program under H.R. 22.

You will recall that there are some areas in which H.R. 22 does not undertake to take over the costs. It is a matter for speculation as to what extent costs that are being incurred or, on the projections basis that are expected to be incurred, but that would not be taken over into the scope of H.R. 22, would continue.

For example, there are expenditures for certain dental services and institutional services, expenditures for drugs and medicines, et cetera that are not embraced within H.R. 22. Whether those costs would continue outside the H.R. 22 program, as in the projected model, or not, is an area of speculation.

We think that there would be considerable reduction in the expenditures expected to be incurred in projection models from the present scene for goods and services not embraced by H.R. 22, less being expended for these noncovered areas of goods and services by reason of the fact that more comprehensive services are made available to people under H.R. 22, so that they would not have need or interest or occasion or stimulus to spend outside the H.R. 22 program what would be expected to be their expenditures if we don't have H.R. 22.

Let me put it in another way. If you project the total costs from the present scene toward 1975, let us say, and reach a figure of $100-plus billion, if H.R. 22 were enacted and were operational at that time, after the necessary preparatory work, the difference between the H.R. 22 expenditures and the total in the nonintervention model, we believe, would be narrowed.

Many expenditures that otherwise are likely to be incurred in the years ahead will not be incurred. So that the total costs, the total national expenditures, are likely to be less, considerably less, than is in the nonintervention projection models. The gap between H.R. 22 and the total national expenditures will be less than simply deducting one figure from the other.

Mr. ULLMAN. I am sure that other members are going to have questions on this whole problem of costs. I wish, though, that you could give us a more refined table or chart that would give us real comparability according to your best estimates as to the total cost of H.R. 22, not only the services coming under the bill but the total services, so that we could compare it with your projections of the existing situation.

Could you do that and submit it for the record?

Dr. FALK. I hesitate to give you an unequivocal answer, Mr. Chairman, because I don't think we know how to do quite that. I emphasize the point I made a moment ago that how much noncovered services under H.R. 22 would be reduced, as we believe they would be, by how much in the years after H.R. 22 becomes operable, is a highly speculative matter.

We have made no special studies in that field.

(The following information was received by the committee:)

The following tabulations are intended to summarize the information requested by the Acting Chairman of the Committee. They show total expenditures for personal health care services without and with the Health Security program proposed in H.R. 22, the sources of the funds expended, and differences in the amounts of expenditures and in the sources of the funds that would result if H.R. 22 were enacted.

As in our study "The Costs of a National Health Security Program and Their Financing," two sets of estimates are presented. Table A shows actual expenditures incurred in Fscal Year 1969–70 (the latest year for which detailed data are available at this time), and estimates of the expenditures that would have been incurred in that year if the Health Security program (HSP) in H.R. 22 had been operational. Table B presents a corresponding comparison for Fiscal Year 1974–75, using (1) our projection of expenditures that are to be expected if there is no major program intervention to moderate the escalation of costs

or to improve the system of medical care delivery, and (2) our estimates for that year if the Health Security program of H.R. 22 is operational.

The actual total expenditures of $60.1 billion for personal health care services shown in Table A for FY 1969–70 is expected to be $92.8 billion in FY 1974–75 if there is no major intervention. That increase reflects the *non*-implementation of H.R. 22 in that five year period. The longer that lag, presumably the higher the level of expenditures without or with the Health Security program when it becomes operational.

In both Tables A and B, total expenditures are presented in the same total amount whether without or with the proposed program. Increases in medical care utilization are expected to be offset by cost controls built into the program. In other words, the main fiscal effect of the Health Security program is to rechannel expenditures, to increase the resources for medical care, to improve the efficiency of their availability, and to control cost escalations through budgeting processes and other means, not to increase those costs. For future years, the cost escalations otherwise to be expected would be moderated to rates in accord with changes in the general economy rather than to permit escalations such as have characterized medical care costs in the recent past.

It will be seen in the tables that the principal effect of the Health Security financing pattern is to channel the covered expenditures through the national Health Security trust fund mechanism, with 50 percent of the program's funds deriving from Federal general revenues and 50 percent from the earmarked Health Security taxes. Medicare taxes and premiums and nearly all private insurance purchase would be eliminated.

Table A shows that in FY 1969–70 expenditures from Federal general revenues for personal health care services were actually $8.4 billion, of which $4.5 billion were for services outside the scope of HSP and $3.9 billion were within. With HSP, this figure would have been increased to $19.5 billion—an increase of $15.6 billion. Of this increase, $5.5 billion is an offset against Medicare taxes and premiums eliminated by HSP, and $2.5 billion reflects absorption of expenditures incurred by state and local governments. Thus, the net increase from Federal general revenues directly attributable to the HSP financing pattern would have been $7.6 billion.

Table B shows a corresponding picture for FY 1974–75 if that is the first operational year for the Health Security program. At the higher expenditure levels to be expected for that year, *without* the proposed program, expenditures from Federal general revenues would be about $13.0 billion based on 1969–70 proportions of expected total national expenditures for personal health care services, of which $6.4 billion would be for HSP services and $6.6 billion for non-HSP services. *With* the Health Security program operational, the demands on Federal general revenues would be about $37.9 billion, or net for HSP $31.3 billion. This is an increase of $24.9 billion. This increase includes $4.5 billion relief to state and local governments and $8.4 billion take-over of Medicare taxes and premiums. Thus, HSP's net increased demand on Federal general revenues would be about $12.0 billion.

Simultaneous with these changes in the governmental sector, the net effects on employers would have been in FY 1969–70 a net increase of $4.1 billion in their obligations (Health Security taxes of $14.7 billion *less:* reductions of $8.4 billion for private insurance eliminated and $2.2 billion for Medicare taxes repealed); and the net effect on employees and other individuals a net reduction of $16.4 billion (Health Security taxes of $4.9 billion *less:* $7.1 billion for private insurance premiums, $3.3 billion for Medicare taxes and premiums, and $10.9 billion for reduced direct payments for medical care services). In FY 1974–75, the corresponding changes in the private sector would be (1) a net *increase* on employers of $6.5 billion, and (2) a net *decrease* on employees and other individuals of $26.9 billion.

I would emphasize that throughout Tables A and B, the expenditure figures for medical care services *not* covered by the Health Security program have been treated as though they would be unaffected and unchanged following the implementation of the proposed program. This is a procedure of convenience for the comparisons in the tables, but we believe it is not warranted. On the contrary, we believe that *non*-covered expenditures would be *decreased* when the Health Security program's benefits become available. We therefore believe that the total national expenditures, covered and not covered by the program, shown in these Tables are too high. We have not, however, engaged in detailed studies to develop estimates of the probable downward adjustments.

SUMMARY OF NATIONAL COSTS FOR PERSONAL HEALTH CARE SERVICES, SHOWING ESTIMATED FINANCIAL EFFECTS OF HEALTH SECURITY PROGRAM (H.R. 22, 92d Cong., 1st SESS.) [1] [2]

[A: If the program (HSP) had been operational in fiscal year 1969–70. B: If the program first becomes operational in fiscal year 1974–75]

A. FISCAL YEAR 1969–70: ACTUAL EXPENDITURES; AND REDISTRIBUTION OF EXPENDITURES IF THE HEALTH SECURITY PROGRAM (HSP) HAD BEEN OPERATIONAL

[In billions]

Spending agencies and sources of funds	Actual expenditures by spending agencies		Estimated expenditures with the HSP operational					
			HSP payments			Total with HSP [4]		Differences col (6) minus col (1) (transref payments)
	Expenditures	Transfer payments	Expenditures	Transfer payments	Non-HSP payments [4]	Expenditures	Transfer payments	
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Total	$60.1	0	$39.1	0	$21.0+	$60.1	0	0
Governmental programs, total	20.9	−$5.5	39.1	−$19.6	9.0	48.1	−$19.6	+$27.3
Federal, total	13.9—	−5.5	39.1	−19.6	4.5	43.6	−19.6	+29.8—
From general revenues	8.4		19.5		4.5	24.0		+15.7—
From medicare taxes and premiums	5.5	−5.5	0		0	0		−5.5
From health security taxes			19.6	−19.6		19.6	−19.6	+19.6
State-local, total	7.0		0		4.5	4.5		−2.5
Private expenditures, total	39.3—	+2.2	0	+19.6	12.0+	12.0+	+19.6	−27.3—
Employers, total	8.4	+2.2	0	+14.7	0	0	+14.7	−8.4
Insurance premiums	8.4		0		0	0		−8.4
Medicare taxes		+2.2	0		0	0		(−2.2)
Health security taxes [5]			0	+14.7		0	+14.7	(+14.7)
Employees and other individuals, total	30.0	+3.3	0	+4.9	12.0+	12.0	+4.9	−18.0
Insurance premiums	7.1		0		0	0		−7.1
Medicare taxes and premiums		+3.3	0		0	0		(−3.3)
Direct payments	22.9		0		12.0	12.0		−10.9
Health security taxes [5]			0	+4.9		0	+4.9	(+4.9)
Other private agencies	.9—		0		0	0		−0.9+

B. FISCAL YEAR 1974–75: ESTIMATED EXPENDITURES BY PROJECTION FROM FISCAL YEAR 1969–70; AND REDISTRIBUTION OF EXPENDITURES IF THE HEALTH SECURITY PROGRAM (HSP) FIRST BECOMES OPERATIONAL IN FISCAL YEAR 1974–75

Spending agencies and sources of funds	Projected expenditures by spending agencies [2]		Estimated expenditures with the HSP operational					
			HSP payments			Total with HSP		Differences col (6)—col (1) (transfer payments)
	Expenditures	Transfer payments	Expenditures [3]	Transfer payments	Non-HSP expenditures [4]	Expenditures [4]	Transfer payments	
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
Total	$92.8	0	$62.5	0	$30.3	$92.8	0	0
Governmental programs, total	32.2	—$8.4	62.5	—$31.2	12.9	75.4	—$31.2	+$43.2
Federal, total	21.4	—8.4	62.5	—31.2	6.6	69.1	—31.2	+47.7
From general revenues	13.0		31.3		6.6	37.9		+24.9
From medicare taxes and premiums	8.4	—8.4	0		0	0		—8.4
From health security taxes			31.2	—31.2		31.2	—31.2	+31.2
State-local, total	10.8				6.3	6.3		—4.5
Private expenditures, total	60.6	+3.4	0	+31.2	17.4	17.4	+31.2	—43.2
Employers, total	13.0	+3.4	0	+22.9	0+	0+	+22.9	—13.0
Insurance premiums	13.0		0		0+	0+		—13.0
Medicare taxes		+3.4	0		0	0		(—3.4)
Health security taxes [5]			0	+22.9		0	+22.9	(+22.9)
Employees and other individuals, total	46.3	+5.0	0	+8.3	16.1	16.1	+8.3	—30.2
Insurance premiums	11.0		0		0+	0+		—11.0
Medicare taxes and premiums		+5.0	0		0	0		(—5.0)
Direct payments	35.3		0		16.1	16.1		—19.2
Health security taxes [5]			0	+8.3		0	+8.3	(+8.3)
Other private agencies	1.3		0		1.3	1.3		0

[1] Based on the assumptions, data and analyses in "the Costs of a National Health Security Program and Their Financing," by I. S. Falk, September 1971.

[2] "Personal health care services" includes all expenditures for health services and supplies other than Government public health and related activities, expenditures of private voluntary agencies for other health services, medical research, and medical-facilities construction.

[3] Table A does not include estimated expenditures for resources development ($780,000,000). Table B inclused $1,200,000,000 for this function under HSP.

[4] To effect a balance in each table, this column makes an unwarranted asssumption that the non-covered expenditures, actual in fiscal year 1969–70 and estimated for fiscal year 1974-75 from proportions in the benchmark year, would be in amounts not reduced by the availability of the health security Program's benefits.

[5] For fiscal year 1969–70 based on allocation of 37½ percent HSP expenditures to employers and 12½ percent to employees, etc.; for fiscal year 1974–75, based on the tax rates proposed in H.R. 22, adjusted to the level of expected expenditures (i.e., avoiding accumulation of reserves).

[6] Allocations to sources of funds assume the same proportions as in the actual expenditures in fiscal year 1969–70.

Note: Small discrepancies in totals result from roundings.

Mr. ULLMAN. Do you have any questions, Mr. Burke?

Mr. BURKE. Yes.

Mr. ULLMAN. Mr. Burke.

Mr. BURKE. In view of the poor track record of the United States as pointed out in the statistics provided by the Ways and Means staff for life expectancy, where the life expectancy at birth of the U.S. males is 66.86 years, nearly 5 years shorter than the life expectancy in a Swedish male and among the 20 industrial nations in 1967 the United States ranked 14th in the rate of infant mortality, we seem to have a rather poor health care record here.

How do you think we can get about the tremendous powerful group, the entrenched group that has more or less controlled health care here in the United States? How do you think we are going to be able to circumvent this and bring about the enactment of legislation such as H.R. 22?

Mr. WOODCOCK. Our hope, sir, rests in this committee, to begin with. When the appalling need of the Nation is clear as it is now, when, as has been said, everyone agrees to the diagnosis, from the President of the United States on down, that the health care system is headed for disaster, when everyone agrees on the diagnosis, then we should be able to find the political means to a remedy.

We suggest that H.R. 22 is the only one that has the remedy which goes to the critical overriding question of cost controls and quality performance. The other programs will simply escalate the inflationary factor, which is leading us to a situation where tens of millions of more Americans will be denied health care.

It is already a national scandal that we have some 30 million Americans without adequate access to health care today. The Congress has the power within itself to bring that remedy to the Nation.

Mr. BURKE. I believe you have been following the hearings here since the day we began them and you see these same groups coming in here day after day, powerful insurance groups, the medical groups, the hospital groups, and they all seem bent on keeping the status quo.

Mr. WOODCOCK. Well, that is unfortunate, but I think there have been exemplary times in the past when the Congress, sensing the needs of the people, the will of the people, have overridden self-interest groups in the national interest. The national interest is paramount.

Mr. BURKE. I want to commend you on your statement here today and also George Meany, who testified here the other day. You men deserve a great deal of credit for being in the vanguard leading the fight for proper and fair and equitable health care.

Mr. GLASSER. May I supplement Mr. Woodcock's testimony with one brief item, because before this committee and in public statements the assertion is frequently made that there are many problems that affect the health status of this Nation and, in fact, that is an accurate statement.

The question is then raised will the introduction of adequate medical services, in fact, do anything about the medical or health status of the Americans? I commend to the committee's attention two items: One, the articles in the New York Times of October 2 and 3 by Anthony Lewis, a reporter of the Times, in which he carefully cites the evidence of the British experience compared with that of the United

States after they introduced comprehensive health care whereby every major index that he cites, the health status of the British people was dramatically improved and is improved over our own; and, two, a small but significant study cited in the June 1971 issue of the Journal of the American Medical Association where the authors conducted a study of what happened to a large group of poor people in Denver, white and black, when good medical services were made available to them and the study shows a marked drop in infant mortality in the city of Denver in the population which got medical services which they had not hitherto received.

Mr. BURKE. Has anyone any observation to make on how we can get the AMA to change their closed-shop attitude about educating more doctors and training more physicians with the need of 50,000 more physicians in the country? How do you think we can go about pulling them into the 20th century in recognizing the need for physicians?

Mr. WOODCOCK. I think, sir, that the fact that for the first time in its history less than half of the profession are members of the AMA should tell them something. I think the younger doctors now coming out of medical school, for the most part, have a much different outlook on the social problems that we face in this area. Of course, we have had on our committee for national health insurance many very prominent physicians.

One of our vice chairmen is Dr. DeBakey, so there are currents at work within the medical profession that are looking toward solution of the problem.

Mr. BURKE. I think one of the troubles is that a lot of these young doctors are not joining the AMA, they are staying outside of its organization, and the result is that they still retain this backward outlook. I have had letters from many of these young doctors who want to testify before the committee to give their opinions, which are quite contrary to the opinions given by the AMA.

I am just wondering how we are going to get the AMA to come into this century and start recognizing the tremendous need for doctors and medical schools in this country. I know that Boston University has a group in Mississippi, and there are literally millions of people throughout the country that are not getting even minute care.

So that I just wondered if somebody could send them a booklet or something and tell them that now is the time to start moving. I merely raise that question because this is one of the powerful groups in the country that has not recognized the need of health care here in the United States and they seem to want to maintain a closed shop in the operation of medical care.

Mr. GLASSER. May I reply to this, sir?

Mr. BURKE. Yes.

Mr. GLASSER. The first semifacetious reply is that I would urge the leadership of the AMA to read the journal of the American Medical Association. In the June 21, 1971, issue there is a careful study by Dr. K. V. Castleton, which concludes, and I quote:

> We shall never solve the national problem of health care merely by increasing the number of physicians. Making existing doctors more productive is much less costly than establishing new medical schools.

And this comes to the heart of H.R. 22, sir, because while we recognize full well the need to train additional physicians, if one takes

HEW estimates of the 50,000 shortage at this time, we probably, none of us, will last long enough to see those 50,000 net increase in physicians arrive, but H.R. 22 through offering incentives to the team delivery of health care and maximizing the time of physicians, in fact, offers promise of producing many more physicians' services through the same number of physicians.

In addition, H.R. 22 through the resources development fund would encourage the training of additional physcians in a way that is not now being done and at a rate we believe not now possible in the persent setup. We need more health professionals of all types and we can get more health services, we believe, and as the AMA Journal article illustrates, through increasing productivity of physicians as well as training additional ones.

Mr. BURKE. I just hope that we are able to get someone that can prevail upon the AMA to change their attitude and be a little more cooperative in the problems that this country faces in health care.

That is all, Mr. Chairman.

Mr. ULLMAN. Mr. Betts. Mr. Conable.

Mr. CONABLE. Thank you, Mr. Chairman.

Mr. Woodcock, you have talked about cost control a good deal here. What other elements besides medical fees go into the cost of medical care? What other significant elements? For instance, isn't hospital care a very substantial part of the cost of medical care at the present time?

Mr. WOODCOCK. No question about it. Hospital costs, of course, are rising at an astronomical rate. One of the difficulties with the present situation, for example, is that our membership in general has as good coverage I think, as is available, but, however, the question of maintaining health, of preventing illness, the question of necessary diagnostic work that has to be done unfortunately inflates hospital costs, because if it is done in the hospital where it is more convenient to the doctor and it is less expensive to the patient, it unnecessarily uses hospital space and pushes up the costs where, of course, group practice would meet that problem.

Mr. CONABLE. But under any circumstances we are still going to have a substantial part of medical care costs related to hospital costs, are we not?

Mr. WOODCOCK. Of course, and the cost study we have filed includes all of those costs.

Mr. CONABLE. I know that one of the major targets of the labor movement recently has been hospital employees who have been traditionally very badly paid. Do you have any idea what proportion of hospital costs is based on wages?

Mr. WOODCOCK. Possibly Dr. Falk does. I might say that even where they have been unionized and have had their wages moved up, they are still at not a very high level.

Mr. CONABLE. That's right. I think many of the lower skilled hospital employees are at the minimum wage in many parts of the country. I am wondering what the impact of increasing the minimum wage will be on hospital costs. I served on a hospital board for some time before I came to Congress and every time the minimum wage went up, we had to raise our room rates very substantially in the little hospital on whose board I served.

I am not saying that that was necessarily a bad thing, but I am wondering how far you would go in trying to control hospital costs which are a substantial element in the cost of health delivery generally.

Mr. Woodcock. May I have Dr. Falk comment on that, sir?

Mr. Conable. Yes.

Dr. Falk. You are quite right, Mr. Conable. The hospital cost component in the totals that we use is now the largest single item, nearly approximately twice as much being expended for what is identified as hospital costs as for physicians' services, which is a reversal of what the situation used to be years ago.

The hospital costs have been escalating very steeply for many different reasons one reason being the one to which you referred. The hospital subprofessional and subtechnical personnel were very low-paid wage workers. By their low wages, in effect, they have been subsidizing hospital costs and hospital operations. However, there has been a very extensive and very rapid catching up in the wage levels of the most underpaid or most lowly paid workers in the hospitals.

Now the hospital people show in their accounting operations that today approximately two-thirds of hospital operating costs on the average are wages and salaries, about 66 percent or 67 percent of the total. However, a very considerable portion of that is not the expenditures for wages and salaries of the very lowly paid workers in the hospital, so that the escalation which has been occurring in that 66 percent or 67 percent has been, in part, to catching up of the wage levels of the lowest paid workers.

The increases have also reflected considerable escalation in the wages and salaries of persons who have not been in those very low-wage categories, subtechnical and subprofessional presonnel, the technical and professional personnel who are on the payrolls of the hospitals.

Mr. Conable. Every time you move the bottom, to avoid wage scale compression you have to move people farther up also so that you will still have a wage scale that makes some sense.

Dr. Falk. That is true, but the contrary is also true. The distance between the wage levels of the lowest paid and those of the highest paid were very considerable. Nevertheless, the important thing to take into account is that upgrading is supstantially done, though not wholly by any means, so that the wage levels of the professional and subprofessional and subtechnical personnel in the hospitals generally have come to be very close to the wage levels and salary levels in society in general for the similar categories of personnel.

Accordingly the escalation curve for these hospital costs is flattening out very considerably.

Mr. Conable. So, looking forward then, we won't see the rises in hospital costs we have seen in the past?

Dr. Falk. We most certainly shouldn't.

Mr. Conable. And, therefore, control of those costs is not likely to be the same problem it has been in the past?

Dr. Falk. It should not be for the reasons I referred to and it should not be continued if there is some provision made for putting an end to the guarantee of full cost reimbursement to hospitals, which has become the fashion ever since this was introduced in 1965 under medicare and medicaid.

If that signed blank check guarantee to the hospitals which, in substance, they also have under the Blue Cross programs and under the insurance company programs, continues there will be invitations and even incentives for the escalation to go up at a relatively steep rate. If those guarantees of full cost reimbursement begin to come to an end and the hospitals get their reimbursements on the basis of well and carefully considered prospective budgeting, then the steepest escalation of the recent past should come to an end.

Mr. WOODCOCK. May I just comment?

Mr. CONABLE. Yes.

Mr. WOODCOCK. I know you would, of course, agree that the answer is not to go back to the old system where too low-paid workers were subsidizing the system. We are not going back to that and you would not agree to do that. The answer is a more efficient use of the hospitals.

The group practice plan, which is the core of H.R. 22, goes to that question. If the average hospital stay is reduced by 1 day, HEW estimates a saving of $2 billion annually so that on the beginning end, on preventive care and diagnostic out of the hospital, you begin to reduce the uses of the hospital and by emphasis on ambulatory care and other nonbed use of hospital recovery periods, you meet this problem.

Mr. CONABLE. Yes. I don't disagree with what you are saying. I wanted to know, though, your view of some of the other elements of medical cost increases in the past. I think we have a tendency here to try to set up the AMA as a scapegoat and blame them for everything that is happening in this field, ignoring sometimes the other elements of cost that go into medical care.

I wanted to be sure that we were putting on the record the fact that there are other elements of cost. I don't quarrel with your statement about hospital employees. I think the fact that we have seriously underpaid them in the past has been one of the problems of service we have had in our hospitals.

I also don't quarrel with Dr. Falk's statement about full cost reimbursement, because I think that is a rather unhappy part of our present system of medical delivery.

Mr. ULLMAN. Mrs. Griffiths will inquire.

Mrs. GRIFFITHS. I really don't have any inquiry to make. You support the bill. That is all that is really necessary. I can't resist pointing out that the real supporters of hospitals in this country have been women employees. This is because they have never been paid a fair amount. I have never supported any bill since I have come to Congress that would ask women to subsidize the hospital care in this country.

Long, long after men workers in Ford plants were furnished clean uniforms daily, the nurses in Ford Hospital were still ironing their own. I understand, because I have made inquiry, that they are now being furnished those uniforms and, believe me, I am for this bill covering the costs.

Mr. ULLMAN. Mr. Duncan will inquire.

Mr. DUNCAN. Mr. Woodcock, what would you propose that the Government do with the Veterans' Administration medical program that they are currently operating? Under your proposal what would happen?

Mr. WOODCOCK. May I have Mr. Glasser comment on that?

Mr. GLASSER. The proposal does not bring in the VA hospitals and medical care system, but provides that all Americans, and that includes all the veterans, are eligible for care wherever they wish to receive the care, so that they have a choice of either taking their care through the VA medical system or through the general system.

Mr. DUNCAN. I take it that a great number of your members are veterans who might be eligible for dual benefits?

Mr. GLASSER. Oh, yes.

Mr. DUNCAN. Thank you, Mr. Chairman.

Mr. ULLMAN. Mr. Burleson.

Mr. BURLESON. Thank you, Mr. Chairman.

My good friend from Massachusetts just left the table, but I do take issue as a matter of record, Mr. Chairman, that other proposals than H.R. 22 do not change the status quo. We have heard witnesses in the last several days stating that other proposals before this committee are progressive proposals which many of us think would get the job done and are proposals that the Nation can afford.

I certainly don't think that any part of the health industry, as far as I know, is contending that we do nothing. I agree with you that it is rather obvious that there is much to be desired. I think other proposals provide for that.

May I ask Mr. Woodcock this question? You mentioned the 30 million people who are without medical care or have inadequate medical care, to whatever degree you might assess. I am not questioning the figure because I don't know, but this is a little bit like our bureaucrats, and I don't say that disparagingly, but when you come in and throw a lot of statistics at me, I don't know their accuracy. How do you arrive at that figure?

You know we as individuals don't have investigative staffs which can go out and determine these things. Where do you get that figure?

Mr. WOODCOCK. We got that particular figure, sir, from the president of the AMA, who cited it from one of their studies last year. These people are people in rural areas, people in the center cities across our Nation.

The Wall Street Journal had a heartbreaking story yesterday about the lack of medical care in West Virginia and that sort of thing is duplicated in Michigan, Mississippi, California, any State you name.

The 30 million may not be a scientifically accurate figure but it is a gross number whatever it may be.

Mr. GLASSER. May I supplement that a bit?

Mr. BURLESON. Please.

Mr. GLASSER. That 30-million figure, which was Dr. Gorman's estimate, is substantiated by HEW's figures when they look only at those eligible for medicaid and assuming, in fact, that there are needy people who need medical care who are not eligible for medicaid, the HEW estimates about 22.5 million did not receive medical care services.

Mr. BURLESON. As I recall, the HEW's figures are considerably lower overall.

Mr. GLASSER. Yes; they are.

Mr. BURLESON. As I recall some testimony indicated a figure of about 45 million. The degree of lack of adequate care would seemingly be a consideration. Mr. Woodcock, let me ask you this: Without arguing or ignoring the point at the moment of whether it is good or bad or whatever assignment of title description of these various programs, but particularly H.R. 22, would you consider it to be a nationalization of the health industry generally?

I mean the nationalization of insurance, hospital, medical care of one sort and another?

Mr. WOODCOCK. No, sir. It is a partnership of a national financing scheme just like the social security system plus private implementation, with freedom of choice to the profession and with freedom of choice to the patients.

Mr. BURLESON. Of course, social security didn't replace anything. It came into being on its own without the massive effort called for in this type of legislation. The Congress decided—the Government decided, that we couldn't run the Post Office Department so we gave it away. We are trying to give it away at least. It is a little like a sticky piece of flypaper where you can't get it off of your fingers, but we are trying to give it away because the Government couldn't operate it efficiently and at reasonable cost.

Do you think the Government can totally run a program like this with efficiency?

Mr. WOODCOCK. Well, first of all, we start with the system as it is. This is no revolutionary proposal to blast away. We start with the system as it is and through budgetary incentives move it to a more efficient system, to group practice which has been proven in the private system as being much more efficient usage of the profession and of the hospitals and every other related institution.

We are not dealing with something unknown. We are dealing with a proven fact and it will be publicly administered but in private hands. It is a uniquely American approach to this problem.

This is not a copying of the British or Soviet system or any other system. It starts by building on the system as it is and using budgetary incentives and in the best sense of that word moving toward a more efficient system.

I as a person am absolutely convinced it can work most successfully for our country.

Mr. BURLESON. But to remove an industry like the insurance industry completely from the health care guarantee of people, along with hospitals and other medical care is a radical departure from what we have. I can't see where there is a very great partnership in your recommendations.

Mr. WOODCOCK. The insurance industry doesn't provide medical care. They are simply fiscal intermediaries. They have no concern with the quality. Just as long as the bill is paid and the premium is paid, that is their only interest.

Mr. BURLESON. I am speaking of the insurance as being a facet of the entire health industry—the medical profession itself, paramedical, all medical personnel, hospitals, even child care in day care centers. Anyway I just can't imagine that the Government is designed for this

sort of thing and, when we see the failures in so many of our programs right now with all the good intents—public housing, schools, all the things we see wrong today, and as has been reiterated time and again including the inadequacies of the health care system, it would just suggest to me that the Government could not efficiently run such a program.

Mr. WOODCOCK. Well, there is one program that is operating exceedingly well. Its benefits are too low for the social good, but the social security system to which this is most analogous is operating very successfully.

Mr. BURLESON. Yes, I think so. I would agree to that. It didn't supplant something that we had before. We had insurance, of course, for retirement, annuities in industry and labor and other parts of our society that it did not supplant. It was something new for people who didn't have that sort of coverage.

Mr. WOODCOCK. The only supplanting that there would be, sir, is the fiscal intermediaries who perform no service in providing care.

Mr. BURLESON. Thank you, sir.

Thank you, Mr. Chairman.

Mr. ULLMAN. Are there further questions on this side?

Mr. VANIK. Mr. Chairman?

Mr. ULLMAN. Mr. Vanik.

Mr. VANIK. I want to ask Mr. Woodcock this question. We have a problem in getting physician cooperation with the medicare program under the present system. There are many doctors who collect their fees where the patient pays his own fee. Then they won't cooperate other than by putting a blanket amount due on their statement. The patient has a difficult time recovering his payment through the medicare system with an incomplete bill.

I have two questions: What are the chances or possibilities of having the same kind of problem extend into the plan that you offer. What assurances do we have that there will be doctor cooperation—without which we can't do very much?

Mr. WOODCOCK. Under the system as proposed in H.R. 22 there would be no charging by the doctor to the patient. The charge would be from the provider of service to the appointed body within the program so that kind of possible harassment would disappear. It couldn't exist.

Mr. VANIK. That was originally the format that we had on social security. Then we amended it by permitting the patient to make the payment and then recover it from social security. In my community there is a large group of doctors who still refuse to take medicare claims and who are very uncooperative with respect to what they ought to do to help their patient recover his payment from the medicare system through the carrier.

What would the doctor's reaction be to the proposal you submit?

Mr. WOODCOCK. Well, that form just couldn't exist under the program as proposed by H.R. 22.

Mr. VANIK. It would be up to the individual doctor to decide whether or not he wanted to handle a patient under the plan. So what would happen if a great many doctors didn't participate in this program?

Mr. WOODCOCK. Well, for that to be possible, he would have to stay out of the system entirely and in different ways other countries have

gone to this and that has not been the case with the medical profession. I don't accept the fact that the medical profession in large part is determined to make any system that the Congress determines to be the answer to this crying problem unworkable.

I don't think that is true. I think sometimes doctors institutionally appear in a bad light just as organized labor sometimes appears in a bad light, but as individuals they are thoroughly patriotic Americans.

Mr. VANIK. In my community we have a medicare crisis, because there are millions of dollars in claims that have not been cleared by the carrier. They are claims in which the individual patient paid the bill under medicare. The patient is now seeking to recover his payment and they are running head on into the reaction and resistance of a great many doctors who don't want to cooperate with them in helping them recover their payment.

Mr. CORMAN. Would the gentleman yield for a question?

Mr. VANIK. I would be very happy to yield.

Mr. CORMAN. I think H.R. 22 is substantially different from medicare in that medicare permits a surcharge of the patient by the doctor so that the fee determined to be allowable under medicare would be substantially lower and he just surcharges the beneficiary. It is anticipated under H.R. 22 that there be no participation by the patients, that the doctors' total recovery would be through the system.

That doesn't get around the problem of what if the doctors refuse to serve, but it does get around the problem of the doctors, first of all, quarreling with the system over the reasonable cost and surcharging the beneficiary maybe double that amount.

I suppose that that is where most of the problem comes in, in the administration of medicare. I thank you.

Mr. ULLMAN. Mr. Corman, did you have any further questions?

Mr. CORMAN. Yes, Mr. Chairman.

First of all, I want to express my sincere appreciation to Mr. Woodcock and the great number of people who worked on the Committee of 100 to evolve what has become H.R. 22.

Off the record.

(Discussion off the record.)

Mr. CORMAN. One of the great complaints about H.R. 22 expressed by Secretary Richardson and representatives of the medical profession is that it is monolithic. So far as I can see, the only thing monolithic about H.R. 22 is that it offers uniform medical care to all people depending on their physical rather than their economic condition.

Isn't that a fairly accurate statement as to what is monolithic about this program?

Mr. WOODCOCK. Yes; plus, of course, the financing is monolithic. It is national just as social security financing is.

Mr. CORMAN. The only way you can get away from having medical care based on a person's economic condition is to make the financing uniform. So far as the method of practicing medicine, there is nothing monolithic about that.

Mr. WOODCOCK. Absolutely not, no, sir.

Mr. CORMAN. So far as the kind of medical care available to people they certainly have freedom of choice. We talk about who in America doesn't have access to good medical care. Would you agree with me

that if someone dies prematurely in this country because he didn't have preventative care, because there was not early diagnosis, for instance, of cancer or some other malady which might be treated if it had been detected early, that person doesn't have adequate medical care either?

Mr. Woodcock. Of course he doesn't, no.

Mr. Corman. I would suspect that 30-million-person figure is about 100 million shy. I suspect that very few people in this country have access to adequate preventative medical care. I would hope that whatever system we adopt includes that, because regardless of one's financial circumstances, the method of practicing medicine in this country makes preventive care available to a relatively small number of people. I think those of us who support H.R. 22 have to admit that we are undertaking a substantial new Government financing effort and it is going to mean that we have to collect more taxes, part of it through a special earnings tax and a part of it out of general funds.

But it is my assumption that if the American people are relieved of their medical bills, they are going to be willing to pay more taxes because they will be buying an adidtional service which they do not now get through the taxing system. Would you agree with that?

Mr. Woodcock. Yes; plus, of course, now they are paying it in other forms.

Mr. Corman. We pay it now. The point is that we pay it through insurance premiums and pay it through out-of-pocket expenses. We pay it through taxation for the poor in financing medicaid and county hospitals and a wide range of things. So we are going to pay either way.

I think we ought to admit that taxes will have to go up if medical bills are going to disappear in the private sector and in the insurance field. I think that it is a much more manageable way for one to provide for his medical care. As one of the sponsors of this proposal, I don't want to imply that medical care is going to be free. It is going to cost money, but it will be paid for in a much more efficient manner and the system will be available to many more people.

I wanted to be sure that we share that view.

Mr. Woodcock. I might say, Mr. Corman, let's take General Motors Corp. and General Motors workers. They pay now on average a wage equivalent of 35 cents an hour for their hospital, surgical, and medical protection, which is in the range of 7 to 8 percent of the average wage. They are paying directly a very high tax and this gets into the import problem because all the competing automobile-producing countries have Government-financed health care systems and have to inflate the cost factor by that kind of money.

Mr. Corman. Secretary Richardson pointed out that if we undertook such a comprehensive program as H.R. 22, that we would have to sacrifice other social needs. That is not my position as to this legislation.

I think that this has a very high priority among our national priorities, but it doesn't mean that we have to give up slum clearance or good public education or any of the other things we need. It is rather that we anticipate that we will raise additional resources for this program and judge our other national priorities, whether they be

security or whatever else, each standing on its own feet, but not contend that because we are advocating this program that we are opposing other social needs.

Would that be your view?

Mr. WOODCOCK. I would agree with that, yes, sir.

Mr. CORMAN. Thank you, Mr. Chairman.

Mr. ULLMAN. Are there further questions?

If not, Mr. Woodcock, we very much appreciate your testimony. You have been most constructive.

Dr. Falk, your cost analysis is something that we will certainly have to analyze and take into consideration. If you can put together some additional supplementals that would put the comparisons in a little better perspective, we would hold the record open for that purpose.

Dr. FALK. We would be glad to do it, Mr. Chairman.

Mr. ULLMAN. Thank you very much, Mr. Woodcock.

Mr. WOODCOCK. Thank you.

(See p. 583 for supplemental material.)

Mr. ULLMAN. Our next witness is Dr. William S. Apple.

Dr. Apple, if you would further identify yourself for the record and identify your colleagues we would be happy to recognize you.

STATEMENT OF WILLIAM S. APPLE, Ph. D., EXECUTIVE DIRECTOR, AMERICAN PHARMACEUTICAL ASSOCIATION; ACCOMPANIED BY CARL ROBERTS, DIRECTOR, LEGAL DIVISION

SUMMARY

1. APhA endorses the basic concept of national health insurance.
2. No system of health care can be expected to achieve meaningful results unless it provides comprehensive pharmaceutical service.
3. The need for comprehensive pharmaceutical service and its feasibility in federally supported health care programs has been documented by numerous studies of the Medicare program.
4. Comprehensive pharmaceutical service can be provided under a system of national health insurance with reasonable and controlled costs.
5. Methods for controlling the costs of drug products include amending state antisubstitution laws and establishment of a federal drug formularly system.
6. Methods for compensating pharmacists can be revised to achieve cost control and the value of dollars expended for pharmaceutical service maximized by increasing health care functions performed by pharmacists.
7. Costs of program administration can be controlled through improvements in claim processing procedures and the per prescription claim procedure can eventually be eliminated.

Dr. APPLE. Mr. Chairman, I am the executive director of the American Pharmaceutical Association and my colleague is Mr. Carl Roberts, director of our legal division.

Mr. Chairman, with your permission we would like to have our national affiliate the American Society of Hospital Pharmacists file a statement for the record on pharmaceutical services in hospitals.

Mr. ULLMAN. The additional testimony that you have referred to without objection will be placed in the record.

(The statement referred to follows:)

STATEMENT OF THE AMERICAN SOCIETY OF HOSPITAL PHARMACISTS

Mr. Chairman and Members of the Committee:

The American Society of Hospital Pharmacists appreciates the opportunity to present this written statement, for inclusion into the hearing record, concerning national health insurance proposals being considered by the Congress. The American Society of Hospital Pharmacists is a national association of approximately 7,000 pharmacists practicing in hospitals and related institutions throughout the nation.

On October 28th, other pharmacy representatives presented their views on national health insurance. This statement is intended to highlight certain aspects of pharmacy practice which we believe are necessary components of any meaningful comprehensive health care program. It is intended to emphasize that the drug component of health care includes services as well as drug products and that such services are an integral part of the practice of pharmacy. In the past, health legislation has generally emphasized the provision of "drugs and biologicals." We feel this has represented a shortcoming of such previous legislation.

Pharmaceutical services over the past decade have taken on a new character and importance of their own as a complement to the use of drug products. In fact, they become essential to the safe and effective use of pharmaceutical products. These services are encompassed by a concept which has been termed drug-use-control, "the sum total of knowledge, understanding, judgment, procedures, skills, controls, and ethics that assures optimal safety in the distribution and use of medications."

The importance of the proper control and use of drugs is more evident in this era of potent, specific and costly drugs than ever before. In the hospital, for example, the need for pharmaceutical services has progressively followed the movement of drugs through the institution. Medications are no longer stored in one central area, they are no longer prepared in one location, and the need for pharmaceutical services has become as decentralized as the use of drugs themselves. The following developments in the practice of pharmacy in hospitals will serve to illustrate the professional and clinical services which we feel are an essential component in the drug component of health care.

Pharmacists are no longer restricting their activities in the hospital to a mere supply function with responsibility ending when they have placed the drug the physician ordered at the disposal of the nurse. Pharmacists have assumed responsibility for drugs wherever they appear in the hospital and this responsibility is evolving to its ultimate in those cases where pharmacists are actually responsible for the administration of drugs to patients. We do not mean to imply that the concern of pharmacists for drugs throughout the hospital is anything new. In fact, the American Hospital Association and the American Society of Hospital Pharmacists issued a joint statement nearly 15 years ago, urging "hospital pharmacists, through appropriate channels, to extend their responsibilities to include participation in programs dealing with the safe handling of drugs throughout the hospital." What is new, however, is the many ways in which pharmacists have exercised this responsibility in light of their desire to make a more direct contribution to patient care.

The earliest indications of implementation of this action were pharmacists' involvement in hospital medication error studies and in the development of improved intrahospital drug distribution systems. A study conducted in a university hospital and published in 1962 truly shocked the hospital world. This report uncovered, by the disguised observation method and according to an established definition of a medication error, one error per every six doses of medication given, or, by extrapolation, more than 51,000 medication errors in a one-year period. The results of a study of medication errors at another university hospital, conducted in connection with a pilot study of an experimental unit-dose medication system, seemed to confirm those obtained earlier, suggesting that medication errors were occurring at an alarming rate under the traditional hospital drug distribution system. A follow-up study conducted at a nonuniversity general hospital revealed a rate of one error for every 6.7 opportunities, again substantiating earlier observations. These studies, together with work describing the excessive amount of time spent in distribution and administration of medications in the hospital, began to evoke considerable interest in the subject of improved hospital medication procedures. Pharmacists were made vividly aware of the serious consequences of their lack of involvement in drug-use-control throughout the institution.

Most of the improved medication systems developed during the past several years can be described as unit-dose systems. Whether they operate from one centralized pharmacy in the hospital or from two or more decentralized pharmacies or pharmacy substations, they involve preparation and packaging of drugs in single doses which, generally, are sent to the nursing unit at the time they are to be administered. In one study, the medication error rate decreased from 18.3 percent under the traditional system to 3.3 percent under the pharmacy-controlled unit-dose system.

In addition to the potential for reducing medication errors and improving communication of the medication order, unit-dose medication systems have been reported to reduce inventory and losses and to free nursing time. A considerable proportion of nursing—more than 25 percent according to some studies—is spent in the preparation of drugs for administration, including reconstitution of injectables and compounding of intravenous mixtures, and in charting and ordering. Results with a decentralized unit-dose medication system in one university hospital indicate that the nurses' time expended in these functions has been reduced to about 5 percent. Hopefully, time thus freed will be used to return the nurse to bedside care.

Unit-dose medication systems imply the extemporaneous sterile compounding of intravenous prescriptions which involve the addition of one or more additive drugs to a large volume intravenous solution, and the batch or extemporaneous reconstitution of injectibles. These procedures, of course, have always been performed in hospitals, but they have been performed by nurses rather than pharmacists. With respect to intravenous admixtures alone, it has been estimated that in excess of 50 million are administered yearly in hospitals in the United States. There is now a great deal of interest and activity among hospital pharmacists in centralizing, in the pharmacy, the addition of drugs to intravenous solutions using sterile work benches. This procedure can be accomplished more efficiently, more accurately and with greater safety by a pharmacist or trained technician working in a quiet area than by the busy nurse faced with constant interruptions in the patient care area. Pharmacists who have involved themselves in this activity have also reported a decline in the prescribing of intravenous admixtures in their hospitals.

Another illustration of the pharmacist's new role is embodied in the concept of clinical pharmacy. Pharmacists in many hospitals have developed and are maintaining medication profiles, coordinating adverse drug reaction reporting programs, preparing and disseminating drug utilization data, making patient rounds with physicians, and conducting other patient-centered programs which have often been done poorly or not at all in the past. A function very closely related to the maintenance of patient drug profiles is that of taking a patient's medication history upon admission to the hospital. Pharmacists are beginning to perform this task with good results. A recent study of pharmacist initiated drug histories showed that upon interviewing a group of 100 newly-admitted hospital patients, a pharmacist recorded 70% more drugs than were routinely recorded by physicians.

In a few hospitals in the United States, pharmacists are performing what may be the ultimate in their responsibility for the safe handling of drugs throughout the hospital—they, or technicians trained by them and under their supervision, actually administer all drugs to patients. In each of the hospitals where this is being done, this activity is an extension of a unit-dose drug distribution system and has been implemented with the cooperation and support of the medical and nursing staffs. These are said to be "coordinated drug distribution and administration systems" and the pharmacist has responsibility for drugs from the time they enter the pharmacy inventory to the time they are administered to patients.

Closely related to the concept of clinical pharmacy is the area of drug information. The pharmacist, being a drug information specialist, can be of great help in the hospital. Some hospitals have established central drug information centers as a division of the pharmacy department. These centers are geared to assisting with the complex problems concerning the indications, cautions and adverse reactions or interactions of drugs, usually in specific patients. Other institutions rely on the pharmacist in the patient care area for this service or have a drug information center supported by roving pharmacists.

We hear much about adverse drug reactions and the difficulties in getting them reported. One carefully controlled study has shown that 5 percent of the patients entering a general medical and surgical ward were hospitalized in part, at least, because of a reaction to a drug they were taking at home. A study at the

Johns Hopkins Hospital indicated that during a three-month period, more than 17 percent of 714 general medical service patients had an adverse reaction to a medication. Ninety-seven patients (13.6% of the total medical population) *acquired an adverse drug reaction during hospitalization.* Of 36 patients admitted with a drug reaction, 11 (30.4%) acquired another reaction in hospital. Eight of the 36 patients died; five from the reaction which occasioned their admission and three of a reaction acquired in hospital. When an adverse drug reaction occurs in the hospital, it usually increases the patient's length of stay and this may add to the problem of overcrowding experienced by many hospitals. Hospital pharmacists have sought ways in which they can be of service related to this problem. In a recent study, a group of pharmacists showed that significantly more suspected adverse drug reactions were discovered in a group of patients interviewed for this purpose by a pharmacist than in a group interviewed and monitored only by physicians. The monitoring of patients for drug interactions is an important aspect of the pharmacist's role in the control of adverse drug reactions.

Coupled with the trend of increased involvement in patient care is a trend toward specialization of practice according to function. No longer do we have just "hospital pharmacists," each routinely involved in all of the tasks and responsibilities of the pharmacy. Rather, pharmacists are becoming specialized in certain specific areas of practice. For example, a particular pharmacy department in a large hospital might have one or more pharmacist-specialists in administration, electronic data processing, drug information, pediatric pharmacy, clinical pharmacy, manufacturing pharmacy, and unit-dose packaging. All of these pharmacists would have been initially trained in a standard pharmacy curriculum, but to fulfill the needs of the hospital, they became expert in a specialized aspect of practice. It has been projected that we eventually will have certification programs for these specialties. Even today, pharmacy residency programs in hospitals are being modified to provide specialized training in some of these areas.

Because of increasing demands being placed on America's health care resources, health care administrators and planners have become very interested in utilization review. Utilization review involves a continuous ongoing study of the frequency of use and cost of health care services from which patterns of patient use can be determined. Drug utilization review is a necessary component in the overall utilization review of health care services. Pharmacists have become involved in such programs in many hospitals. In a hospital, a drug utilization review program may involve determining usage patterns for each drug according to medical service or department and according to individual prescribers. This information is relayed back to physcians as part of an educatonal program to cope with problems of misutilization. Ideally, this function is closely tied in with the educational functions of the pharmacy and therapeutics committee on which a pharmacist generally plays an important role. It is evident that involvement of the pharmacist in drug utilization review programs is another extension of his desire to play a larger role in patient care services.

The acceptance of and need for pharmaceutical services in the drug component of health care in the institutional setting are exemplified by the Medicare Conditions of Particiaption and by the Standards of the Joint Commission on Accreditation of Hospitals. We believe these services can be implemented in varying degrees in whatever environment pharmacy is practiced.

An aspect of national health insurance that is of interest to us is the concept of "group practice." Over the years, health services have become more and more centralized in an effort to improve the availability, efficiency and utilization of health resources. Practice in a structured health care delivery system, such as a health maintenance organization or health care corporation, increases the potential for implementation of drug-use-control. Since most national health insurance proposals include incentives to the development of comprehensive health organizations, it is important that pharmaceutical services embodied by the concept of drug-use-control be recognized and stimulated.

As you know, several of the national health insurance bills now before Congress provide for the financial and technical assistance for planning or devolpment of comprehensive health service systems which encompass group practice. For example, in a speech to the U.S. Senate, Senator Kennedy stated that under his bill, S. 3, "The financial and administrative arrangements are designed to move

the medical care system toward organized programs of health services, with special emphasis on teams of professional, technical and supporting personnel . . . Federal law will supersede State statutes which restrict or impede the development of group practice plans." He went on to further explain that "It will provide incentives for comprehensive group practice organizations." The legislation refers to group practices as "Comprehensive Health Service Organizations" and requires them to "perform the functions of a pharmacy and therapeutics committee, and monitor and review the utilization and quality of all health services (including drugs)."

On January 25, 1971, the same day Senator Kennedy introduced S. 3, Mrs. Griffiths, a member of this Committee, presented H.R. 2162 to the U.S. House of Representatives. We note that this bill is essentially identical to S. 3, especially as it encourages the development of and provides for additional performance payments to group practices under national health insurance.

Likewise, Senator Javits, in his national health proposal, recognizes the need for improvement in the organization of health services. This proposal authorizes the Secretary of the Department of Health, Education, and Welfare to contract with a "comprehensive health service system" for the provision of services to members of the system and to pay incentives to such systems over and above normal reimbursements. In a companion proposal, Senator Javits also provides for the financial and technical assistance for planning comprehensive health services systems.

We believe that any of these plans, to be complete, must include the provision of pharmaceutical services, as outlined above.

To exemplify these thoughts, we would like to apply them to H.R. 2162. In the table of contents, Part B of Title I lists the nature and scope of benefits to be covered. It speaks in terms of physician *services*, dental *services*, institutional *services*, other professional and supporting *services*. However, Section 25 is entitled merely "Drugs." We believe this section should be changed to read "Pharmaceutical Services." Turning to the text of H.R. 2162, Section 25 speaks only in terms of the drugs that may be furnished as a covered service. Nowhere does the section provide coverage for pharmaceutical services of the nature discussed above. We recommend that Section 25, therefore, be amended to make it clear that the services of pharmacists are required and reimbursable under the law. With such a change, Section 25 would then mesh with Section 86(b) which mentions services provided by the pharmacist.

Section 47 describes a comprehensive health service organization. Subsection (a) (3) of that section requires that the organization furnish, as a minimum, all services described in Part B. The changes we have suggested for Part B, Section 25 would insure that comprehensive health service organizations retain the services of a pharmacist in order to provide the drug component of health care. This would insure high quality service in relation to the drugs comprehensive health service organizations distributes to their patients.

The foregoing comments on H.R. 2162 are exemplary and the same principles should be incorporated into any national health insurance plan considered by Congress. We would welcome the opportunity to provide additional specific comments on any specific legislative proposals being seriously considered by the Committee.

Dr. APPLE. Thank you, Mr. Chairman.

Mr. ULLMAN. You are recognized.

Dr. APPLE. Chairman Mills, members of the subcommittee, I am Dr. William S. Apple, executive director of the American Pharmaceutical Association. Accompanying me this morning is Mr. Carl Roberts, director of the APhA legal division. We are pleased to have this opportunity to present to you our views on the subject of national health insurance and, particularly, the role of pharmaceutical service in the health care delivery system.

The American Pharmaceutical Association is the national professional society of pharmacists in the United States. APhA has over 52,000 members. Its policymaking body is a house of delegates of 336 members representing every State pharmaceutical association, national

affiliates, and subdivisions of the association. It is the largest professional practitioner society in pharmacy.

Let me state at the outset the APhA endorses the basic concept of national health insurance. This policy position was adopted by the APhA house of delegates at the association's 1971 annual meeting. In adopting this policy, the house reversed a prior association policy dating back to 1946, which stood in opposition to any form of compulsory national health insurance program.

Naturally, we have been following the debate over national health insurance very closely. APhA has devoted much time and effort to informing the Nation's pharmacists about the various plans for national health insurance, which have been put forth to date.

Our study of the major national health insurance proposals has led us to the conclusion that all contain at least one significant common deficiency. I refer to the fact that these plans fail to include pharmaceutical service as a mandatory requirement. It is clear to us, and we believe it should be clear to everyone, that no system of health care can be expected to achieve meaningful results without providing such service. In all of the legislative proposals you are considering, drugs when included are offered as a limited or as an optional health care benefit.

Congress must recognize that total patient care cannot involve the tradeoff of one component of health care for another. Congress must recognize the difference between providing drugs and providing pharmaceutical service. Anybody can hand a bottle of tablets to a patient, but pharmaceutical service includes making certain that the patient receives the proper drug in context of his drug history and immediate treatment. It includes advising the patient how and when to use the drug.

Congress must also recognize that when the pharmaceutical service benefit is authorized, accessibility becomes a key factor. Sick people should not be forced to commute to a centralized facility. Pharmacy has already demonstrated in medicaid drug vendor programs that it can deliver a highly personalized professional service effectively and economically in the patient's immediate neighborhood through the Nation's community pharmacies.

When Congress enacted the medicare program in 1965, no one doubted the necessity to include prescribed drug costs for hospitalized patients. It was recognized as futile to put patients in hospitals without providing for their full recovery through necessary treatment.

Yet, some apparently believed, and continue to believe, that a distinction can be made in the case of the nonhospitalized patient. The result under medicare is that the program pays for a nonhospitalized beneficiary's examination and diagnosis by a medical practitioner, but if the individual does not have the financial resources with which to obtain required medication, that is his bad luck.

The result is that some elderly patients are unnecessarily hospitalized so that they can receive the pharmaceutical service they require. More often, the health of the elderly patient deteriorates, because of the lack of pharmaceutical service, to the point that prolonged hospitalization, the most expensive component of health care, becomes necessary.

We should think that after 6 years of experience under medicare, every national health insurance proposal would seek to correct this obvious mistake. APHA takes the position without reservation that the providing of comprehensive pharmaceutical service must be an absolute requirement if the patient is to benefit. That isn't just our opinion.

In May of 1967, at the direction of President Johnson, Secretary Gardner established the HEW Task Force on Prescription Drugs. This task force was charged with the responsibility for studying the question of adding an out-of-hospital prescription drug benefit to the medicare program. On February 7, 1969, 2 years later, the final report of the task force was presented to then Secretary Finch. The essential conclusion of the task force flowing from its exhaustive study was that an out-of-hospital prescription drug benefit could and should be added to the medicare program.

In March of 1969, Secretary Finch named a 17-member "blue ribbon committee," under the chairmanship of Prof. John P. Dunlop of Harvard University, to review the findings and recommendations of the HEW task force. This committee concurred in the basic findings and conclusions of the task force.

Despite the in-depth studies of the task force and the careful review of the Dunlop committee, yet another committee to review the question was appointed by the Secretary of HEW. This committee, under the chairmanship of Mr. Walter J. McNerney, president of the Blue Cross Association, added its support to the work and conclusion of the task force. Finally, the report of the 1971 Advisory Council on Social Security, the Flemming report, also recommended expansion of the medicare program to include coverage of out-of-hospital prescription drugs.

Mr. Chairman, these unanimous recommendations have had substantial support in Congress. In the Senate, Senator Joseph Montoya has regularly introduced legislation to implement a medicare out-of-hospital prescription benefit. His current bill is S. 936.

In the House, a companion bill, H.R. 2354, has been offered by Representative David Obey, of Wisconsin. We understand that the Obey bill is being reintroduced with 111 cosponsors. Despite such support, however, Congress has failed to respond by enacting the necessary legislation.

We believe that congressional reluctance has been based solely on fears relating to the cost of such a program. We are convinced, however, that it is possible to provide necessary pharmaceutical service benefits under medicare, medicaid, and any system of national health insurance, with reasonable and controlled costs.

According to a recent HEW report, in 1970, 17 cents of every dollar spent for health care was for drugs and appliances. The total national bill for these items in that year was $11 billion. The Raymond E. Gosselin Co., which specializes in statistical reporting on drug distribution, reports that only approximately 8 cents out of every health dollar, for a total of aproximately $5.1 billion, was spent in 1970 for prescriptions by nonhospitalized patients. If one objective of national health insurance, more medical care, is achieved, one clear

result will be a significant increase in the requirement for pharmaceutical service.

At this time it is impossible to project the extent of such an increase, because we also are unable to project to what extent medical care would become more accessible under the system of national health insurance finally adopted.

The important point here, however, is that whatever increase in the accessibility of medical care may be achieved, it does not have to follow that the cost of pharmaceutical service would increase by the same magnitude.

Much attention in health care circles is being devoted to the subject of "rational prescribing," that is, providing the right amount of the right drug for the right patient at the right time. With proper drug utilization review programs including pharmacy participation and expertise, we believe that substantial improvement in prescribing practices and reduction in the cost of drugs prescribed can be achieved. The objective would be to achieve the greatest possible value for each penny of the taxpayer's dollar devoted to drugs and pharmaceutical service. To reach this objective, national health insurance legislation must include remedies for present inequities in the pricing policies of the pharmaceutical industry.

The Lilly Digest reports that in 1970 the average prescription charge in the United States was $4.06. Of this figure, more than 50 percent is attributable to the acquisition cost of the drug product dispensed. We believe that drug product costs are generally artificially inflated due to a lack of meaningful price competition among manufacturers of prescription drug products. This situation can be corrected in several ways.

In 1970, the APhA house of delegates adopted a policy calling for the repeal of the so-called State "antisubstitution laws." These laws, in force in every State, prohibit the pharmacist from dispensing a different brand of drug product from that brand specified by a prescriber. Thus, if a physician prescribes Meticorten, Schering's brand of prednisone, which costs the pharmacist $10.80 per 100 tablets, these laws prohibit the pharmacist from dispensing prednisone produced by the Upjohn Co. under the brand name Deltastone, which costs the pharmacist only $2.25 per 100 tablets. The only way in which the pharmacist can legally dispense a different brand of the same drug product is by obtaining the prior authorization of the prescriber.

The primary effect of the antisubstitution laws is to protect the brand name marketing practices of the drug industry, including frequent significant variations in cost for the same drug product from different manufacturers. Moreover, these laws place an unnecessary burden on already overworked physicians, thousands of whom each day receive calls from pharmacists requesting authority to dispense a different brand because the brand prescribed is too expensive for the patient or taxpayer. Such authority, by the way, is routinely granted.

The other aspect of the problem is that virtually every pharmacy in the Nation carries an inventory of 3,000 to 5,000 different prescription drug products. For each drug, several brands, often numbering in excess of a dozen, must be stocked in multiple strengths, sizes and dosage forms. The situation is ludicrous. It is discussed in exhaustive, and I believe objective, detail in a position paper issued by the APhA board of trustees in March 1971 entitled "White Paper on the Pharmacist's Role in Product Selection." We have attached a copy of this position paper as an addendum so that you can fully appreciate the way in which such artificial restrictions work to keep the pharmacist from providing the highest quality drug products at the lowest possible cost.

(The paper referred to follows:)

A WHITE PAPER ON . . .

The Pharmacist's Role in Product Selection

An Overview of the Antisubstitution Laws and the American Pharmaceutical Association's Advocacy of Their Amendment Relative to Drug Product Selection

A Background and Position Paper Issued by the Board of Trustees
American Pharmaceutical Association, March, 1971

American Pharmaceutical Association
2215 Constitution Avenue, N.W.
Washington, DC 20037

SYNOPSIS

The American Pharmaceutical Association in April 1970 committed itself officially to "seek the repeal of anti-substitution laws." Specifically, the Association wishes the laws to be amended to give the pharmacist the option of selecting the source or manufacturer of a drug product to be dispensed when the prescription order specifies a multisource drug product by product trade name alone. If the prescriber specified the source of a drug product by company name, the pharmacist, as he does today, would dispense that company's product. Under no circumstances, moreover, would he have the right to dispense a drug entity different from the one prescribed. The APhA policy, if implemented, would have far-reaching effects, and the Association's action, therefore, has generated widespread controversy. APhA wishes, consequently, to clarify its policy on the antisubstitution laws, for both health professionals and the general public, and to examine, in depth, the issues that are involved.

The state "antisubstitution laws" and/or comparable state board of pharmacy regulations have come into being since about 1950 in 49 states. Only Alaska and the District of Columbia have no such provisions. Under these laws, generally, if a prescription order specifies the brand of drug product prescribed, the pharmacist must dispense that brand. APhA's position is that the pharmacist is the person best qualified by education and experience to select the source of a multisource drug product to be dispensed. To deny him this option, as the laws in large measure now do, represents a clear detriment to the pharmacist and the public.

The American Pharmaceutical Association's interest in amending the antisubstitution laws is based in part on its duty to maintain the professional status of pharmacists. The Association's membership includes 38,000 active members and 13,000 student members. Among APhA's publications is the *National Formulary*, one of the two official drug compendia in the U.S. (The other is the *United States Pharmacopeia*.)

The Association's position on the antisubstitution laws reverses its stand of 15 to 20 years ago. After World War II, the success of the U.S. drug industry had bred a proliferation of duplicate prescription drug products, made by different manufacturers but embodying the same drug entity. This situation, plus the high prices at which drugs were being sold, produced a rash of counterfeit prescription drug products on the U.S. market. The drug industry fought the counterfeiting problem in part by mounting its successful campaign to bring the antisubstitution laws into being. Pharmacists supported the campaign.

The drug companies also had a second motive for seeking antisubstitution laws. The proliferation of duplicate products created costly inventory problems for the community pharmacist. Among pharmacists, these problems led to mounting pressure in favor of "brand substitution," a term that can be fairly applied to the policy that APhA endorses today. Brand substitution was a threat to the drug companies' marketing system, however, and partly for that reason the industry pressed its campaign for the antisubstitution laws.

The drug product inventory problem today is even more severe than in the past, but drug counterfeiting has been suppressed. The latter development removed the only therapeutic justification for the antisubstitution laws. The laws in consequence now bear no reasonable relationship to the public health that they are alleged to protect. They protect instead the trade name marketing system of the drug industry and, in the process, eliminate the pharmacist as a decision-maker in providing rational drug therapy for patients.

Those who oppose APhA's policy on the antisubstitution laws argue partly on therapeutic grounds. They maintain that the legal specifications for drug products are either inadequate or inadequately applied, and that the patient, therefore, is exposed to a significant number of substandard drug products. They maintain further that competing, ostensibly comparable drug products that meet the official standards often are not equivalent therapeutically, and that brand substitution thus would threaten the public health. Both contentions focus on exceptions to the prevailing high standards and quality of the U.S. drug supply.

For some few types of drug entities, the comparable drug products may meet the official standards and still vary widely in therapeutic effect. The relatively few drug entities which have been so implicated are well known to the competent pharmacist. A prescription order that called for one of them by company name would represent a clear therapeutic judgment that no competent pharmacist would ignore.

The quality of the U.S. drug supply, moreover, is better today than ever before. The new science of biopharmaceutics is adding steadily to man's knowledge of the biological effects of drugs and drug products. The U.S. Food and Drug Administration has started to require *in vivo* data on biological availability for drug products that may be a problem in this respect.

If a significant number of competing drug products were not, for practical purposes, therapeutically equivalent, the facts would be reported in the medical literature. The literature in fact reports relatively few instances of therapeutic nonequivalence.

Amendment of the antisubstitution laws in line with the APhA policy would produce lower costs to the patient for a number of widely prescribed drug products. The pharmacist could dispense the least costly of the competing drug products that embody the drug entity prescribed. At the same time he could reduce his inventory costs and pass the savings in part to the patient.

To control the cost of drugs in tax-supported health programs, several states have adopted progressive procedures related to brand substitution. These procedures, in effect, neutralize the states' antisubstitution laws. Hospitals for years have pursued practices that neutralize the antisubstitution laws, again in order to provide more rational and economic drug therapy. The laws, in this light, impose a double standard on the community pharmacist and on the patients he serves. The result, APhA believes, is lower efficiency and higher cost.

Implementation of the APhA policy would cause significant economic effects in the drug industry, a fact attested to by the vigor of the companies' campaign against the policy. The effects would be noticed most in the industry's marketing system. They would intensify in the next few years as more drugs emerge from patent shelter and competing products appear. Nevertheless, while the Association cannot speak for the drug industry, it does not consider the probable economic effects of brand substitution a serious threat to the industry's vital ability to discover, develop, and market new drugs.

Amendment of the antisubstitution laws would allow the pharmacist to use his modern professional education much more effectively than he is allowed to use it today. The result would be overall improvement in the utilization of health manpower. The physician could concern himself mainly with prescribing the most effective drug entities. The pharmacist could concern himself mainly with dispensing the most effective drug products containing those entities, giving due consideration to both cost and quality. APhA sees no danger that the pharmacist, under its policy, would begin to encroach on the physician's prerogatives *vis-à-vis* the patient. The Association maintains rather that implementation of its policy would strengthen the professional relationship between physician and pharmacist.

Some will contend that in selecting the source of multisource drug products prescribed by product tradename alone the pharmacist would create for himself certain legal problems: potential liability for negligence, breach of contract or warranty, trademark infringement, unfair competition, and the like. In none of these possibilities does APhA see insuperable legal bars to implementing its policy. The pharmacist's best means of avoiding legal problems in general is to dispense only quality drug products and to disclose fully the nature of the products dispensed. Pharmacists for years have been selecting the source of a number of widely used drug products that are commonly prescribed by established name. The record shows that they have discharged this duty consistently at a high professional level.

Opponents of APhA's policy on the antisubstitution laws have suggested that its implementation would cause the pharmacist to commit offenses under state and federal food, drug, and cosmetic acts. The language of these laws makes clear, however, that they are designed to protect the public health and not the proprietary rights of drug manufacturers.

APhA does not expect immediate amendment of the antisubstitution laws in the manner that it espouses. It foresees instead a few successful initial efforts to amend the laws, based on education and rational discussion. These efforts, the Association believes, would breed additional efforts elsewhere until eventually all such laws and regulations will have been amended or otherwise rendered inapplicable. APhA will provide staff and technical support to state pharmaceutical associations that wish to launch campaigns to amend the laws.

The Association expects the Federal Government to develop proposals analogous to its policy in order to control the cost of drugs in tax-supported health plans. When such proposals materialize, APhA will support them. In addition, the Association will continue its dialog on the antisubstitution laws with physicians and other prescribing professionals on a number of fronts. These include the American Medical Association, which officially opposes the APhA policy.

The American Pharmaceutical Association believes in short that amendment of the antisubstitution laws in the manner that it endorses would constitute a clear, timely, and cost-reducing benefit to the public health. The Association intends to continue to press strongly for public and professional acceptance of its policy.

INTRODUCTION

In April 1970, the House of Delegates of the American Pharmaceutical Association approved by a vote of 150 to 89 a resolution that APhA should "seek the repeal of antisubstitution laws." The sense of the resolution, which thus became official APhA policy, is to seek amendment of the antisubstitution laws so as to allow the pharmacist to select the source of any drug product to be dispensed when that product is prescribed by drug trade name alone. This practice can fairly be called "brand substitution," and physicians, pharmacists, and others who deal with prescription drugs may see unsettling implications in any form of "substitution."

We feel, therefore, a need to explain in some detail our policy, our reasons for adopting it, and the consequences that we believe would result from its implementation. Hence this document.

The so-called "antisubstitution laws" have come into being since about 1950 in 49 states as state laws and/or regulations by state boards of pharmacy. Only Alaska and the District of Columbia have no such provisions. Under these laws, if a prescription order specifies the manufacturer of the drug product prescribed, either by product trade name or company name, the pharmacist must dispense that manufacturer's product. We believe, however, that with rare exceptions the pharmacist is the person best qualified to select the source or manufacturer of a drug product to be dispensed. We believe that existing antisubstitution laws and regulations should be amended to allow him to do so.

Modification of the antisubstitution laws along the lines that we advocate would have far-reaching effects. It would increase the overall efficiency of the highly-trained people who prescribe, dispense, and otherwise play a role in the use of drug therapy. It would reduce the cost of some widely used drugs to the patient. It would allow the community pharmacist to reduce his drug inventory, thus effecting additional savings that could be passed in part to the patient. It would require drug manufacturers to revise their marketing practices. It might require changes in the means by which physicians today acquire their information on drugs.

Some such developments no doubt would cause problems. We believe, however, that they would be economic and procedural problems and that they could be solved without reducing in any way the benefits of drug therapy to the patient. We believe further that the modifications that we espouse in the antisubstitution laws would in no way affect the physician's prerogatives in treating his patient.

The American Pharmaceutical Association's interest in the antisubstitution laws stems in part from its responsibility for maintaining the professional status of pharmacists. The 118-year-old APhA is the national professional society for individual pharmacists in the U.S. It has 38,000 active members and 13,000 student members. The Association serves the scientific and professional interests of pharmacists in a variety of ways, including its publications. The latter include the *National Formulary*, one of the two official drug compendia in the U.S. (the other is the *United States Pharmacopeia*).

We serve a purpose of our own, therefore, in seeking amendment of the antisubstitution laws, since one of the effects would be to increase the responsibility and thus the professional status of pharmacists. But in serving this purpose of our own, we believe that we serve the public interest as well.

We have come to this view, which in fact reverses our stand of some 15 years ago on the antisubstitution laws, after careful perusal of the several complex questions involved. To explain fully the rational progression of thought that produced our current policy, we examine the situation here, in depth, in each of its major aspects:

- Current APhA policy and its meaning.
- Historical background.
- Therapeutic issues.
- Professional issues.
- Economic issues.
- Legal issues.
- Roles of professional associations of health practitioners.

CURRENT APhA POLICY AND ITS MEANING

The philosophical basis of our opposition to the antisubstitution laws has been stated by the APhA Policy Committee on Public Affairs, the group that recommended that the Association seek repeal of the laws:

> *The pharmacist's training and expertise qualify him as an expert on drugs and permit him to make judgments about quality drug products. Thus, in the Committee's view, antisubstitution laws serve for the most part to eliminate the pharmacist as a decision-maker in providing rational drug therapy for patients. To state the proposition in other terms, a major effect of antisubstitution laws is to make the pharmacist's function more mechanical than professional . . . . repeal of antisubstitution laws would not disturb the existing prescriber-pharmacist relationship or deprive the prescriber of the right to insist that a particular drug product be dispensed. Repeal of antisubstitution laws would simply act to remove the state as a decision-maker in the prescribing and dispensing of medication.*

APhA is concerned mainly herein with the provisions of the antisubstitution laws whose effects depend simply on how the physician or other prescriber chooses to name the drug or drug product that he prescribes. He has several basic choices:

- Trade name (brand name): The name coined and usually registered by the manufacturer to describe a specific drug product made by him alone.
- Established name (generic or nonproprietary name): Under the Kefauver-Harris amendments of 1962 to the Federal Food, Drug, and Cosmetic Act, established names include:
  1. Names used in the *National Formulary* and the *United States Pharmacopeia* to describe drug entities.
  2. Names promulgated by the Secretary of the U.S. Department of Health, Education, and Welfare to describe drug entities.

3. In the absence of a name in category (1) or (2), the common name of the drug entity if it has one.

- Chemical name: The name that identifies the drug entity unequivocally in chemical terms.

The prescriber, in addition, may use any of these three types of names combined with the name of a specific manufacturer. Most often, however, he will use simply the trade name, or the established name with the name of a specific manufacturer, or the established name alone. Rarely will he use the chemical name. Normally he will not know it, and in any case it will be more complex as a rule than is necessary for his purpose. (Caffeine, for example, is 1,3,7-trimethylxanthine; prednisone is 17,21-dihydroxypregna-1,4-diene-3,11-20-trione.)

Let us take, for example, the physician who wishes his patient to have the steroid whose established name is prednisone. The drug is available under a number of trade names, including Meticorten (Schering), Deltasone (Upjohn), and Deltra (Merck Sharp & Dohme). It is available also under its established name from several dozen manufacturers. Depending on how the physician writes the prescription order, the antisubstitution laws now in effect offer the pharmacist one of three general courses of action:

- If the physician prescribes Meticorten or Deltasone or Deltra, the pharmacist must dispense the trade-named product specified.
- If the physician prescribes "prednisone Schering" or "prednisone Merck," the pharmacist, again, must dispense the drug product of the manufacturer specified.
- If the physician prescribes simply "prednisone," the pharmacist may dispense prednisone made by any legitimate manufacturer, including those who sell it under trade names.

Of these three courses of action, APhA quarrels only with the first. The Association's position is that where a drug product is prescribed only by trade name, the pharmacist should have the right and responsibility to dispense for good reason a therapeutically effective drug product made by any legitimate manufacturer. Where a drug product is prescribed by established name and manufacturer's name, the presumption must be that the prescriber, for good reason, has consciously selected a source of supply. Where a drug product is prescribed by established name alone, the presumption is that the prescriber has consciously left to the pharmacist the selection of source of supply.

To put it another way, APhA believes that where the prescriber wishes consciously to specify the source of a drug product, it is reasonable to expect him to name the manufacturer on his prescription order. The presumption here is that use of the trade name alone on a prescription order cannot be taken to represent conscious selection of a source of supply. The Association emphatically does not contend that the pharmacist should have the right to change anything in the prescription order except the source of supply. Drug entity, strength, dosage form, and the like would remain inviolable except where the prescriber, after consultation with the pharmacist, decided that a change should be made.

In this paper, then, APhA defines "substitution" as the substitution of one manufacturer's therapeutically effective and chemically equivalent drug product for the product of another prescribed by trade name alone. The Association strongly opposes "substitution" in its older, alternative sense: the practice of using ingredients other than those prescribed which changes the desired quality or strength of the final product. The likelihood of this latter form of substitution has declined steadily as laws have grown stronger and as drug manufacture has moved from the pharmacy to the factory. The analogous act today would be, say, to dispense tetracycline when ampicillin is prescribed, and this practice APhA opposes unequivocally.

In acquiring the right to substitute one drug product for another prescribed by trade name alone, the pharmacist would also assume the responsibility for determining that the substituted product is as effective therapeutically as the one prescribed. This determination would be a professional judgment based on the pharmacist's training and his knowledge of pertinent, recognized scientific information.

We are aware that in supporting the modification of the antisubstitution laws to legitimatize substitution, as defined herein, we raise complex issues that some consider debatable. To clarify our view of these issues we think it useful to start with the evolution of the concept of "substitution" and the laws and regulations that have grown up around it.

HISTORICAL BACKGROUND

The concept of antisubstitution laws in this country can be traced as far back as the 1880's. In that period, pharmacists and physicians felt growing concern over the large number of secret remedies that were being advertised to the public. The contents of such remedies were not disclosed, and standards of purity for them did not exist. It became common practice for pharmacists to recommend their own or officially recognized formulations when patrons asked for a "secret nostrum."

When The Proprietary Association was organized, in 1881, one of its aims was "the extermination of imitation goods." The association argued that the real evil was the pharmacist who might sell his own formula as a substitute for patent medicines made by others. This evil the association labeled "substitution." The issue of substitution came to the fore again in 1928, when *The Druggists Circular*, a private trade publication, published a series of articles and editorials that compared substitution to robbery. *The Druggists Circular* advised "that proprietors instruct their clerks and managers on the illegality of giving any other product when a trademarked preparation is called for, be it on prescription or over the counter . . . misguided philanthropy to poor customers may lead to embarrassing complications. It is better that the poor pay a little more or that the druggist sacrifice some or all of his profit rather than lose his reputation and $500 as a fine."

Substitution remained a troublesome question through the next two decades, which saw a succession of brilliant triumphs in drug research: the sulfas, the antibiotics, the steroids, the tranquilizers. The pharmaceutical industry, of course, had much to do with developing the so-called miracle drugs and making them widely available in therapeutically useful form. At the same time, the industry brought to full flower a marketing system that depends on advertising and detail men to induce the physician to prescribe drug products by trade name.

Duplicate Products, Counterfeits

This marketing system, combined with drugs of unprecedented effectiveness, produced excellent commercial results. Each link in the distribution chain, from producer through community pharmacist, did very well indeed. Success, how-

ever, brought certain untoward consequences. One of these has been the growing number of duplicate products: those based on the same drug entity, but made by different producers under different trade names.

As duplicate products proliferated, the pharmaceutical companies worked effectively to convince the pharmacist that he better served both himself and the public by stocking all available brands. Because of this campaign and the pharmacist's ingrained aversion to substitution of the traditional kind, he tended not to substitute one brand of drug product for another. Then, when the antisubstitution laws came into being, it became illegal for him to do so. The pharmacist who wished to be able to supply whatever drug product was specified, was compelled to stock each brand of a given drug entity. This situation created costly inventory problems for the pharmacist, problems reflected in higher costs to the patient.

One result, in 1953, was a campaign by the Consolidated Brooklyn Retail Pharmacists' Association to persuade every physician in Brooklyn, N.Y., to prescribe by established name and to specify "any reliable brand" (A.R.B.). At about the same time, the Westchester County (N.Y.) Medical Society suggested to its members that they adopt a similar practice.

The American Pharmaceutical Association, at its annual meeting in 1953, took an unequivocal stand against substitution of any kind. The pharmaceutical industry, meanwhile, vigorously opposed the A.R.B. concept on the grounds that it was "substitution" and a serious threat to the public health. At the same time, the industry began to press for state antisubstitution laws, and the Drug, Chemical and Allied Trades section of the New York Board of Trade launched a national program to adopt a model antisubstitution bill. In 1953, the industry formed the National Pharmaceutical Council to push such legislation. NPC's president said at the time that "substitution is a threat to all levels of pharmacy." Pharmacists, meanwhile, felt that antisubstitution laws were "a definite slap at the ethics of the profession" and that NPC was "maligning the profession, and sowing seeds of uncertainty, bewilderment and distrust."

While this intramural debate was in progress, a second consequence of the great commercial success of modern pharmaceuticals, drug counterfeiting, was reaching unprecedented proportions. The counterfeiters made prescription drugs that looked like the original in shape, in color, and even in packaging. Duped or unethical pharmacists would then substitute these products when dispensing prescriptions for the originals. The problem was serious, both commercially and therapeutically. As a result, APhA and other pharmacy organizations joined the drug industry in supporting antisubstitution legislation. The resulting laws helped greatly to correct the counterfeit drug situation.

Government Programs

In the mid-1960's the rise of tax-supported health programs, particularly at the state level under Medicaid, brought the antisubstitution laws into question once again. Several states developed welfare formularies, placed cost limits on drug products listed in them, and emphasized prescribing and dispensing by nonproprietary name. When the physician prescribed a drug that was not in the formulary, or that cost more than the stated maximum, the pharmacist had three choices: he could refuse to dispense the prescription; he could dispense it, charge the state the allowed maximum cost, and make up the difference himself; or he could dispense the prescription with an equivalent drug product that met the requirements of the formulary, thus violating the antisubstitution law.

Some have suggested that the pharmacist had a fourth choice: to telephone the physician, explain that he had prescribed a drug product not included in the formulary, and ask him to change his prescription order appropriately. This is not a practical alternative. Often the physician is not readily accessible to the telephone, he resents the disruption of his practice, and both physician and pharmacist would find it inefficient to resort regularly to the telephone.

In 1965 the California Health and Welfare Agency began issuing preprinted prescription forms designed in part to solve this problem. They carried a statement that authorized the pharmacist to dispense a *National Formulary, United States Pharmacopeia*, or generic equivalent of the drug prescribed where the latter did not meet the welfare program's requirements. The physician's signature on the prescription authorized the pharmacist to make the change. Also in 1965, the Attorney General of California ruled that a pharmacist who followed the preprinted statement, in order to comply with the welfare program's rules, would not be held to have violated the state antisubstitution law.

In both 1965 and 1966, APhA's Committee on Social and Economic Relations recommended that ". . . state agencies utilizing a system of listing drugs by generic name or by cost, or by a combination of these factors, include a printed statement on their prescription order blanks which, when signed by the prescriber, permits the pharmacist to dispense a comparable drug from the approved list." This recommendation became APhA policy in 1966. The Association, however, continued to study the issues involved in the antisubstitution laws, both in the light of developments in state welfare programs and, more broadly, of the modern practice of pharmacy. Conclusive action resulted in the spring of 1970, when APhA adopted its current policy on the antisubstitution laws.

Interest has remained high, meanwhile, in reducing the costs of state and federal health care programs by allowing pharmacists to dispense drugs under a system of nonproprietary nomenclature.

In 1969, Maryland enacted a statute which created a formulary for use in the state's Medicaid program. The formulary lists "generic equivalents" and is developed by a committee of physicians and pharmacists who consult with the staffs of schools of pharmacy and with other medical and pharmacological experts. In addition, prescription blanks under the program are to bear the following statement:

This prescription shall be filled by a generic equivalent from the State Health Department Formulary, unless checked by the prescribing physician.

In 1970, Massachusetts enacted a statute that established a drug formulary commission in the Department of Public Health. The commission, which has been recently appointed, must prepare a formulary of generic or chemical and brand names of drugs and pharmaceuticals that it considers therapeutically equivalent. Physicians who prescribe by brand name a drug listed in the formulary must include the generic or chemical name of the drug product on the prescription order.

The new Massachusetts law applies to all prescription orders, written or oral, not just those covered by government programs. The law allows pharmacists to decide what drug product to dispense on the basis of the generic name on the prescription order.

In Delaware, the state pharmaceutical and medical societies, in cooperation with the State Department of Health, are jointly discussing the development of a state formulary to serve as the basis for prescribing and dispensing drug products by nonproprietary name. The two societies went into the project voluntarily. They have not yet agreed on a final plan of action, but their aim is to cooperate to reduce the cost of medication.

A second voluntary plan, described in the *New England Journal of Medicine* [**280**, 1442 (1969)], was worked out cooperatively by the Albemarle County (Va.) Medical Society and the Charlottesville-Albemarle Pharmaceutical Association. In this plan, physicians agreed to prescribe by nonproprietary name and pharmacists agree to dispense accordingly and pass on cost savings to the patient.

Pertinent action also took place in Canada in June 1970 at the pharmacy convention of the British Columbia Pharmaceutical Association and the British Columbia Professional Pharmacists' Society. Delegates to the convention voted overwhelmingly to approve the concept that pharmacists should select the source of supply of drug products prescribed, unless the prescriber specifies otherwise.

Today's Perspective

Several salient points emerge from this history of substitution and the related issues:

- "Substitution" describes either of two distinctly different practices: dispensing a *drug entity* different from the one prescribed; or dispensing a *drug product* different from the one prescribed, but containing the same *drug entity*.
- Drug makers' advocacy of the current antisubstitution laws was inspired by their opposition to drug counterfeiting and to both types of substitution. Pharmacists' advocacy of the laws was inspired by their opposition to drug counterfeiting and to substitution of the traditional kind—dispensing a drug entity different from the one prescribed.
- Drug makers today wish to retain the antisubstitution laws primarily to combat substitution of one manufacturer's drug product for the comparable drug product of another; pharmacists have favored this form of substitution for two decades and want the laws amended primarily to permit the practice.

Until the early 1960's the therapeutic basis of the current antisubstitution laws was not a major issue. Everyone agreed, and still agrees, that drug counterfeiting and substitution of the traditional kind were therapeutically unsound. Pharmacists considered comparable drug products of different reputable manufacturers to be therapeutically equivalent and, on that basis, wished to be allowed to dispense any reliable brand (A.R.B.). In the face of the drug counterfeiting problem, however, pharmacists set aside the A.R.B. concept and lent their support to the passage of antisubstitution laws. Drug makers opposed the A.R.B. concept, but did so largely on economic grounds; they did not question the therapeutic equivalence of comparable drug products of different legitimate producers.

In the past decade, these views have felt the impact of two converging developments: growing concern over the allegedly high prices of prescription drugs, particularly trade-named drugs; and new scientific insights that cast a measure of doubt on the therapeutic equivalence of otherwise comparable drug products.

Concern over the prices of prescription drugs has been exacerbated by the rise of welfare medicine. Various agencies, particularly at the state level under Medicaid, have tried to control drug costs by means of formularies, enforced prescribing by established name, and related measures. Such measures generally depend on the idea that comparable drug products of different legitimate manufacturers are therapeutically equivalent unless proved clearly to be otherwise.

The steadily improving techniques of medical science, meanwhile, have shown that in some few cases, at least, ostensibly comparable drug products may not in fact be therapeutically equivalent. On this basis rests the argument that the therapeutic equivalence of comparable drug products must be proved experimentally; equivalence cannot be assumed simply because no evidence exists to the contrary.

Therapeutic equivalence has thus become a vital element in the debates over prescribing by established name (generic prescribing), modification of the antisubstitution laws, and similar matters. The issue, moreover, transcends such debates. The point of drug therapy is, after all, to help the patient. In this context, therapeutic equivalence is basic to the practice of drug therapy as well as to the development, manufacture, testing, and marketing of prescription drug products.

THERAPEUTIC ISSUES

The problem of therapeutic equivalence arises because the comparable drug products of different manufacturers are not identical, either chemically or physically. The results produced in the patient by any such product must, therefore, differ from the results produced by any other. The question is whether the differences are therapeutically significant.

The belief that they are not significant has long been implicit in the prescribing habits of physicians and dispensing habits of pharmacists in the U.S., and in the pertinent laws and regulations, including the antisubstitution laws. That is to say, the physician regularly has the option of prescribing and the pharmacist of dispensing one of two or more drug products based on the same drug entity but made by different manufacturers. Not uncommonly the option may be exercised on other than therapeutic grounds—on economic grounds, for example. In doing so it is presumed that the available products are, for practical purposes, therapeutically equivalent. In the past decade, however, sound scientific evidence has shown that the presumption is not always correct. It thus becomes logical, in fact imperative, to ask whether it is even generally correct.

We are not concerned here with drug products that do not meet the established standards. The problem lies rather with differences among products that do meet the existing legal standards.

Drug products are manufactured and tested to tolerances based on safety, efficacy, manufacturing economics, and related factors. Thus the content of active ingredient or drug entity may vary by several percent from tablet to tablet or from capsule to capsule. The degree of compression, and thus the rate of disintegration, may vary in the same manner. Differences may occur in the crystal structure and particle size of the active ingredient with consequent therapeutic effects. Most drug products contain excipients, substances added to make tablets large enough to handle conveniently, to stabilize the product, to promote disintegration, and the like. Excipients as a rule are therapeutically inert in themselves, and manufacturers often use different ones to achieve the same end. It has become increasingly apparent, however, that excipients and the manner in which they are formulated can influence significantly the overall therapeutic effect of the drug product.

Since drug products are manufactured to fall within cer-

tain tolerances, physical and chemical differences occur not only among those of different manufacturers. They occur as well between batches made by the same manufacturer, or even among single tablets or capsules from the same batch. In any event, these differences as a rule will be detected only by sophisticated chemical and physical techniques and instrumentation. The practicing physician or pharmacist, as a result, is in no position to test prescription drugs against the established standards. He must rely instead on the drug manufacturers and the federal Food and Drug Administration to exclude and, failing that, to remove defective drug products from the channels of distribution. The producers and FDA rely in turn on a system of quality assurance based largely on physical and chemical tests.

These tests are designed basically to insure that a given drug product, whatever its source, will produce essentially the same therapeutic effect as all comparable drug products. The tests are designed to achieve this end indirectly. That is, they measure outside the body (*in vitro*) those chemical and physical characteristics of the drug product that the scientific evidence indicates will affect the drug product's behavior in the body (*in vivo*).

In the U.S., the most important compendia of official drug standards and specifications are the *United States Pharmacopeia (USP)*, published by the U.S. Pharmacopeial Convention, and the *National Formulary (NF)*, published by the American Pharmaceutical Association. The *USP* and *NF* standards and specifications, along with certain others, are established as a result of intensive consultation among experts in all branches of the manufacture and use of prescription drug products. Manufacturers and some large buyers of drug products often use additional tests, but the official standards are the ones that any drug product must conform to under federal law.

The prevailing system of assuring the quality of prescription drug products can break down in two general sets of circumstances: if the tests are applied inadequately; or if the tests themselves are inadequate. Substandard drug products do enter the channels of distribution. Some, perhaps most, are detected after the fact and recalled; others, no doubt, are never detected. Breakdowns of this kind may call for improvements in the operational use of the tests, but they are not truly germane to the questions at hand:

- Do the existing *in vitro* standards and specifications, properly applied, insure the therapeutic equivalence of comparable drug products?
- If they do not, are they susceptible of improvement to the required level?
- Does *in vivo* testing offer a practical alternative to *in vitro* methods?

Clearly such questions have no simple answers. They touch on the basis and nature of both *in vitro* and *in vivo* tests, the advantages and disadvantages of each, and the relationship between the two.

Basis of Official Standards

The official standards and specifications for prescription drug products today are established initially on the basis of *in vivo* studies and clinical evaluation by the manufacturer who originates the product. The manufacturer uses the data thus obtained to demonstrate to the Food and Drug Administration that the drug product is safe and effective for its stated purpose. If FDA finds the data satisfactory, it clears the product for marketing. In the course of this process, FDA also must approve the basic *in vitro* tests that the manufacturer develops for use in routine production of the drug product. These tests are designed to insure that the product that is marketed remains consistently the therapeutic equivalent of the product that was cleared initially for marketing.

These basic *in vitro* tests, perhaps in modified form, become the benchmarks used by FDA and others to determine whether routine production runs of the drug product meet the official standards and specifications. If other manufacturers enter the market, their products must conform to the same standards. These same standards and specifications, perhaps further modified, are those promulgated by the *United States Pharmacopeia* and the *National Formulary*.

The standards and specifications vary with the nature of the drug product, and their technical details are not to the point here. In general, however, they combine several types of determinations. These may include such parameters as the chemical identity of the active ingredient, the uniformity of content of the active ingredient from tablet—to—tablet or capsule—to—capsule, the time of disintegration, and the time of dissolution. Excipients as a rule are not identified chemically, but their effect may be evident in such parameters as the times of disintegration and dissolution.

The official standards and specifications are not static; they are changed from time to time as the state of the art advances. Some chemical substances, for example, are polymorphic; they can exist in the solid state in more than one crystal form. In recent years, moreover, it has been demonstrated clinically that the crystal form of a drug entity in some cases can markedly affect its absorption profile. Thus the *XIII*th (1970) edition of the *National Formulary* includes for the first time an x-ray diffraction specification to be applied to a number of drug substances in which polymorphism in the active ingredient might be therapeutically important.

NF XIII also includes a new test of dissolution rate, the rate at which a drug can be expected to dissolve in the gastrointestinal fluid. Of the drug product parameters that are commonly determined *in vitro*, dissolution rate is perhaps the most important indicator of biological availability and thus of therapeutic equivalence. The reason is that when a drug product is administered orally, the body normally absorbs the drug entity from the gastrointestinal tract and normally absorbs it rapidly once it's dissolved in the gastrointestinal fluid. About 90% of U.S. prescription orders, moreover, call for premanufactured drugs that are administered orally.

The existing standards and specifications for drug products in the U.S., then, are based largely on *in vitro* tests that are designed to indicate the therapeutic equivalence of comparable drug products, regardless of their source. The tests are precise and reproducible. They are used routinely to monitor the quality and consistency of drug products. The standards and specifications are based initially on the results of *in vivo* testing and clinical evaluation and, until roughly 1960, were generally believed to be a sound, if indirect, indication of the degree of therapeutic equivalence of comparable drug products.

Therapeutic Equivalence

The early 1960's, however, saw the start of a searching re-evaluation of the effectiveness of the traditional standards and specifications for drug products. The move stemmed primarily from progress in medical science. New techniques and new knowledge combined to raise difficult questions about drug products and their therapeutic effects, questions that had not previously been considered or, if considered, had lain beyond the reach of medical science and technology.

This marked trend was reinforced by the Nelson hearings in the U.S. Senate, which began in 1967 and are still in progress. These hearings are a lineal descendent of the Kefauver hearings on prescription drugs that led, in 1962, to the Kefauver-Harris amendments to the Federal Food,

Drug, and Cosmetic Act. The question of therapeutic equivalence of comparable drug products has arisen repeatedly in the Nelson hearings. It became clear at the outset that the views of many authorities on the problem, whether accurate or not, suffered from a lack of clear-cut scientific data.

The ability of pharmaceutical science to get at the facts, meanwhile, has improved to the point at which a new science has emerged. This new subdiscipline of the medical arts goes under several names, one of which is "biopharmaceutics," and was recognized formally in 1961 in the *Journal of Pharmaceutical Sciences:*

> *The term biopharmaceutics was recently coined. In its broad sense we may define biopharmaceutics as the study of the relationship between some of the physical and chemical properties of the drug and its dosage forms and the biological effects observed following administration of the drug in its various dosage forms.*

Ultimately, in other words, biopharmaceutics involves the direct measurement of the biological effects of drug products, as opposed to the indirect measurement provided by *in vitro* tests. Biopharmaceutics in addition involves an intermediate measure of equivalence, biological or physiological availability. Conceptually, therefore, comparable drug products can be considered to be equivalents—or nonequivalents—at three different levels:

- **Chemical Equivalents:** Those multiple-source drug products which contain essentially identical amounts of the identical active ingredients, in identical dosage forms, and which meet existing physicochemical standards in the official compendia.
- **Biological Equivalents:** Those chemical equivalents which, when administered in the same amounts, will provide essentially the same biological or physiological availability, as measured by blood levels, etc.
- **Therapeutic Equivalents:** Those chemical equivalents which, when administered in the same amounts, will provide essentially the same therapeutic effect as measured by the control of a symptom or a disease.

Direct determination of the degree of therapeutic equivalence requires comparison of drug products that contain identical amounts of the same active ingredient in the same dosage form (capsule, tablet, etc.). The products involved must be compared in terms of their effects, in humans, on a specific disease or symptom(s). In addition to the requirement for human patients, afflicted by specific maladies, such a comparison can be complicated at best: differences in individual biochemistry, in the symptoms of the disease at hand, and in other factors introduce a variety of complex and interrelated variables. The problems created by the need for human subjects are solved only partly by using laboratory animals. One major reason is that results in animals may differ from those in humans in a manner that makes extrapolation from one to the other unreliable to a significant degree.

Biological Availability

Because of such difficulties, medical scientists have resorted to the measurement of biological availability as an indicator of the therapeutic equivalence of drug products. The concept is based on the general agreement among clinical pharmacologists that the therapeutic effectiveness of most drug products is related closely to the degree of absorption of the active ingredient into the bloodstream. Certainly the correlation is correct for drugs taken orally for their effects on internal tissues and organs. The degree of absorption may be measured in several ways, including direct measurement of the concentration of the drug entity or its metabolites in blood or urine. The drug's biological availability can then be expressed as a curve or profile showing concentration *vs.* time.

The determination of biological availability involves considerably fewer complexities than direct measurement of therapeutic equivalence, but it is not perfectly straightforward. The shape of a blood absorption profile, for example, can be affected markedly by the intervals of time at which the concentration of the drug entity or metabolite is measured. The optimum interval must thus be established experimentally, and it may vary with the biochemistry of the subject.

Another imponderable is the range of differences that can occur in the blood absorption patterns of comparable drug products. If one product produces consistently high blood levels and the other produces consistently undetectable blood levels, the two can reasonably be said to be nonequivalent both biologically and therapeutically. There may be, however, a gray area. The two products may produce different, but significant blood levels; the blood levels may peak at different intervals of time after administration; one product may produce a relatively high average blood level over a relatively short time, the other may produce the converse. The therapeutic significance of such differences often is far from clear.

In view of complications of this kind, *in vivo* testing of drug products plainly can offer nothing like the precision and reproducibility of *in vitro* testing. The latter, consequently, remains the only reasonable choice for routine use in manufacturing and monitoring drug products. It is true that the science of biopharmaceutics is progressing steadily, but it is difficult nonetheless to perceive a time when *in vivo* testing might supplant *in vitro* methods.

In vivo testing, on the other hand, does have one great advantage: it tells us things about the biological performance of drug products that *in vitro* testing can never tell us. The practical course of action then is to use *in vivo* testing nonroutinely, whenever the need demands it and the state of the art permits it, and at the same time to improve steadily the correlation between *in vivo* and *in vitro* methods. This in fact is what has been happening in the past decade to an ever-increasing degree.

The growing emphasis on *in vivo* testing of drug products has been spurred in part by the Kefauver-Harris amendments of 1962. The amendments require FDA to clear drug products for marketing on the basis of both safety and effectiveness. From 1938, when the Federal Food, Drug, and Cosmetic Act was last previously amended, until 1962 the basis for clearance was safety alone. The required demonstration of effectiveness can reasonably be expected to have intensified the *in vivo* studies and clinical evaluations done by the originators of drug products cleared by FDA since 1962.

The Kefauver-Harris amendments required also that the 3,000 drug products that FDA had cleared as safe between 1938 and 1962 be reviewed for effectiveness. This review was undertaken by the Drug Efficacy Study Group of the National Academy of Sciences–National Research Council. Primarily it involved thorough evaluation of the scientific data that had accumulated on the drug products in question. During the same period, doubts about the therapeutic equivalence of comparable drug products continued to multiply, whether justifiably so or not. These doubts became a critical issue in discussions of the advisability of instituting widespread generic prescribing as a money-saving measure in welfare medicine. In 1967, FDA itself began a modest study of the biological availability of certain multiple-source drug products.

New FDA Requirements

One result of these activities is that FDA now requires manufacturers to produce evidence of biological availability for drug products that might present problems in formulation. The requirement concerns mainly those drug products that were cleared as safe in 1938-1962 and that the Drug Efficacy Study Group has cleared as effective. It applies to all manufacturers of such products, including the originator. The originators of drug products cleared since 1962, of course, have been required to supply clinical evidence of effectiveness as part of the clearance procedure. As new makers of these products enter the market, all manufacturers other than the originator will be required to produce evidence of biological availability where FDA deems it to be a problem or a potential problem. While the patents on such products remain in force, licensees of the originator must meet the same requirement.

It should not be concluded that these requirements for data on biological availability have resulted from anything like a catastrophic breakdown in the U.S. system of drug quality assurance. We regard that system as fundamentally sound, but subject to continuing improvement. Beyond question, one can find defects in the system and in the drug products whose quality it purports to assure: such defects are found regularly, and they are corrected regularly. By no means, however, can they be equated with a widespread lack of therapeutic equivalence among comparable drug products.

Tests of biological availability, it is true, have shown differences among comparable drug products that meet the official standards and specifications. In some such cases, FDA has ordered that drug products be withdrawn from the market pending suitable reformulation. In no case of withdrawal, however, have scientifically acceptable clinical studies been reported that equate biological nonequivalence among the affected products with therapeutic nonequivalence among the same products. A difference in biological availability does not indicate, *a priori*, a difference in therapeutic effect. We think it entirely correct to view differences in biological availability as grounds for precautionary steps, including withdrawal from the market and reformulation where indicated. We think it entirely incorrect to extrapolate a few such findings to the entire universe of prescription drug products.

The official compendia have never guaranteed that adherence to their standards and specifications constitutes ironclad assurance of therapeutic equivalence. They do assert, however, that compliance with the standards assures therapeutic equivalence, for practical purposes, in all but a very few cases. Fewer than five scientifically acceptable clinical studies have been reported that demonstrate significant therapeutic differences among two or more products that have met the chemical and physical standards of the official compendia.

Because of its economic ramifications, the question of therapeutic equivalence was reviewed by the Task Force on Prescription Drugs of the U.S. Department of Health, Education, and Welfare. In its final report, in 1969, the Task Force said, "On the basis of available evidence, lack of clinical equivalency (therapeutic equivalency) among chemical equivalents meeting all official standards has been grossly exaggerated as a major hazard to the public health."

Large buyers of multisource drug products often specify the least costly ones. This practice is found, for example, in certain foreign drug programs, in state welfare programs, in Veterans Administration and Public Health Service hospitals, and in the military services. In such programs, the Task Force found, instances of clinical nonequivalence have seldom been reported, and few of those that were reported had significant therapeutic consequences.

Nonequivalence Arguments

The Task Force recognized, as do we, that some do not accept the therapeutic equivalence of comparable drug products as a workable concept today. Their skepticism is based on several interrelated arguments:

- The official standards and specifications are not sufficiently stringent to assure therapeutic equivalence among comparable drug products.
- The reported instances of therapeutic nonequivalence understate the number that actually occur.
- FDA does not, and cannot, monitor the makers of prescription drugs and their products extensively enough to assure an acceptable level of quality, whatever the standards.

Plainly we disagree with the conclusion to which these arguments must lead. Each of them, however, bears sufficient weight to warrant rational consideration.

The official standards for prescription drug products are constantly being revised in the light of new knowledge. One can thus argue that many or even all existing standards are inadequate in some degree at any point in time because they are subject inevitably to revision. We accept this argument, specious though it may seem. We contend, on the other hand, that the standards are fully abreast of current knowledge, barring only the time required to publish new knowledge and incorporate it into the standards. We contend further that the existing standards do assure an adequate degree of therapeutic equivalence among comparable drug products in all but a relatively few cases. While it is inappropriate to go into detail here, we can say that any who choose to study the matter will find the weight of scientific evidence is with us on this score.

We accept the assertion that the reported instances of therapeutic nonequivalence understate the number that actually occur, but we accept it with important reservations. The practice of medicine remains in many respects an art, albeit a highly complex art. No reasonable authority would question the existence of cases of therapeutic nonequivalence whose effects are obscured by other factors to the point at which they go undetected or are misinterpreted.

Most hospitals, however, use a relatively small armamentarium of drug products, whose effects and side-effects become well known to the medical staff. Let us say that a pharmacy and therapeutics committee that has accumulated considerable experience with a particular drug product elects, for economic reasons, to select a comparable product made by a different manufacturer. Should the two products turn out to be therapeutically nonequivalent to a significant degree, we believe that the medical staff as a rule would detect the difference quickly and report it. But medical records and the clinical literature reveal very few instances of such reports.

The circumstances we describe may not be universally applicable. Physicians can err. Patients do not always report the effects of drug therapy accurately. We are convinced nevertheless that if significant therapeutic nonequivalence were a widespread problem, the reports of its existence would surely be far more numerous than is the case today.

The third broad argument of those who question the concept of therapeutic equivalence is that FDA does not, and cannot, monitor the makers of prescription drugs and their products extensively enough to assure an acceptable level of quality, whatever the standards. This argument

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in itself is certainly correct. Drug quality can be assured only by a cooperative effort among all who are involved. The argument gains weight, therefore, only when one presumes the presence of the incompetent or unscrupulous elements that exist in any field of endeavor, if only on a purely statistical basis. The degree to which such elements may exist in the field of prescription drugs was outlined in December 1970 by a spokesman for the Pharmaceutical Manufacturers Association:

. . . we must recognize that [FDA's] administrative assignment . . . is made more difficult because of the existence of two very different and distinct drug industries in the United States. One is composed of research-oriented, quality conscious, full-service firms . . . The other group is made up of marginal operators. . . .

. . . there are an estimated 1,200 manufacturers of prescription drugs in this country . . . One hundred and twenty-five of them are members of the PMA and they produce 95% of the drugs on the market. This means that over 1,000 establishments are producing 5% of the drugs. Where and how they do it—under what conditions—and with what scientific safeguards, if any—is a mystery to the public and, I suspect, to the FDA. It's also a mystery to the reputable manufacturers.

It is patently beyond the capabilities of a Government agency to supervise, oversee and control every activity and every step taken by a far-flung scientific industry . . . There are just not enough scientists, inspectors and other experienced, skilled personnel available to [FDA] to cope with any such undertaking.

. . . It is a matter of public record . . . that approximately half the firms that want to sell drugs to the Department of Defense, and half the drug samples submitted to procurement officials for analysis, fail to meet DOD standards . . . there are drug firms which have failed inspections of the Defense Supply Agency a dozen or more times in less than two years. Yet these same firms, many of which have never been inspected by the FDA, are quite free to sell their drugs on the civilian market, and they apparently do.

. . . the firms which produce 5% of the nation's drug supply are responsible for 80% of the recalls, and have been over a period of years.

This analysis in some respects is pessimistic in the extreme, but one must not overlook the fact that the speaker questions the quality of only 5% of the nation's drug supply. One can, of course, quibble with the numbers. The 125 companies that make 95% of the nation's drugs are not free of error: the 1,200 companies who make the remaining 5% include some of worldwide repute, justly earned. We believe, in fact, that to question the quality of even 5% of the nation's drug supply is to err on the pessimistic side. Nevertheless, the fact that the quality of the nation's drugs is 95% assured must be considered high tribute to the effectiveness of the system responsible for that drug supply. The goal, surely, must be 100%. In the nature of things such a goal will remain forever out of reach, but if 80% of the drug recalls involve only 5% of the drug supply, whatever problems exist must lie well within manageable limits.

Problems do exist, and the FDA increasingly has been coming to grips with them. One example is the agency's intensified drug inspection program. In January 1971, an FDA spokesman said that since mid-1968 the agency had undertaken intensified inspections of 287 drug manufacturers and associated commercial testing laboratories. Of these cases, 96 were still in progress. Of the 191 that had been terminated, 147 companies had complied voluntarily with the regulations on Good Manufacturing Practices. Twenty-three companies were the subjects of legal action, and 21 were abandoning the drug business because they could not comply with the stringent regulations.

As we see the concept of therapeutic equivalence, then, the weight of the scientific evidence and of expert opinion support three broad conclusions:

- Comparable drug products that meet the official standards and specifications are, for practical purposes, therapeutically equivalent in all but a relatively few cases.
- Some instances of therapeutic nonequivalence go undetected or unreported, but the generally low level of reported instances demonstrates that the problem cannot be widespread.
- Substandard drug products do enter the channels of distribution, but they amount to well under 5% of the nation's prescription drug supply, and most of them are quickly detected and rapidly recalled.

It is evident in these conclusions that practitioners of medicine and pharmacy do have at their disposal some small number of drug products that may not perform therapeutically in the manner that the prescribing physician intends. This will always be true to some extent, however limited. For protection against such products the patient must rely in the final analysis on the professional skill and judgment of the physician and pharmacist.

PROFESSIONAL ISSUES

The American Pharmaceutical Association's decision to seek modifications in the antisubstitution laws is based on our knowledge of the professional competence of the pharmacist. The fundamental issue is whether the pharmacist is qualified to assess the available scientific information on drug products and thus to distinguish among them in terms of their quality and their degree of therapeutic equivalence. The modifications that we seek in the laws would affect, professionally, not only the pharmacist, but those with whom he practices—physicians, dentists and others licensed to prescribe. The modifications also would affect the patient. It is thus to the point to outline briefly the training and functions of the modern licensed pharmacist.

The pharmacist's education today includes a minimum of five years of post-high school training leading to a Bachelor of Science degree. (It may also include one to three years of further study, in a school of pharmacy, leading to a Doctor of Pharmacy degree.) The five-year curriculum is designed to provide a broad yet thorough knowledge of the actions and uses of drug substances, as well as of the preparation, purity, quality, and suitability of the dosage forms

in which drug substances are supplied by manufacturers for convenient use by the patient. To achieve these goals, the curriculum includes courses in chemistry, biochemistry, and biopharmaceutics. To an increasing degree it includes study of pharmacology and orientation of the student toward the effects of drugs on patients as opposed to concentration on drug products as ends in themselves. Often the pharmacist's training includes emphasis on internships and residency programs in clinical environments.

The pharmacist's training familiarizes him with the techniques and difficulties of manufacturing prescription drugs. He learns to retrieve and comprehend chemical, analytical, and clinical data and to understand drug-patient reactions. To obtain a state license to practice, the pharmacist must demonstrate his competence in these and other aspects of his profession by passing stringent examinations.

The practicing pharmacist performs a number of functions. He may inform the patient of the storage requirements of the drug products dispensed and of any side-effects that they may induce. Increasingly, pharmacists are maintaining medication profiles of their patients. These profiles, whose importance is growing, constitute a current and continuing record of all medications that the patient is taking. They become particularly valuable when a patient is taking several medications, dispensed by the same pharmacist but prescribed by different physicians. If the patient informs his physician inaccurately or incompletely about the medications he is taking, the pharmacist is in a position to consult with the physician should questionable combinations of drug products be prescribed.

The pharmacist also is qualified to select the source of supply of drug products, a function largely denied him by the antisubstitution laws if he is in community practice. Where excessive recalls or other evidence cast doubt on the quality of a given company's drug products, the pharmacist will know that they are questionable and will not stock them. He knows that biological availability can vary widely with certain drugs, such as dicoumarol and diphenylhydantoin. He knows that in such cases the physician who prescribes such a drug should be consulted before a different source of supply is selected.

Prescriber Consent

In contrast to the community pharmacist, the pharmacist who practices in a hospital has the opportunity to use such knowledge effectively. As the hospital formulary system usually operates, physicians on the pharmacy and therapeutics committee largely determine the drug entities to be used. Pharmacists on the committee largely determine the sources of supply of the products embodying those drug entities. The pharmacist assumes this responsibility with the consent of the physician which, under the antisubstitution laws, allows him to practice brand substitution. In the hospital, this consent usually is written into the staff rules. In agreeing to abide by the rules, the medical staff endorses the practice on a continuing basis. Prescribers may withdraw their consent, on an order-by-order basis, but they exercise this option only rarely in practice. This procedure is also available to the community pharmacist, but only in principle. Unless it is implemented as it is in the hospital —and as a rule it is not—the community pharmacist must apply it on a prescription-by-prescription basis. Plainly it would be generally inefficient for him, and for the physician, to attempt to apply it to more than a fraction of the prescriptions that he dispenses.

Those who support the antisubstitution laws maintain in any case that the pharmacist is not qualified to select the source of supply of drug products. This argument on occasion takes curious forms. We quote from the *Journal of the Congress of County Medical Societies*, March, 1969:

> *One could legitimately expect the pharmacist, like the physician, to become aware of the therapeutic equivalency fallacy—either through close contact with physicians or from his modern professional education in chemistry, biochemistry, pharmacology, compounding, and formulation. . . . The pharmacist, in his day-to-day dispensing, sees the unsatisfactory results of one agent, compared to a similar agent, in the experience of his customers. The pharmacist's training and experience in compounding also equip him to recognize the potential influence of the physical state of chemical particles in drug products, and of dispersion related to different dispersing agents.*

One could indeed "legitimately expect the pharmacist . . . to become aware of the therapeutic equivalency fallacy. . ." He has not become aware of it because it is virtually nonexistent. He is well aware of the fact, which we have stressed repeatedly, that for a limited group of drug entities the comparable drug products may not be therapeutically equivalent. He is well aware of that fact because of his training and experience, so ably described in the *Journal of the Congress of County Medical Societies*. That training and experience qualify the pharmacist in every way to select, in consultation with the physician where indicated, the source of supply of drug products prescribed.

The antisubstitution laws largely prevent the community pharmacist from using this knowledge. In so doing they effectively hamstring a considerable body of trained manpower. To use trained minds inefficiently is rarely wise, and it is manifestly unwise in this case at a time when greater efficiency and lower costs are needed so badly in the delivery of health care services.

We think it not unreasonable to postulate that the antisubstitution laws affect the pharmacist in another, more subtle way. That is, that by doing part of his thinking for him, they tend to blunt those talents that the laws do allow him to use, thus compounding the inefficiency. Some will speculate that the pharmacist, unshackled by modification of the antisubstitution laws, may indulge in practices that range from innocently unsound to knowingly unsavory. He may dispense inferior products; he may dispense substitutes in defiance of the physician's therapeutic judgment; in one way or another he may breach the ethics of his profession. Some such speculation results from legitimate uneasiness, but we are satisfied that all such fears on the whole are groundless.

The modern pharmacist is professionally trained, he is licensed by examination, he is bound by a code of ethics. He is no more likely to dispense prescriptions incompetently than is the physician to prescribe incompetently. Under the modifications we seek in the antisubstitution laws, the physician who wishes unequivocally to specify the source of a drug product need only designate the manufacturer by name. Doing so would represent a clear therapeutic judgment that no competent pharmacist would ignore. Unethical practitioners, no doubt, can be found in pharmacy as in any other profession. Their incidence, however, is not a function of the presence or absence of antisubstitution laws.

Our views on these points are supported fully by the evidence at hand. Pharmacists for years have been selecting the source of a number of widely used drug products that commonly are prescribed by established name: phenobarbital, codeine, paregoric, penicillin G, and others. The record will show that experience in these cases has been uniformly good. We see no reason to believe that the situation would differ with drug products commonly prescribed by trade name.

Dissemination of Information

In one professional area, however, we do expect change to result from modification of the antisubstitution laws. That area is the dissemination of scientific information on drug entities and products. Through the published scientific literature, both physician and pharmacist today have access to a variety of such information. Through drug manufacturers' detail men, on the other hand, physicians have access to certain additional information, particularly clinical information, that is not generally available to pharmacists.

The detail man traditionally has provided a useful two-way channel for information between physician and manufacturer. His primary task nonetheless is to induce the physician to prescribe his company's products, and whatever unpublished information he transmits is intended fundamentally to achieve that end. Thus, were the selection of source of supply to devolve upon the pharmacist to any significant degree, the detail man would assume a dual function: to persuade the physician to prescribe his company's products and to persuade the pharmacist, where appropriate, to dispense them. To some extent, of course, this situation exists today, but it could intensify markedly were the antisubstitution laws to change.

Ideally, APhA believes, all significant information on drug entities and products should be made available in an authorized published source. The importance of the detail man as a source of information for both physician and pharmacist would thereby be greatly diminished, although a certain amount of personal contact will always be required. In such a situation and without the antisubstitution laws, the physician could concern himself largely with the therapeutic effects of drug entities; the pharmacist could concern himself largely with the quality and cost of the drug products embodying those entities. Calls by detail men, particularly on the physician, could be reduced sharply. Both physician and pharmacist could practice their professions more effectively, with consequent benefits to the public health.

We regret that such a development seems unlikely to materialize soon. Until it does, modification of the antisubstitution laws would compel drug manufacturers to shift their marketing emphasis in some noticeable degree from physician to pharmacist. This could cause a certain interim upset, but we see no cause to expect damaging disruption of the drug marketing and distribution system in this country.

ECONOMIC ISSUES

The changes that APhA advocates in the antisubstitution laws have important economic ramifications. They would achieve many of the goals of generic prescribing, although perhaps on a somewhat lesser scale, and thus would produce a more efficient dispensing system with a consequent reduction in the cost of drug products to the patient. That much is certain. Less certain are the economic effects that the changes might produce—or induce—in the drug industry, particularly in research, development, and marketing.

APhA is advocating in effect that pharmacists be given the option of practicing brand substitution among multisource drug products prescribed by trade name alone. About 80% of the most widely used drugs are single-source products, largely because they are covered by patents, and thus would not be subject to the practice today. Already something like 10 to 15% of all prescription orders are written generically and thus would be unaffected by brand substitution. These numbers, to be sure, are neither precise nor precisely comparable. They do suggest, however, that the form of brand substitution that APhA supports, if it were implemented at once, could affect the sales of perhaps 10% of the prescription drug products now on the market.

This picture will change significantly in the next few years, when the patents will expire on a number of today's single-source drug products. It is virtually certain that these products will become available from more than one source. Physicians today prescribe these single-source drug products very largely by trade name alone, and we see no evidence to indicate that they will change this habit markedly when competing products become available under new trade names and under their established names. Most such products, therefore, would become subject to brand substitution under the APhA proposals. One must assume as a result that the proposals would affect the sales of a minimum of perhaps 10% of the drug products now on the market and that the percentage would rise substantially in the next few years.

The sales of such drugs would be affected mainly on the basis of their cost to the pharmacist. Confronted by comparable drug products, each of acceptable quality, the pharmacist tends to stock the least costly. He does so for two reasons: to avoid unnecessary investment in drug product inventory; and to meet more effectively the economic needs of the patient who is seeking reasonably priced quality medication, whether on his own initiative or with the encouragement of his physician.

The community pharmacist today can apply these economic principles only to products that tend to be prescribed generically. For single-source products he has no option. For multisource drug products that tend to be prescribed by brand name he has two options: stock all of the popular brands; or be prepared to send many prospective patients elsewhere. The pharmacist, naturally, learns to maintain his inventory at the economic optimum. But given the option of brand substitution, the overwhelming majority of community pharmacists could sharply reduce their investment in inventory and thus their cost of providing pharmaceutical services.

The cost of drugs to the patient, consequently, would reflect both the pharmacist's lower wholesale costs and his lower operating costs. The pattern would not be entirely straightforward. Pharmacists' costs will differ; the fees they charge for their services will differ; some pharmacists would pass more of their savings to the patient than would others. Brand substitution, on the other hand, would broaden markedly the patient's opportunity to save money on prescription medication, and both patient and physician would become aware of the fact. This situation, on the whole, could not fail to produce lower prices to the patient.

TABLE I

Relative Cost for 100 Tablets of Commonly Prescribed Drugs*

	Manufacturer	Amount	Price†
Ampicillin			
Omnipen	Wyeth	250 mg	$22 51
Penbritin	Ayerst	250 mg	21.82
Polycillin	Bristol	250 mg	21.84
Principen	Squibb	250 mg	19.14
Diphenhydramine			
. .	McKesson	50 mg	1 75
Benadryl	Parke-Davis	50 mg	2.22
Erythromycin			
Erythrocin	Abbott	250 mg	21 99
Ilosone	Lilly	250 mg	21 99
Ilotycin	Lilly	250 mg	21 99
Penicillin G			
. .	Lilly	250,000 units	6.72
. . .	Parke-Davis	250,000 units	5 01
. . .	Pfizer	250,000 units	2 30
Pentids	Squibb	250,000 units	5.25
. . .	Wyeth	250,000 units	1.59
Phenobarbital			
. .	Lilly	0 1 gm	0 66
Luminal	Winthrop	0.1 gm	0.61
. . .	Wyeth Redipak	0.1 gm	0 92
Phenoxymethyl penicillin			
Compocillin VK	Abbott	250 mg	8.95
Pen-Vee	Wyeth	250 mg	9.35
V-Cillin K	Lilly	250 mg	8.95
Pentobarbital			
Nembutal	Abbott	0.1 gm	2.16
. . .	Lilly	0.1 gm	2.25
. . .	Wyeth Redipak	0.1 gm	2.26
Prednisone			
Deltasone	Upjohn	5.0 mg	2.25
Deltra	Merck Sharp & Dohme	5 0 mg	2.20
Meticorten	Schering	5.0 mg	10 80
. . .	McKesson	5.0 mg	1.75
Reserpine			
. . .	Wyeth Redipak	0.25 mg	1 48
Sandril	Lilly	0 25 mg	1.05
Serfin	Parke-Davis	0.25 mg	1.20
Serpasil	Ciba	0 25 mg	4.50
Sulfisoxazole			
. . .	McKesson	0.5 gm	2.25
Gantrisin‡	Roche	0.5 gm	2.94
Secobarbital			
. . .	Wyeth Redipak	0.1 gm	2.15
Seconal	Lilly	0 1 gm	2 16
Tetracycline			
Achromycin	Lederle	250 mg	11.22
Panmycin	Upjohn	250 mg	7.89
Steclin	Squibb	250 mg	4.25
Tetracyn	Pfizer	250 mg	4.25
Tetrex	Bristol	250 mg	14.95

* Data from *Red Book*.
† Price to the pharmacist.
‡ Price from wholesaler on request. The 1968 listing is indicated in this table.
Source: Friend, Dale G., *et al*, "Generic Terminology and Cost of Drugs," *Journal of the American Medical Association*, **209**, 83 (1969)

Basic Price Patterns

The soundness of these views is hardly open to question. We do not intend here to examine drug prices exhaustively, but a few examples will be to the point. Table I gives the 1968 price to the pharmacist of 12 groups of comparable, commonly prescribed drug products. The differentials are clear. Prices have come down since 1968, and they may vary from time to time as a result of "deals" offered by manufacturers and wholesalers, but the prices shown establish the continuing basic pattern. At one extreme in the 12 examples, each of three brands of erythromycin costs the pharmacist precisely the same amount. At the other extreme, the most expensive brand of prednisone costs him more than six times as much as the least expensive prednisone product, which is sold under its established name. Within this range fall the price differentials in the remaining 10 groups of products.

In addition to his basic cost for a drug product, the pharmacist must charge the patient for his services. To the basic cost he will add either a markup, calculated as a percentage of the cost of the drug product, or a professional fee which is the same for all prescription orders. APhA favors the professional fee on the grounds that the service rendered tends to be independent of the basic cost of the drug product dispensed. The professional fee method, moreover, lowers the cost to the patient for the more costly drug products. Roughly half of the practicing community pharmacists use the professional fee today for the general public and we expect them increasingly to adopt it in favor of the percentage markup. Most government and other third-party drug programs also use the professional fee. At any rate, even cursory examination of Table I will show that the pharmacist often could save the patient money were he allowed to substitute, for a drug product prescribed by trade name only, a comparable but less costly product.

Task Force Study

In a broader sense, the economic impact of modifying the antisubstitution laws is an important question of public policy. This would be true in any case, but it is especially so in view of the enormous and rising costs of welfare medicine. The most thorough study to date in this context was made by the HEW Task Force on Prescription Drugs.

The basis of the Task Force study was a Master Drug List, the 409 most frequently prescribed drugs dispensed to the elderly in 1966. These drugs accounted for 174.7 million prescription orders, 88% of the total prescription orders dispensed by community pharmacists for the elderly in that year. Using the Master Drug List, the Task Force analyzed the economic impact that would have resulted from generic prescribing. The overall conclusion:

> *The Task Force finds . . . that the use of low-cost chemical equivalents can yield important savings, especially in the case of patients with cardiovascular disease, kidney disease, arthritis, and mental and nervous conditions, and the use of such products should be encouraged wherever this is consistent with high-quality health care.*

The 409 products on the Master Drug List included 63 that were available from multiple suppliers at costs distinctly lower than those of the brand name products actually dispensed. For these 63 products, the use of low-cost chemical equivalents could have reduced the total acquisition cost to the pharmacist from nearly $74.9 million to $33.4 million, a potential saving of $41.5 million or 55.3% at the wholesale level.

The Task Force also analyzed the saving to the patient:

- If the pharmacist set his charge so as to achieve the same gross profit as before ($1.81 per prescription dispensed)—neither gaining nor losing by dispensing a low-cost chemical equivalent—he would reduce the total patient cost of the 63 drug products involved from $150.0 million to $108.5 million. The patient would save the full $41.5 million or 27.7%.
- If the pharmacist set his charge by adding $1.50 per prescription dispensed, the patient would save $54.4 million or 36.3%.

- If the pharmacist set his charge by adding $2.00 per prescription dispensed, the patient would save $33.8 million or 22.5%.

The savings that might thus have been achieved by the use of low-cost chemical equivalents would be less significant when spread over the entire drug program studied by the Task Force. For all of the 409 products on the Master Drug List, the prescriptions dispensed cost the patient a total of $682.3 million. Overall, then, the saving of $41.5 million at wholesale would have produced these effects at the consumer level for the full program:

- A saving of 8.0% with $1.50 added by the pharmacist.
- A saving of 6.1% with $1.81 added by the pharmacist (this was the actual average amount added).
- A saving of 5.0% with $2.00 added by the pharmacist.

The Task Force emphasized that these calculations were based solely on the 1966 costs of the drug products involved. The analysis did not consider possible differences in the quality of the products studied, administrative or other costs of a drug program that required generic prescribing, nor the use of formularies or other guidelines.

Savings of 5% to 8% on the cost of the total drug program may not seem large. Nevertheless, the Task Force pointed out, an absolute saving on the order of $41.5 million "can scarcely be considered insignificant. Moreover, such savings would involve many products used in long-term maintenance therapy, and thus would provide particular help to patients with chronic illness whose drug needs are often the most burdensome."

We would point out also that the Task Force study assumed compulsory generic prescribing. The APhA policy would have parallel, if slightly diminished, effects, but without requiring generic prescribing. Manufacturers could logically be expected to attempt to circumvent brand substitution by urging physicians to specify their products by company name, but a counterweight would exist in the enhanced consumer awareness of the opportunity to save money on prescription medication. The net economic impact of such factors is not entirely clear, but it is difficult to see how the APhA policy under any circumstances could produce other than a general decline in the cost of drugs to the patient

Impact on Drug Industry

The impact of this decline on the drug industry itself is problematical to a degree. We must assume that it would be significant, if only because the industry opposes the APhA policy so vigorously. We are not privy to corporate financial data, but some guidelines can be established. Manufacturers' pharmacy prescription medication sales reached an estimated $2.23 billion in 1969, and we will assume that APhA's policy would reduce the dollar volume of such sales by 10%. The absolute decline in volume, therefore, would have been $223 million in 1969. This is not a trifling sum. Some companies, no doubt, would be hurt more than others, depending on their product lines and patent situations, but the effect would intensify for both as more drug products emerged from patent shelter.

One question that must be asked is whether such a decline would cripple the vital research and development effort of the U.S. drug industry. We contend that it would not. Drug research and development is costly work and has been growing steadily more so under the pressures of inflation, regulation, and legislation. The companies that do it well, however, have been able in the past to profit well enough from their investment during the life of patented single-source products. We believe that this would continue to be the case.

The APhA policy unquestionably would strike hard at the existing drug marketing system, which relies heavily on inducing the physician to prescribe by trade name. One result of this practice is that when a drug product with an established trade name enters the public domain, many physicians continue to prescribe it by trade name. As a result, when comparable competing products enter the market, the originator of the drug extracts a substantial carryover benefit from the marketing work that established the trade name originally. Under the APhA policy he would lose this advantage as soon as competing products became available.

For this and related reasons, we think it reasonable to expect that the APhA policy would induce the drug industry to revise its marketing strategy. For single-source drug products, excepting those that the originator might license to other producers, trade names would seem to have no particular advantage. They may be simpler, even catchier, than established names, but we believe that physicians would manage adequately in their absence. Under the APhA policy, in any event, the promotion of trade names by detail men and in advertising would appear not to warrant the effort expended today. Companies would still wish to maintain personal, two-way communication with the physician, particularly for new, single-source drug products. Such communication might well be managed in part, however, by means of technically thorough written material, with a consequent reduction in the number of calls that detail men must make on physicians. The detail man, on the other hand, might wish to call considerably more often on pharmacists, who would become a more critical buying influence for multisource drug products. This might improve marketing efficiency, since one call on a pharmacist would represent, in effect, a number of calls on individual physicians.

For the same general reason, some undetermined volume of drug product advertising might shift from journals read mainly by physicians to those read mainly by pharmacists. Shifts of this kind might be dismissed as an accepted vagary of publishing, except that the advertising in question helps to support journals whose function is to keep practitioners of the medical arts abreast of progress in their professions. Journals of this kind certainly would not be allowed to founder as a result of declines in advertising revenue, but some might have to seek new sources of financial support. Journals read by pharmacists no doubt would profit by the shifts in advertising that we visualize, and the fact that APhA publishes some such journals puts the Association in an invidious position. On this score we can say only that our policy on the antisubstitution laws is not rooted in a desire to increase APhA's advertising revenue. The Association's operating budget is virtually independent of advertising income, which currently accounts for roughly 6% of total income.

We should emphasize at this point that APhA is not qualified to speak for the drug industry and does not pretend to be doing so. We do feel qualified to assess within broad limits, as we have done, the economic impact that the industry might face as a result of the amendments we seek in the antisubstitution laws. Our assessment leads us to conclude that that impact would not fundamentally damage the industry's ability to discover, develop, and market new drug entities and products. The impact seems likely to fall most heavily on drug marketing practices. Even there, however, we see no danger of a level of disruption that would materially affect the prerogatives of the physician or the care of the patient.

LEGAL ISSUES

The modifications that APhA seeks in the antisubstitution laws involve certain legal issues that bear directly on the practice of pharmacy. They include negligence, breach of contract or warranty, trademark protection and unfair competition, and misbranding. Legal authorities may take differing positions on some of these issues. APhA believes nevertheless that implementation of its proposals would present no insuperable legal problems.

The pharmacist's most pervasive legal concern is his potential liability arising from claims by patients. There can be little question that the pharmacist who assumes greater responsibility assumes potential liability in like measure. This is true of any professional. The pharmacist's best protection against liability for negligence is to exercise due care. For this reason, amendment of the antisubstitution laws should heighten, rather than diminish, his desire to discharge his duties on a high professional level. The record leaves small doubt that he is legally obligated to do so.

In some states, cases have been decided which hold that a pharmacist who follows a prescription order literally is not liable to the patient for injury caused by the drug product dispensed. These cases hold the prescribing physician alone responsible. In other states, meanwhile, cases have been decided which hold with equal force that the pharmacist cannot insulate himself from liability by pleading that he followed the physician's instructions literally. Such cases hold that the pharmacist's independent professional responsibility obligates him to question the physician's prescription order and not to dispense if he believes it to be medically unsound. Some cases hold that the pharmacist is obligated even to question the patient on such points as the use of the medication prescribed, potential allergic reactions, and the like.

The net effect of the existing legal decisions, in other words, is that in some states the pharmacist can protect himself merely by counting and pouring, but that in other states he cannot. From the legal point of view, APhA believes that the trend of more recent cases casts serious doubt on the validity and future of the "count and pour" defense. From the professional point of view, the Association believes that the pharmacist should function not as a robot, but as a thinking professional, discharging his duties to patient and prescriber.

The pharmacist may be potentially liable for errors or misjudgments whenever he dispenses prescription medication, but he can become liable in fact only if the patient is harmed as a result. If the pharmacist dispenses a brand of a given drug entity different from the brand prescribed, and if the patient recovers from the ailment being treated, no liability exists. If, on the other hand, the patient can prove that he was harmed by the drug product dispensed, the pharmacist may well be held liable. He would be liable not because he substituted one brand for another, but because he dispensed a drug product that harmed the patient. Suppose that, in the same case, the patient was harmed because the pharmacist dispensed a drug product that was adulterated. The presumption is that it would have been only a question of time before he dispensed the product on a prescription order that called for it by brand name. The patient was harmed, therefore, not because the pharmacist changed brands, but because he stocked and dispensed an adulterated drug product.

The potential liability of the pharmacist who selects the source of a drug product to be dispensed can be evaluated also in the broader context of medical malpractice. Medical malpractice claims against physicians have increased enormously in recent years. Many are settled by insurance companies for amounts that range from a few dollars to thousands of dollars. Of the claims that go to trial, the physician prevails on an average of two to one over the patient. The ratio is much higher in some areas. In California, for example, physicians win nine of every ten cases.

Drug therapy is the basis of relatively few medical malpractice claims, and those few tend to involve misprescribing rather than failure of the drug to achieve the desired therapeutic result. Drug therapy claims, in other words, generally allege that the wrong drug was prescribed or that the right drug was used improperly. Rarely does a plaintiff claim that the quality of the drug was unsatisfactory; even more rarely does he prove it.

Lawsuits involving pharmacists generally are based on dispensing errors. The pharmacist may have dispensed the wrong drug, labeled the prescription container incorrectly, changed ingredients when compounding, or failed to warn the patient of side-effects or to instruct him in the proper use of the drug. We find no reported case in which a pharmacist has been held liable to a patient for dispensing one brand of a drug when another had been prescribed. We find, in fact, no case based on such a claim either before or after the antisubstitution laws were enacted.

Despite the very small number of lawsuits that allege that the pharmacist was negligent in dispensing medication, the potential for liability should not be minimized. This is particularly true in the light of the prevalent judicial view that the pharmacist is more than a mere "seller of drugs." APhA believes that no practicing pharmacist should be without liability insurance. The Association sponsors a professional liability insurance program for pharmacists who are not insured under standard liability policies.

APhA concludes that, on balance, modification of the antisubstitution laws would not significantly increase the pharmacist's potential liability to patients. The greatest potential for liability would likely lie in dispensing inferior drug products. Dispensing only quality products, therefore, is the pharmacist's surest means of protecting both the patient and himself.

Pharmacists for years have selected the source of drug products prescribed by established name and under hospital formulary systems. In those states which have never enacted antisubstitution laws, pharmacists have been free to dispense brands of drug entities other than the brands pre-

scribed. Reported lawsuits show no evidence that these activities have either harmed patients or subjected pharmacists to legal action by patients.

Breach of Contract or Warranty

In addition to potential liability for negligence, APhA's policy on the antisubstitution laws raises questions concerning breach of contract or breach of warranty. Specifically, is the pharmacist potentially liable for either when he dispenses a different brand of a drug entity than the brand prescribed?

The first point to consider here is the legal effect of a prescription order. The prescription order creates no contractual rights for the physician; it serves merely to communicate to the pharmacist the physician's instructions and his authorization to dispense. The prescription order does not obligate the pharmacist to dispense the medication, and the physician cannot sue the pharmacist for breach of contract for refusing to dispense.

It seems clear, moreover, that when a physician prescribes a drug by brand name, he creates no contractual rights for the manufacturer. The latter, that is to say, cannot sue a patient who fails to obtain the prescribed drug or who buys a brand of a multisource drug product other than the brand prescribed, nor can he sue the dispensing pharmacist. In neither case does a contract exist.

A contract does exist, however, between the patient who presents a prescription order and the pharmacist who dispenses it. A contract requires three elements: offer; acceptance of the offer; and consideration. When the patient presents the prescription order, he offers to buy the drug product involved. The pharmacist accepts the offer by dispensing or promising to dispense the prescription medication. The third element, the consideration, is the patient's payment or promise of payment for the drug. The pharmacist-patient contract is created whether the pharmacist accepts the prescription order directly from the patient or from a physician acting on the patient's behalf.

The basic question is whether the pharmacist breaches the contract when he dispenses a brand of drug other than the brand prescribed. Let us assume the extreme case, that the patient in fact is aware of the existence of different brands of the drug and wishes explicitly to receive the brand named on the prescription order. If the pharmacist then substitutes another brand without notice to the patient, he is guilty of a technical breach of contract, but a breach not likely to result in harm to the patient. If, on the other hand, he gives the patient the substituted brand properly labeled, we contend that he made a counter-offer to the patient. If the latter accepts the drug thus dispensed, a new contract is created, based on the substituted brand, and the pharmacist has not committed even a technical breach of contract.

The contract between the pharmacist and the patient also involves various warranties created expressly by the contract or implied by law. One of these is the so-called "warranty of fitness for use," which means that the seller warrants that the item sold is appropriate for the use intended. This warranty does not constitute an absolute guarantee that a particular drug or drug product will produce a particular therapeutic effect in a particular patient. The law, that is to say, recognizes that medicine is not an exact science and that factors such as patient idiosyncrasies may cause the same drug or drug product to have different therapeutic effects in different patients. The warranty of fitness for use applies rather to the applicability of the drug therapy to the condition involved. The drug manufacturer and pharmacist, for example, warrant that an anti-infective drug is appropriate in treating infections, but not as an anticoagulant.

A second type of warranty relates to goods purchased by description. This kind of warranty clearly is important where the brand products involved differ significantly. When one offers to buy a Chevrolet, the seller undertakes to deliver a Chevrolet and not a Ford. The practical significance of this type of warranty, however, is questionable where, as with comparable prescription drug products, the products involved do not differ materially. It can be argued, for example, that the use of the brand name of a drug product on a prescription order is meant to describe the drug entity and not the particular brand. Prescription orders that specify Omnipen, Penbritin, or Amcil, for example, all describe ampicillin, a drug entity whose biological availability has been shown not to vary significantly among brands.

We would emphasize that in breaches of contract or warranty the ultimate issue remains damage to the patient. In the absence of provable damage, such breaches constitute "wrong without injury," which cannot legally support an award of damages.

Trademarks, Unfair Competition

Although a prescription order does not create contractual rights for a manufacturer, some authorities hold that it may give him other legally protectible rights. These relate to trademarks and protection from unfair competition.

Under federal law, one who has used a particular name or symbol to identify goods that he produces and markets in interstate commerce may register his "trademark" with the U.S. Patent Office. If a registered trademark is infringed by another party, the registrant may obtain an injunction in a federal court directing that the unlawful use be stopped. The registrant also may be awarded monetary damages. A pharmacist who dispensed a drug product and labeled it with the trademark of another drug product would be guilty of trademark infringement. If he substitutes one drug product for another, but identifies the product dispensed by its own brand name, he commits no trademark infringement. In other words, a trademark claim must be based on use of the trademark on the product of another party. In relation to APhA's policy on the antisubstitution laws, the most serious problem in trademark infringement lies in laws in some states that require the pharmacist to label every prescription dispensed with the name of the drug as prescribed by the physician. No problem would exist were these laws to require labeling with the name of the drug or drug product dispensed. At least one trademark law authority has suggested that, in such a situation, an appropriate disclosure statement on prescription labels could avoid the trademark infringement problem. In any event, APhA does not consider the problem serious, since it could be resolved by simple changes in the language of the pertinent statutes. Such changes could be made in conjunction with legislative modification of the antisubstitution laws.

In addition to trademark protection, a drug manufacturer is entitled to protection from so-called "unfair competition," a right generally recognized by all states. For our purpose here, unfair competition can be regarded as those practices in which the product of one manufacturer is rep-

resented to the purchaser as the product of another. The practices of "pawning off" and "counterfeiting" generally fall within this area and raise ethical as well as legal problems. The pharmacist can protect himself against a claim of unfair competition by fully disclosing the source of the drug product dispensed. Substitution of one brand of drug product for another, we contend, does not in itself constitute an unfair competitive practice.

Food, Drug, and Cosmetic Acts

Some opponents of APhA's policy on the antisubstitution laws argue that brand substitution violates the Federal Food, Drug, and Cosmetic Act. Section 301 of the Act prohibits the "adulteration or misbranding of any food, drug, device or cosmetic in interstate commerce." Under Section 502 of the Act, a drug or device is deemed to be misbranded "if its labeling is false or misleading in any particular" or "if it is an imitation of another drug," or "if it is offered for sale under the name of another drug." In our opinion, if the pharmacist fully discloses the brand or source of the drug product dispensed he will avoid these prohibitions as well as similar prohibitions in state food, drug, and cosmetic acts. Such prohibitions define and refer consistently to "drug" and not "drug product." In this and all other respects, their language makes clear that they are designed to protect the public health and not the proprietary rights of manufacturers.

One writer has suggested that even in the absence of specific antisubstitution laws, substitution of one brand product for another prescribed by brand name would constitute "gross immorality" under either a statute or state board of pharmacy regulation. A board of pharmacy, this writer suggests, should punish such an offense by revoking or suspending the pharmacist's license or in some other way. The argument assumes deception by the pharmacist and therapeutic nonequivalence among drug products. We have dealt herein with both assumptions. APhA believes, moreover, that antisubstitution laws that prohibit brand substitution of comparable drug products are economic in nature and not reasonably related to considerations of public health. It follows that sanctions imposed by boards of pharmacy on such grounds can be challenged successfully in court. In fact, a circuit court decision in Michigan (Casden *vs.* Michigan Board of Pharmacy, 1959) held that no "substitution" was involved where a pharmacist dispensed a brand of a particular drug entity different from the brand prescribed.

We stated earlier that opinions may differ on some of the legal issues involved in modification of the antisubstitution laws. We would emphasize, therefore, that implementation of APhA's policy on these laws would not compel any pharmacist to act contrary to his own interest as he sees it. Implementation of the policy would act merely to remove existing legal impediments that many pharmacists believe restrict their ability to exercise their professional rights and responsibilities. Such implementation would compel no pharmacist to modify his habit of practice in any way if he did not choose to do so; it would compel no pharmacist to substitute brands if he preferred to dispense the brand specified on the prescription order.

ROLES OF PROFESSIONAL ASSOCIATIONS OF HEALTH PRACTITIONERS

The American Pharmaceutical Association's goal in seeking modification of the antisubstitution laws is basically to broaden the pharmacist's authority to select the sources of the drug products that he dispenses. We are convinced that this broadened authority will bring with it not only higher professional status for the pharmacist, both in name and in fact, but will bring important benefits to the public health as well. We have explained herein the reasoning that underlies this conviction. We wish now to examine the role that APhA intends to play in implementing its policy, and the role that might be played by state and local pharmaceutical associations.

While it is not our place to define the role that associations of other health professionals might play in these matters, APhA's policy on the antisubstitution laws does raise important interprofessional questions. We explore these questions regularly with associations of physicians and other prescribing professionals. We believe, furthermore, that pharmaceutical associations at all levels would welcome similar discussion and, where appropriate, cooperative action with their analogous professional associations.

In any event, we do not expect immediate amendment or repeal of all antisubstitution laws or regulations. Because organized opposition to our policy has developed, state legislatures will be facing a controversial issue. The resolution of controversy requires a persuasive educational effort. APhA will provide staff and technical support to assist state pharmaceutical associations interested in mounting such an effort. Successful efforts in a few jurisdictions, we believe, will prompt others in positions of influence to proceed vigorously along the same lines.

APhA in addition will act on its own at the federal level. The federal government is seeking ways to maximize the value it receives from tax dollars spent for pharmaceutical services under the health care programs that it finances. Some states already have instituted cost-reduction measures for pharmaceutical services in their publicly supported health programs. We expect the federal government to enact similar controls as the dollar amount of federal funds being spent on drugs and pharmaceutical services continues to rise. When feasible measures are proposed, APhA can be expected to support them. Federal controls that broaden the pharmacist's opportunity to exercise his professional abilities and responsibilities can be expected to preempt the state antisubstitution laws.

Dialog with Medical Profession

APhA intends to continue its dialog with the American Medical Association on antisubstitution laws and other professional matters. AMA voted officially to oppose our policy on the antisubstitution laws in less than 10 weeks from the time we adopted the policy. The discussion that preceded this action focused on guarding the physician's prerogatives. It failed to consider the professional benefits that implementation of our policy would yield for the practicing physician. In its discussions with AMA, the Association will emphasize those benefits as well as the important public benefits that can be achieved by allowing the pharmacist to assume the responsibility for selecting the

source of drug products prescribed. We believe, with President Nixon, that sweeping changes are essential to improve the delivery of health care services in this country. We believe that these must include mutually beneficial changes in the relationship between physician and pharmacist that will improve service to patients. We intend also to stress the pharmacist's ability to assume certain other responsibilities that will assist physicians.

In addition to APhA's discussions with AMA, the Association is engaged in interprofessional dialog with the medical profession on a number of other fronts. One of these is the American Public Health Association, which lately has adopted a new and more active stance and intends to pay close attention to the current crisis in health care. Physicians in other influential organizations, both private and governmental, are thinking along the same lines. APhA has been taking every opportunity to acquaint physicians and others involved in health care planning with the pharmacist's potential in helping to relieve today's pressing problems in health manpower.

Public Understanding

Public understanding is a vital element in the actions that must be taken to improve the efficiency and control the costs of health care services. APhA is working to improve public understanding of the pharmacist's function and potential, and a role exists here for state and local pharmaceutical associations as well.

Consumer advocates have recommended various measures intended to reduce the cost of prescription medication, including generic prescribing. The public tends to equate "generic" with "low cost," and "brand name" with "high cost." The pharmacist knows that this relationship is not necessarily correct. In fact, given the opportunity to select the source of the drug product dispensed, the pharmacist often can dispense quality brand name or generic drug products at lower cost than for the brand name product originally prescribed. The public would benefit from wider understanding of the fact that the pharmacist is uniquely qualified to act as the patient's purchasing agent. The patient, indeed, should expect the pharmacist to act in this capacity and not as the manufacturer's selling agent.

State and Local Action

APhA believes that state pharmaceutical associations are obligated to provide their members with all available information on the Association's policy on the antisubstitution laws. The policy evokes emotional, strongly held opinions, and the pharmacist should consider its merits only in the light of careful study of the facts. Pharmacists, moreover, must prepare themselves to advise state legislative and regulatory bodies who elect to repeal, amend, or neutralize the antisubstitution laws. Expert advice is essential to the translation of legislative intent into workable and effective language.

Local pharmaceutical associations also can strengthen the effort to implement the APhA policy. One example of what can be done is the joint work of the Charlottesville-Albemarle (Va.) Pharmaceutical Association and the Albemarle County (Va.) Medical Society. In addition to their program for prescribing and dispensing drug products by nonproprietary name, the two groups worked out agreed-upon policies on matters such as labeling of prescription medication, renewal instructions, the use of preprinted prescription blanks, and multiple prescription orders on a single prescription blank. The joint program illustrated persuasively how local pharmacy and medical groups can work together to develop realistic interprofessional relations.

Pharmacists can work individually to seek from individual prescribers written authorization for brand substitution. These authorizations allow the pharmacist to select the source of a multisource drug product to be dispensed when the prescription order is written by brand name. APhA staff is developing model agreements of this kind. Such a procedure can greatly strengthen physician-pharmacist relations and can help to make the pharmacist an even more effective link in the health care system.

CONCLUSION

The American Pharmaceutical Association's policy on the antisubstitution laws patently raises a variety of issues that involve at one extreme pure fact and, at the other, pure emotion. All of these many issues, however, are subordinate to a single fundamental question: Will the public health benefit if the antisubstitution laws are amended to allow the pharmacist to select the source of multisource drug products prescribed by product trade name alone?

APhA's stand on this question is unequivocal. We believe not only that the pharmacist should assume this responsibility; we believe as well that he is clearly the professional best qualified to do so. We believe further that amendment of the laws in the manner that we support would initiate a new and progressive era in drug therapy:

- The overall cost of prescription drugs to the patient would decline.
- The efficiency of utilization of health manpower would improve.
- The relationship among physician, pharmacist, and patient would be strengthened without affecting the physician's basic prerogatives *vis-a-vis* the patient.
- The methods used to market drug products would change and very likely would become more efficient.

These and related developments, on balance, would redound without question to the benefit of the public health. They can be set on foot, moreover, by amending laws and regulations that no longer bear any realistic relation to the public health. The motivation that created and is attempting to sustain the antisubstitution laws is primarily economic. Whatever therapeutic basis the laws possessed initially—and they did help to suppress drug counterfeiting—has passed away.

The American Pharmaceutical Association contends that the antisubstitution laws in their present form are not a benefit to the public health, but are in fact a detriment. We contend that they should be amended along the lines laid down in the Association's official policy on the matter. We intend to continue to press vigorously to secure such amendment.

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Special Report

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APhA Newsletter

FDA Commissioner Assesses Nation's Drug Supply

Testifying before the United States Senate Subcommittee on Monopoly under the Chairmanship of Sen. Gaylord Nelson, FDA Commissioner Charles C. Edwards, M.D., presented a comprehensive picture of the FDA's assessment of the current status of the quality, effectiveness, and safety of pharmaceutical products in this country.

Due to the timeliness and importance to pharmacy of the Commissioner's views, this issue of the Newsletter is reprinting pertinent excerpts of Dr. Edwards' prepared statement, as well as question and answer dialogue which served to further elaborate on aspects of his text.

In the opening remarks of his Jan. 18, 1971, testimony, the Commissioner stated:

"I think no one would question that the discovery and development of new drugs and new antibiotics over the past three decades have contributed enormously to the eradication and control of disease and to the relief of patient suffering.

"However, over this same period of time, drug misuse has become a major national problem. I speak not just of drug abuse in the conventional sense, but rather of the promotion, the prescribing, and the use of drugs of limited or no value, and, of course, equally important, the consumption of too many drugs, often for no purpose or for the wrong purpose. I think few things are more tragic than the prescribing and administration of a drug of no proven effectiveness followed by a serious and even sometimes fatal adverse reaction.

"We at FDA are concerned first with drug safety, but we must constantly bear in mind that considerations of drug effectiveness and drug safety cannot be separated.

"I would like to briefly discuss where we are today, how we arrived at this point and how we plan to proceed in the days ahead. Our goal is to achieve the objective of excellence in drug quality, honesty in drug promotion, and rationality in drug use at the earliest possible time. We are striving for a uniform and high standard of safety and reliability of all drugs. Of course, this requires us to be concerned with all phases of the drug scene:

- with all manufacturers large and small;
- with the discovery and investigational use and development of all new drugs;
- with the evaluation of safety and efficacy of new products offered to the medical profession;
- with the quality controls that assure the identity, the strength, the quality, the purity, and the reliability of the product that comes off the production line and into the hospital, and the community pharmacy;
- with the labeling and promotion of these products;
- with the experience of these drugs in the hands of the practicing physician; and indirectly, of course,
- with the costs of these products.

"Although we have no specific responsibility relating to drug costs, it is well to recall that Sen. Kefauver's investigation a decade ago focused attention on the causes of the high cost of prescription drugs. They were poor quality research, excesses and exaggeration in promotion and the difficulties encountered by prescribers in obtaining reliable information that would facilitate rational drug therapy. All of these important areas are responsibilities of the Food and Drug Administration."

[*The testimony then focused on a number of specific areas of which the following are of particular interest to pharmacy.*]

Drug Prices

Sen. Nelson. Isn't an additional problem relating to the cost also the problem raised by brand name prescribing? That is to say, State antisubstitution laws. You have a situation in which the doctor prescribes by the brand name, the pharmacist is required by law to give that brand. So, you can have the same compound being sold at a fractional price meeting all appropriate USP or NF standards and yet the brand name prescribing practice holds the price up.

We had, as you know, testimony at some length here on prednisone, which varied in price from 59¢ a hundred to $17.90 a hundred in pharmacies, which is a radical difference; [also testimony] from the *Medical Letter* saying they were all equivalent—all met the same standards.

How do you get around that kind of a problem?

Dr. Edwards. **Well, I think there is probably no simple answer to solving that problem. Certainly, one of the answers is to better communicate to the medical profession the fact that in today's drug scene the brand names and the generic name drugs that are approved by the Food and Drug Administration are for all practical purposes equal drugs in terms of their potency, uniformity, et cetera.**

I think frankly, we have not done enough in communicating this kind of information to the practicing profession.

Therapeutic Equivalence

Sen. Nelson. You do not have any evidence that indicates as a general proposition, then, that brands or generics are better, one is better than the other?

Dr. Edwards. No. I think in today's drugs, I think certainly in the case of the antibiotics that are certified by the Food and Drug Administration, I think we can certainly say there that brand and generics are equal. I think that any drug that goes through the new drug application process, we can say is equal too, be it brand or generic.

I think there are some of the "me-too" drugs, others that we are coming to grips with via the National Academy drug efficacy study; but these present a little different problem, and we cannot make quite that statement in reference to those drugs. But I think certainly on all drugs that have been approved through regular processes we can make this statement. . . .

Both the United States Pharmacopeia and the National Formulary are seeking clinical tests such as excretion and absorption profiles on human beings to evaluate clinical ef-

Sen. Gaylord Nelson
Chairman
Subcommittee on
Monopoly
U.S. Senate

fect. In addition, they are attempting to develop in vitro tests which approximate the in vivo situation.

Sen. Nelson. You mean the USP and NF are seeking these tests on all drugs?

Dr. Edwards. I think eventually that would be their ultimate goal. They are doing this by drug categories at this point in time but they are attempting to increase the scope of what are the various factors that go into developing uniformity for these drugs.

Sen. Nelson. Well, then, will these become additional factors in meeting USP-NF standards?

Dr. Edwards. That is right, yes.

We have made our own efforts to assure that chemical drug equivalents, when administered in the same amounts, will provide essentially the same availability as measured by blood levels, excretion, and absorption profiles, et cetera. We have developed certain in-house biological availability requirements for abbreviated new drug applications but information and techniques thus far in this whole area have been slow in coming and must be considered preliminary.

On the basis of currently available evidence, the quality of marketed drugs in regard to their purity and the uniformity of content of active ingredients is not suspect. This includes all marketed drugs, generic as well as brand name. Even though there have been indications that different brands of a few drugs in chemically equivalent formulations have given significantly different biological responses, we have reason to believe this is not a frequent phenomenon.

Duplicative Drugs

Sen. Nelson. Is there any sound reason for permitting the introduction into the marketplace of a drug if there is another drug in the marketplace that is just as good? No proof that this one is better? Is there really any rational reason for permitting it to be marketed?

Dr. Edwards. I think this is probably the reason that we have some 20,000 drugs on the market today when maybe half or fewer would be enough.

No, I do not think there is any rational justification for it. On the other hand, you know better than I that industry spokesmen would disagree with this position.

Drug Labeling

Dr. Edwards. Our current labeling policy on new drugs is a much tougher one than that in previous years in the FDA.

Sen. Nelson. So, all labels that have been criticized by the NAS/NRC as being inaccurate for one reason or another will be revised.

Dr. Edwards. All of these will be revised and we are moving toward class labeling. Tetracycline is probably the best example. A tetracycline drug, be it brand name, be it generic, the labeling should be the same. I think this will do a great deal to clean up and to make more meaningful the whole labeling.

Sen. Nelson. I do not know that I follow you on that. You mean that now if there are several brand names of tetracyclines that they may have different labeling?

Dr. Edwards. There may be some differences in labeling between various brands of the same drug. We are changing this. We are moving in the direction of class labeling across the board.

Dr. Simmons [Director, FDA Bureau of Drugs]. On the class labeling specifically, what we are trying to accomplish is this. At the present time there are about five different chemical formulations of tetracycline. Now, all of them have minor differences which present and old labeling have shown, and on which advertising claims have been made.

The important thing, however, is that these minor differences, though there, are clinically insignificant. There is no reason why a physician should choose one as opposed to the other.

Now, since there are, I think, over 50 tetracyclines available in these five different chemical classes, what we are trying to do is simplify labeling to point out to the doctor in a simple concise way that basically they are all the same. He can expect the same result from them and he should base his therapeutic judgments on that statement.

That is what class labeling is and what we are trying to accomplish with it.

Sen. Nelson. Well, if the distinctions in the formulations are of no clinical significance, are they permitted to make a claim in the labeling that they are?

Dr. Simmons. They will no longer be allowed to.

Package Inserts

Dr. Edwards. The package insert is the key to what can and what must be communicated to assure safe and effective drug therapy. The NAS/NRC noted that most of the current package inserts require significant revision. As I say, that is being done. Too often they are promotionally slanted. They sometimes are models of clarity when it comes to claims of effectiveness, but models of obscurity in the discussions of limitations, side effects, contraindications, et cetera. In our judgment, our interim labeling regulations will help to correct this problem.

Significance of the "Panalba Case"

Dr. Edwards. As soon as the first NAS/NRC report classifying a drug as "ineffective" was announced, industry resistance appeared. The first line of defense was to throw the issue into hearings, from which protracted delays could be anticipated. There were court suits seeking exemptions of a great number of drugs from the efficacy review—on the ground that they were excused by the grandfather clauses.

The real test, I think, of the agency's determination and ability to translate the scientific reviews into patient benefits

came in mid-1969 with the now quite famous Panalba case. The agency took two important steps to minimize hearing delays. It defined the scientific content of adequate and well-controlled clinical investigations to provide a regulatory base against which medical documentation would be measured, and it established summary rules to limit its hearing procedures to those cases in which the sponsor of the drug could establish that there was a genuine and substantial issue of fact requiring a hearing.

The Panalba case was taken first to the District Court and then to the Court of Appeals. After an expedited appeal, FDA prevailed. The principles on which we would proceed were then firmly established.

Drug Combinations

Dr. Edwards. I would like to make it abundantly clear that FDA is not against all fixed dose combinations. Our problem is to develop and to implement a reasonable policy for dealing with fixed dose combination drugs to make rational prescribing possible. . . .

We are in the process of developing guidelines as to what we consider an adequate combination drug. . . .

In essence what we are saying is that in any combination drug, the various ingredients of the combination must be shown to exert some effect on the total effect of the drug.

Dr. Simmons. No drug should be present in a fixed dose combination unless its presence clearly enhances safety or efficacy. And unfortunately, most combination drugs to this point have not developed that type of efficacy.

Sen. Nelson. I am puzzled a little bit about that. If it is a fixed dosage form, are you saying that adequate control studies would have to be submitted to demonstrate that in that fixed dosage form the combination of these drugs is additive or synergistic?

Dr. Simmons. That is right.

You do not put two antibiotics together unless you can show that those two provide a better result than either one of the ingredients, either a better result in increased safety or increased efficacy. . . .

There are two parts to the combination policy, one, that there should be evidence that both contribute to the therapeutic effect, and two, that the specific formulation can be used rationally. In other words, where you must increase the dose of one antibiotic to take care of a certain organism, you do not carry along with it an increase in the dose of the other for which there is no indication to increase the dose.

Sen. Nelson. In the studies thus far of the NAS/NRC, apart from topicals, were there any fixed combination drugs that met the standard that you are talking about?

Dr. Simmons. Out of, I believe, over 1,300 combination drugs reviewed, a handful were rated effective.

Sen. Nelson. A handful?

Dr. Simmons. Yes.

Drug Quality

Dr. Edwards. Moving on to the subject of drug quality, reliability of claims of effectiveness are of first importance, but we must be equally concerned with product reliability.

We have developed and published improved regulations applicable to Good Manufacturing Practices.

We have several programs to enforce those requirements. The first is the Intensified Drug Inspection Program. This is an effort to improve overall industry performance by concentration on specific manufacturers. In this process the FDA learns practical problems of implementing what may be considered theoretical requirements. The industry learns what concerns the FDA in a concrete rather than an abstract fashion. I think object lessons may be applied across the board. Marginal operations can be brought into compliance and hopeless ones identified and eliminated.

Dr. Charles C. Edwards
Commissioner
Food and Drug Administration

Since July, 1968, FDA has initiated intensified inspection of some 287 drug manufacturers and associated commercial testing laboratories. In 147 of the terminated cases, voluntary compliance with the Good Manufacturing Practices regulations was achieved through a dialogue between FDA District personnel and plant management. In some 44 remaining cases are 23 firms which are now the subject of legal action, and 21 firms which are giving up the drug business because of their inability to come into compliance.

Dr. Simmons. The current Good Manufacturing Practice regulations which we have just repromulgated are such that if a firm follows these, it can reasonably be expected that they will produce an up-to-potency product batch after batch.

Good Manufacturing Practices

Mr. Goodrich [FDA General Counsel]. The Good Manufacturing Practices regulations deal with the nitty-gritty of good production, that is, a proper building, proper equipment, proper cleaning of the equipment, proper controls of the raw materials going into the mixing batch, proper control over the labeling, regulation of the type of personnel, and so forth. They are designed to be compliable by the small manufacturer as well as the large but there are certain minimum things that must be observed by all manufacturers to assure drug quality.

Now, the 21 firms that have not been able to comply either have not had the willingness or the finances to meet these minimum requirements and the public can accept nothing less.

Sen. Nelson. Are there any requirements that must be met by a manufacturer of a drug prior to marketing his drug?

Mr. Goodrich. If it is a new drug, he has to make a commitment at the going-in stage of production that he will observe a protocol of manufacturing control that will assure reliability. If it is an antibiotic drug he must submit each batch to us for batch certification. If he is dealing with drugs that are not new drugs, that it, the old products, he must for all drugs meet the conditions of currently good

manufacturing practice and if he does not, it the drug is adulterated and taken off the market, he can be enjoined or prosecuted.

So the Good Manufacturing Practices are the basic rules that apply to every drug manufacturer, large or small.

Adverse Reactions

Dr. Edwards. The Federal Government is a very substantial purchaser of prescription drugs. We at FDA have a responsibility to do what we can to assure that the Federal purchasers are fully informed about the products they buy.

We do have problems in the use of prescription and nonprescription drugs in this country. It is a serious problem and threatens to become more so if vigorous steps are not taken to correct the basic problem.

The American public is currently receiving approximately two billion prescriptions per year and it is estimated that in five years this is likely to increase some 50 per cent to over three billion prescriptions a year; this figure excludes over-the-counter drugs which are sold in even greater quantities.

The subject of adverse reactions is important and this complication rate has been estimated at some 10%—approximately 5% of all patients admitted to general hospitals are believed to represent some form of drug reaction. . . . The average hospital patient receives between eight and 10 drugs per hospital admission and this goes much higher.

Drug Efficacy Study

Dr. Edwards. The Drug Amendments of 1962 required that drugs be proven effective for their intended uses, as well as safe. Thousands of drugs introduced between 1938 and 1962 had been marketed on proof of safety alone with no obligation upon the manufacturer to prove the truth and validity of their promotional claims of effectiveness.

Surely the most important provision of the 1962 amendments was to define the kind and the quality of medical evidence that is to be required both to justify the introduction of any new product and to sustain the continued marketing of products already on the market. Congress decreed that claims of drug effectiveness must be supported by "substantial evidence"—meaning evidence derived from adequate and well-controlled clinical investigations on the basis of which it can fairly and responsibly be concluded by experts that the particular drug will have the effectiveness it is represented and purported to possess.

The task before the Food and Drug Administration was a monumental one.

In 1966 the agency turned to the National Academy of Sciences/National Research Council for help. NAS/NRC agreed to undertake the evaluation of the more than 3,000 marketed preparations approved by the FDA between 1938 and 1962 that were still on the market, and to determine whether they were effective for the indications claimed in their labeling. The Drug Efficacy Study was established by NAS/NRC in June, 1966, and some 30 panels were set up to evaluate various categories of drugs.

The results are summarized in a report which was given to us in 1969. This review made "an audit of the state of the art of drug usage that has been uniquely extensive in scope and uniquely intensive in time" and is applicable to more than 80% of the currently marketed drugs—80% of all dosage forms that are available in the pharmacy.

The report noted that the quality of the evidence of efficacy, as well as the quality of the labeling, was poor. Many of the presentations submitted by manufacturers in support of the claims made for the use of their drugs consisted of reports of uncontrolled observations and testimonial-type endorsements. There was a conspicuous lack of substantial evidence based on well-controlled investigations by experienced investigators. The panels specifically criticized the labeling of about two-thirds of the drugs that they evaluated. They have found too many of the package inserts to be poorly organized, repetitive, out-of-date, evasive, and promotionally oriented. The majority of the inserts were found to fail in their purpose of providing the physician and the pharmacist with authoritative and objective guides to prescribing or dispensing the drugs in question.

[*Editor's note: Dr. Edwards subsequently added to this testimony in a letter to Sen. Nelson on Jan. 29, 1971, as follows:*

["In the real sense, the industry failed to mount any effort to provide the necessary evidence of effectiveness. Rather, they continued to request hearings, revise labeling, or otherwise avoid the issue of supplying substantial evidence of effectiveness. No drugs of any economic significance were voluntarily removed from marketing, except in those cases where the matter was resolved in the courts, such as some combination antibiotic products. We, therefore, considered it prudent to publish the decisions we made based on the NAS/NRC review.

["Public confidence in our Nation's drug supply cannot be achieved while ineffective drugs remain in our hospitals and neighborhood pharmacies. Public confidence must be built upon the firm foundation of adequate, scientific evidence clearly supporting the effectiveness claimed. The sooner this is accomplished the greater will be the public confidence in the entire medical establishment, be it the drug manufacturer, physician, pharmacist, or the FDA."]

FDA's Mission

Dr. Edwards. Federal policy toward rational prescribing requires attention to drug quality, to sound medical documentation of all allowable promotional claims, and to greatly improved communications with the physicians prescribing these drugs. Government, as a major purchaser of drugs, should and must insist upon the least expensive of equivalent drugs and upon rational choices among different drugs which satisfy the same medical needs. Our role is to assure the reliability of all drugs available in the marketplace and the dissemination of fully informative labeling and promotion to enable the prescribers to make wise choices among the array of products available to them. #

Dr. APPLE. Mr. Chairman, it will probably not surprise you to know that our position with regard to antisubstitution laws is vigorously opposed by the drug industry. Notwithstanding this formidable opposition, we call upon this committee and Congress to examine this situation and to assure that taxpayer-financed national health insurance is not subjected to uncontrolled cost potentials because of existing anti-substitution laws.

We have mentioned drug utilization review programs as one road toward rational drug therapy and a reasonable approach to the control of drug product costs. Another method presently in use in most hospitals is the formulary system for selecting drugs and drug products for the treatment of hospitalized patients.

In the hospital formulary system, the pharmacy and therapeutics committee, as approved by the medical staff, is responsible for determining which drugs are necessary for patient care and should be stocked in the hospital pharmacy. All prescribers practicing in the hospital agree to abide by the decisions of the pharmacy and therapeutics committee, which is made up of representatives of the medical and pharmacy staffs.

Once the list of drugs has been developed, it is the responsibility of the pharmacy department to select the source of supply for each product. The price for drug products paid by hospitals under such a system is far lower than the price paid by community pharmacies for the same drug product. This results because of a highly competitive bidding situation created by the fact that the formulary system permits the hospital to control its drug inventory. Drug product cost savings achieved by hospitals under the formulary system could be realized by the public at large if community pharmacies could similarly control their inventories.

For the past several years, Senator Russell Long of Louisiana has offered a proposal which would be a giant step toward this goal. Under his plan, the hospital formulary concept would be carried over to all health care programs supported by Federal funds. Acceptable cost ranges for drug products deemed necessary for patient care would be established with the advice of a well-qualified panel of nongovernmental advisers. These cost ranges would be established at the lower end of the price spectrum for drug products of acceptable quality. Thus, acceptable quality and reasonable cost would be the basic test for admission of any drug product to the list of those eligible for Federal financial support.

Mr. Chairman, although Senator Long's proposal was included by the Senate in the Social Security Amendments of 1967, it was rejected by the House in conference. The conference committee did recommend further study of the Long proposal, and this was done by the HEW Task Force on Prescription Drugs.

The task force endorsed the Long proposal. Thus, we are here today urging, as APhA has consistently urged, that the concept of the Long proposal for controlling drug costs be adopted by Congress. We believe that if this cost control were presently in effect, we might well have avoided much of the unfortunate drug cost experience associated with the medicaid program and the action taken by this committee in H.R. 1 which permits the States to reduce or eliminate pharmaceutical service benefits under medicaid.

To this point, we have focused on controlling the cost of drug products. We do not believe that the cost of the pharmacist's professional services should go unmentioned. Today, the average professional fee for pharmaceutical service on a per prescription dispensed basis is approximately $1.80. According to the 1970 Lilly Digest, a pharmacy's average net profit was only 4.1 percent of sales, having fallen from 5.8 percent in 1965, a 30 percent decline in the last 5 years. The salaries of employed pharmacists average in the $12,000 to $15,000 per annum range. Pharmacists are not becoming wealthy out of human misery and certainly do not wish to do so. The pharmacist asks only equitable compensation for his service and recognition as a professional member of the health care team.

There is no question but that the practice of pharmacy can and must be made more efficient with the pharmacist utilized in the professional role for which he is trained. We believe that the majority of today's pharmacists and certainly those students who are the pharmacists of the future wish to devote their professional career to the delivery of patient-oriented health care services.

Consider the value, in terms of dollars and improved patient care, of the patient medication record in preventing adverse drug reactions or interactions. It has been estimated by Dr. Leighton E. Cluff, chairman of the department of medicine of the University of Florida, in a recent study that an estimated 1.5 million hospital admissions annually are due to adverse drug reactions. According to the American Hospital Association, the average length of stay in community hospitals in the United States is slightly more than 8 days. However, the hospital stay of a patient whose admission is caused by an adverse drug reaction is roughly 40 percent greater. If one multiplies this period of hospitalization by the average daily costs in community hospitals, $81 per day, a figure which to many may now seem low, one will find that the cost of hospitalization due to adverse drug reactions is roughly $1.3 billion per year.

APhA's concern over the serious public health problem resulting from adverse drug reactions has been translated into an extensive action program. We are in the process of providing practicing pharmacists with the kind of drug interaction information they need to be of service to the prescriber and patient, and we are confident that our program will help to substantially reduce the incidence of adverse reactions.

We would also point out that pharmacists are serving other important roles in their communities, including the role of public health educator. Many pharmacists, both within their pharmacies and in public forums, are serving as the source of reliable, factual information on vital health care concerns including drug abuse and an equally depressing threat, the rapidly increasing incidence of venereal disease.

There is no question but that existing community pharmacies can be utilized to provide comprehensive pharmaceutical service to patients. These convenient primary health centers will continue to serve for many as their initial point of contact with the health care system.

The kinds of service we have described can and will be provided by pharmacists at reasonable costs. With adequate compensation, we

will continue to attract required pharmacy manpower to serve the Nation's health care needs, and with adequate compensation for his professional service and recognition of this service, the pharmacist will be free to devote his full energies toward the efficient delivery of health care service.

Finally, Mr. Chairman, we wish to address ourselves to another aspect of pharmaceutical service cost which has also contributed to congressional reluctance to implement a broad pharmaceutical service benefit. We refer to the costs of program administration. It has been correctly pointed out that the cost of processing claims for pharmaceutical service on a per prescription basis by third parties often exceeds the cost of the drug product and pharmaceutical service combined. Out of our concern for this intolerable situation, APhA founded the National Pharmacy Insurance Council. NPIC has been actively seeking solutions to present weaknesses in the administration of pharmaceutical service programs.

In this connection, NPIC has already developed a universal pharmacy claim form which would serve to bring order out the present chaotic paperwork situation facing both pharmacists and third-party administrators. Yet, for reasons which are totally incomprehensible to us, the insurance industry has failed to adopt this universal claim form. We also believe that there are other methods for reducing the administrative costs associated with the per prescription reimbursement method, for example, the capitation method.

In summary, Mr. Chairman, we are convinced that the documented need for comprehensive pharmaceutical service under a system of national health insurance need not be ignored or such service delayed because the price tag is too high.

We call for the careful consideration by this committee of inclusion of such service in whatever plan for national health insurance may be finally adopted. For our part, Mr. Chairman, we pledge in return that pharmacy stands ready to make the fullest contribution of which the profession is capable in our national goal of achieving solutions to present health care problems in the United States.

Thank you.

Mr. ULLMAN. Are there questions?

If not, we very much appreciate your testimony. This certainly is one of the items that the committee will be considering in some detail in its consideration of this legislation.

Thank you again.

Dr. APPLE. Thank you.

Mr. ULLMAN. Our next witness is Mr. Ralph Engel.

Mr. Engel, if you will further identify yourself for the record we would be glad to recognize you.

STATEMENT OF RALPH ENGEL, DIRECTOR, NATIONAL PHARMACY INSURANCE COUNCIL

Mr. ENGEL. Thank you, Mr. Chairman.

I am Ralph Engel, director of the National Pharmacy Council and I was to be accompanied by Dr. J. Curtis Nottingham, chairman of our board of governors, but unfortunately his flight was fogged in.

Mr. ULLMAN. We are sorry he is not here.

You are recognized, sir.

Mr. ENGEL. Thank you, Mr. Chairman. The profession of pharmacy believes that any health care plan should include pharmaceutical services. At the same time, we recognize that Congress has been reluctant to include out-patient pharmaceutical services as a required benefit in any major health legislation largely because of concern about the administrative costs connected with such benefits.

We are here today to relate to this committee the progress that has been made in developing solutions for the administrative problems connected with the existing third party drug benefit programs as well as those which may become a reality in the months and years ahead.

At the present time, the private insurance industry claims that about 85 percent of the population is protected by one or more forms of private health insurance, yet, only about 2 percent of the people are covered by a drug benefit program. During 1970, according to the figures published by the Social Security Administration, personal expenditures for prescribed drugs and drug sundries reached $6.7 billion. Of this amount, about $6.3 billion can be attributed to the private sector of the economy, while the balance, nearly $425 million, was covered by various government programs. Approximately 17 percent of the total private health expenditures for fiscal 1970 were attributed to drugs and drug sundries.

As prepaid prescription programs proliferate, they produce a substantial impact on pharmacy and it is for this reason that the profession felt some mechanism was needed through which it could address itself to the administrative problems created by such programs and through which it could present a unified approach to many of these problems.

As was stated, the American Pharmaceutical Association conceived the National Pharmacy Insurance Council, believing that the best interest of the public and pharmacy would be served if the profession had a forum which could present proposals as well as action in the prepayment area.

The National Pharmacy Insurance Council was organized in October 1969. Forty-six State associations are represented on the council as well as the American College of Apothecaries, the American Society of Hospital Pharmacists, the American Pharmaceutical Association, and the National Association of Chain Drug Stores.

The activities of the National Pharmacy Insurance Council falls within three general categories—liaison, research, and education.

These activities are carried out through its committees of which there are presently three. The administrative processes committee's function is to design systems and mechanisms for the efficient and economical processing of claims.

The reimbursement methods committee's objective is to develop an equitable and feasible system for reimbursing pharmacists under third-party payment programs. The service benefits committee has the responsibility of identifying pharmaceutical services that contribute to optimal therapeutic utilization.

In an effort to relieve some of the current problems connected with prepaid drug benefit programs, NPIC, through its administrative processes committee, has outlined procedures necessary to expedite identification of eligible recipients of drugs as well as those steps necessary to alleviate the problems of processing the multiplicity of claim forms. It recommends that program subscribers identify themselves by a plastic card similar to a credit card, supplied to them by the insurance carrier or third-party administrator. The information required on the plastic identification card should have a uniform format.

The committee also designed a pharmacy claim form which has universal application today. It is constructed to adapt to any method of administration, from handsorting to sophisticated electronic data processing. It was developed for any type of insurance program and has won the endorsement of virtually every pharmacy organization.

(The document referred to follows:)

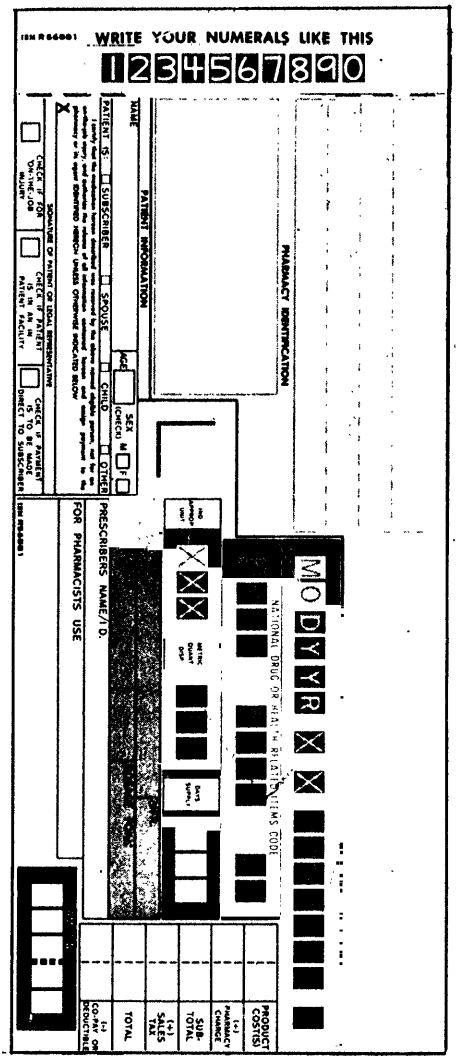


EXHIBIT A

The Pharmacy Claim Form

The following procedures should be used to expedite identification of eligible recipients of drugs as well as to alleviate the problem of processing the multiplicity of claim forms.

Published By:

American Pharmaceutical Association
National Association of Chain Drug Stores
National Association of Retail Druggists
National Pharmacy Insurance Council

I. **The Pharmacy Claim Form**

A. A common claim form is necessary from an administrative standpoint and should be utilized throughout all programs, both private and governmental.

B. The pharmacy claim form was constructed to adapt to any method of administration, from hand sorting to sophisticated electronic data processing including optical scanning. It was developed for both service benefits programs as well as indemnity type of programs and has provisions for recognizing patients in an in-patient facility as well as differentiating between a participating or non-participating pharmacy. The form also provides a means to record health-related items such as canes, crutches, surgical dressings, etc.

C. **Physical Characteristics**

1. Size
   80 column card, which is compatible with most data processing equipment.

2. Copies—three-part form
   A card stock copy and two tissue copies. The card stock copy is to be sent to the carrier or third-party agent for reimbursement; a tissue copy to be utilized by the pharmacy in its accounting and administrative procedures; a second tissue copy can be utilized for follow-up with the carrier or third-party agent when a claim is delayed or in question or for central processing in the case of multi-unit operations.

3. Carbon
   The use of dark black non-smear carbon is suggested, particularly in the case of optical scanning. The carbon is part of the set but should be shorter than the 80 column card size to provide an easy means of snapping the copies apart.

4. The information to appear on the claim form is divided into three (3) general sections.

   a. **Subscriber Identification (Left)**
   The subscriber identification area is left open on the card stock copy but lightly printed on the tissue copies to allow for the imprint of the pertinent information from a subscriber I.D. card or to be written in manually if a card is not available. The information included in this area is:

   Subscriber I.D. number,
   Plan identification number,
   Plan name,
   Deductible or co-pay amount,
   Expiration date,
   Supplemental drug coverage,
   Dependent coverage, and
   Subscriber's name.

   Note, however, if a manual entry is made, the pharmacist should only be required to enter the *subscriber identification number, plan identification,* the *plan name,* and *subscriber's name.*

   Pharmacy Identification

   Positioned in the center left of the claim form or to the right and at the top adjacent to the subscribers identification section. There are a maximum of three (3) lines available for pharmacy name and code number. However, with the use of the pharmacy identification code only two (2) lines are needed: one for the name of the pharmacy and the second for the pharmacy identification code number.

   Patient Information

   Patient information is provided in the lower left corner of the claim form. In this section the *patient's first name, age, sex, and relation to the subscriber is given.* Furthermore, the patient's or agent's signature is required to certify receipt of the medication, verify eligibility, permit release of claim form information, and assign payment to the pharmacy. Below the patient information area there are four (4) check blocks to indicate (1) if the patient is in an in-patient facility, (2) if payment is to be made direct to subscriber in the case of an indemnity-type program, (3) if the pharmacy is a non-participating provider and (4) if the claim is for an on-the-job injury.

   b. **Prescription Information (Center)**
   The claim form will allow the entry of a single prescription or refill per form. The pharmacist is required to indicate the *date dispensed* or the date the prescription is actually delivered. The date should appear as month, day, and year (12-10-71). Since *compounded* and *non-legend* prescriptions often require special handling, boxes have been provided to indicate these special types. In

the cases of compounded prescriptions the pharmacist merely X's this box and lists the major ingredient in the appropriate square. For non-legend items a similar procedure is followed.

The *prescription number* is included for record vertification and audit purposes. Space is provided to indicate whether the prescription is new or a *refill* (New = 0, Refill = 1,2,3,4,5) so that an accurate accounting can be made throughout the life of the prescription.

The *National Drug or Health Related Items Code* should be used to identify the proper drug or device dispensed. If these codes are not readily available, the pharmacist should indicate in the shaded area below: the name of the drug or device, the manufacturer, the strength or size and dosage form. The *appropriate unit* is then X'd on the form so that the carrier can utilize the proper reimbursement formula. The *units* selected are *each, cc,* or *gram.* The pharmacist will then indicate the *metric quantity dispensed* and the *number of days supply.*

Either the *prescriber's name* or *I.D. number* should be provided. Of course, the I.D. number could be utilized in more cases if this information was readily available to the pharmacist; i.e., on the prescription blank.

Space is provided *for the use of the pharmacist* and so marked.

The insurer's identification may be placed in the lower center of the claim form. If the drug program utilizes a plastic identification card it is recommended that the card emboss the plan name directly.

c. **Reimbursement (Right)**

In order to accurately process claims, a cost calculation breakdown is provided to determine the total *amount due* the pharmacy.

D. **Claim Rejection**

A special provision has been made for the rejected claim. In this instance, the carrier or administrator should provide the pharmacy the original claim form with the specific reason for rejection noted on the reverse side.

II. **Imprint Devices**

After a careful review of several types of imprinters, the simple flat bed imprinter is recommended as it is readily available and will accomplish the purpose. The station plate can be located at the left center of the form (22 character type) or to the right and adjacent to the subscriber I.D. (19 character type). Note, also, that the form can be used with the variable type key imprinters in use.

III. **Patient Identification Card**

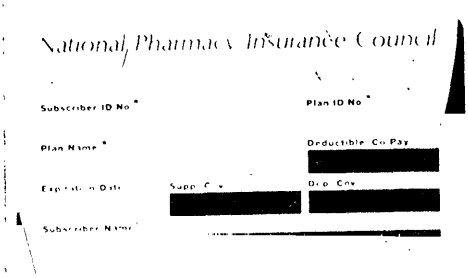
A. It is recommended that program subscribers identify themselves by a plastic card. The card should be supplied by the carrier or third-party administrator and should be of uniform size so that it would fit into any common flat bed imprinter. (3⅜" x 2⅛" and .030 thickness)

B. The plastic identification card should indicate the following:

*1. Subscribers identification number
*2. Plan identification
*3. Plan name
4. Deductible or co-pay amount
5. Expiration date
6. Supplemental drug coverage
7. Dependent coverage
*8. Subscriber's name

(*Denotes the information required to be embossed for print out on the Claim Form.)

C. Example Identification Card



Mr. ENGEL. The significance of the pharmacy claim form is far-reaching. When utilized by all third-party carriers and administrators, it will help reduce the cost of administration and equipment. It is a system which would eliminate the proliferation of forms. A pharmacy would have to stock only one form, and use only one form, thus simplifying the process of submitting as well as processing claims.

However, after all this effort, the Health Insurance Council, individual carriers, and several of the third-party administrators have been strangely silent about the form as if in an effort to boycott its use.

NPIC is hopeful that Blue Cross/Blue Shield as well as all other carriers and administrators adopt the pharmacy claim form. It doesn't make sense to do otherwise because all of us would be subsidizing the cost of needless inefficiency in the country, inefficiency that has approximated $100 million annually.

The proof of such use is in the airline industry. I carry an air travel card, as well as I suppose most of you do.

It happens to be one issued by United Airlines. The card would look exactly the same if it had been issued by American Airlines, Air France, or Japan Air Lines. The same information is embossed in exactly the same place, and all cards fit a common imprinter. When an airline ticket is issued, it is a universial form, and English is the universal language.

The Air Traffic Conference of America and the International Air Transport Association recognized years ago that tens of thousands of travel agents throughout the world writing airline tickets for the hundreds of international, domestic, and commuter airlines would have administrative nightmares unless all used the same universal credit card, ticket, and language. Can you imagine the result if they didn't? Conjure up the same image if a national health insurance program doesn't.

NPIC has also developed a pharmacy identification code system to complement the pharmacy claim form to further increase efficiency while reducing administrative cost. Here too, we have been unsuccessful in getting very wide acceptance. All of these administrators, carriers and fiscal intermediaries appear to be locked into their own antiquated systems regardless of cost to them, to the pharmacist, or to the consumer patient.

Mr. Chairman, although considerable effort is and will continue to be expended to get the pharmacy claim form into widespread use at this time, it was conceded at the beginning of our efforts that a paper system was not the ultimate answer to the problem, but rather a step toward the more sophisticated electronic data processing systems. The application of EDP to the processing of patient data is of prime concern to the entire pharmacy profession since such a system could produce further meaningful reductions in administrative cost as well as allow the pharmacist the opportunity to quickly monitor a patient's medication history. The application of computer technology to pharmaceutical practice does present a challenge, one that will be far-reaching. NPIC will continue to pursue this challenge.

As you can see, pharmacy does recognize its responsibility to the consumer-patient while preparing for a new health care delivery system. Through the National Pharmacy Insurance Council, pharmacy is

looking ahead to develop ways to deliver quality pharmaceutical services more efficiently and economically.

In closing, Mr. Chairman, we urge that any health insurance plan, whether presently before this committee or some other proposal yet to be introduced, contain adequate provisions for administrative safeguards so as to prevent the proliferation of costly procedural processes.

Thank you.

Mr. ROSTENKOWSKI (presiding). Thank you, Mr. Engel.

Mr. Corman?

Mr. CORMAN. I have no questions.

Mr. ROSTENKOWSKI. Mr. Waggonner?

Mr. WAGGONNER. Thank you, Mr. Chairman.

Would the position of your association be that we do at some point recommend a plan involving coinsurers, that you fragment the coinsurers so that you and your association would have the coinsurance involving pharmaceuticals?

Mr. ENGEL. I am sorry. I didn't understand your question.

Mr. WAGGONNER. If we develop a plan for national medical health insurance which utilizes the private sector in coinsurers would your association recommend that that part of the insurance having to do with pharmaceutical costs be separated from the other carriers?

Mr. ENGEL. I think that the pharmaceutical costs should be a part of the entire picture because we believe that pharmaceutical services should be a part of the total comprehensive health services provided.

Mr. WAGGONNER. But you are not recommending a separate carrier for pharmaceutical costs?

Mr. ENGEL. No, we are not.

Mr. WAGGONNER. Thank you, Mr. Chairman.

Mr. ROSTENKOWSKI. Are there any further questions?

Thank you, Mr. Engel.

Mr. ENGEL. Thank you.

STATEMENT OF J. CRAIG HOSTETLER, PRESIDENT, STUDENT AMERICAN PHARMACEUTICAL ASSOCIATION; ACCOMPANIED BY DR. WILLIAM McGHAN, EXECUTIVE SECRETARY

Mr. HOSTETLER. Yes, sir. I am the president of the Student American Pharmaceutical Association. Accompanying me today is Dr. William McGhan, executive secretary of the Student American Pharmaceutical Association. We are pleased to be able to present these comments to you on the subject of national health insurance and particularly concerning the roles of the pharmacist in the health care delivery system.

The Student American Pharmaceutical Association is the national professional society for pharmacy students and our membership includes over 12,000 students. There are 74 student chapters of the association located within each of the schools of pharmacy across the country.

We are testifying here today as future health practitioners who have a right and we feel an obligation to speak on the issues that will shape our future and the future of health care in this country. This Student

American Pharmaceutical Association has been extremely concerned over the form of national health insurance and its effects on future health professionals. We definitely support the concept of national health insurance. We have spent a great amount of time informing our members of the various proposals. At the same time, we have had a great deal of criticism from our members concerning the failure of the proposals to include the benefits of comprehensive pharmaceutical services. As we use the term, comprehensive pharmaceutical services consist of innovative patient oriented roles for the pharmacist in addition to full prescription drug coverage.

THE TEAM

Few people would deny the need to develop more efficient systems of providing health care. With the existing health care crisis in this country and the lack of sufficient health manpower, we need to encourage the development of financial and professional incentives that will result in the greatest efficiency and productivity of health practitioners. As part of the way to improve the existing system and to gain the most from the health care dollar, we feel Congress is obligated to take a hard look toward consideration of a system of national health insurance which encourages the health team approach.

We as students have seen the team approach operate in extracurricular projects such as the Appalachia student health project and the Indian health project. These activities have included the student health professionals not in their traditional stereotyped roles, but as manpower resources whose functions are determined by the needs of the community.

Students who have participated in the projects view the present health care team as a farce without substance or structure, but functioning teams have been demonstrated in the student projects and we feel that it can be done. Students have shared responsibilities for patient care and patient education. Pharmacy students have not only performed drug related services, but they have also functioned in health screening activities to the point of making minor diagnosis on problems all the way from hearing deficiencies to hernias.

With all of the discussions of the shortage of physicians and nurses, little attention has been given to the health manpower implications of the team approach as experienced in the student projects. Various aspects of national health plans have mentioned concepts such as Federal licensing and continuing health education for professionals. A gigantic error will be made in these proposals if consideration is not given to requiring proper education and team training of student professionals who are presently expected to function in perfect harmony in your future health systems.

THE PHARMACIST'S ROLE

When the pharmacist functions as a member of the health team in the true sense of the word, he contributes to patient care in ways which transcend the traditional drug distribution functions.

Pharmacy students feel that national health insurance should encourage a pharmacist's participation not simply as a distributor of prescriptions and drug products but as a full member among the health professions who is involved in the increasing demand for health services.

The profession of pharmacy has been increasingly involved in more patient oriented versus product oriented services.

The present pharmacy curriculum is preparing pharmacy students to assume patient oriented functions in an ever-increasing amount. The typical pharmacy student of the class of 1972 will have completed extensive training in pharmacology including the clinical contact with patients in hospitals and communities.

This educational experience is being supported, and rightfully so, with State and Federal tax funds. Does it make good sense from an economic point of view, if from no other, that the Government should follow up on this investment by fully utilizing the professional pharmacists trained to at least some extent with the Government's own funds?

Another example of existing Government interest and support of these new clinical roles for pharmacists can be found among the projects funded by the National Center for Health Services Research and Development. Preliminary findings of this research lend credence to the position we have stated which calls for full utilization of the professional pharmacists in clinical roles.

Many documents, including the 1971 Task Force from the National Center for Health Services Research and Development on the Pharmacist's Clinical Role have stated that pharmacists have the potential to perform several functions which are not normally considered.

Many pharmacists, after consulting with the physician on the disease diagnosis, actually are selecting the drug therapy for the physician to prescribe. This is the best use of physicians' diagnostic ability and pharmacists' expertise about drugs. Along with supervising the dispensing, the pharmacist is also beginning to assume responsibility for administration of medications when necessary.

The pharmacist has the potential of taking patient drug histories in the community or hospital to prevent possible drug interaction and the adverse reactions from possible drug allergies. Drug utilization review and formulary controls are another function that the pharmacist performs to promote rational therapy and decrease drug costs. Education and consultation to patients and to other health professionals are other ways in which the pharmacist becomes involved in helping to promote better understanding and utilization of drug therapy to its maximum benefit. Education to the public should not exclude the broader health topics that are being presented by pharmacists. The health education subjects include drug abuse education, veneral disease prevention, poison prevention and diabetes screening, among others.

COST-BENEFIT FACTORS

The American public is consuming approximately 2 billion prescriptions per year, on a hospital and on an outpatient basis, and this does not include over-the-counter drugs which is far greater. A recent

1970 HEW Report on Drug Utilization has estimated that about 25 percent of drug therapy is in effective or unnecessary, amounting to a value of between $1 billion and $2 billion in wasted funds. The incidence of complications of drug therapy is roughly 10 percent and some 5 percent of the patients admitted to hospitals are admitted because of serious drug reactions. The cost of this hospitalization due to adverse drug reactions amounts to another $1 billion per year. Totaling this with unnecessary or improper drugs, this amounts to almost $3 billion a year. Much, if not all, of this drug-related cost of health care can be prevented by proper utilization of pharmacists as monitors for prevention of drug interactions and promoters of rational drug therapy.

The present drug distribution services can be greatly streamlined for greater cost efficiency by mechanisms including use of supportive personnel, computerization of data and distribution systems, formularies to limit drug cost, and utilization of the pharmacist as the selector for the product source of a prescribed drug. National health insurance must provide reimbursement incentives to prevent the pharmacist from depending totally upon the dispensing functions as the sole basis of his income, and it must encourage the development of expanded services on a greater team basis to extract the potential contributions which the pharmacist has been educated to provide.

As an example of possible reimbursement systems to encourage team involvement a pharmacist acting as a full-time member of a health care team would become actively engaged in the provision of clinically oriented services to patients and other members of the health care team. If incentives were created such that pharmacists were a part of the pool of profits or losses incurred in an interdisciplinary group practice, the group would be motivated to utilize the pharmacist to a maximum extent to promote rational prescribing by physicians and more appropriate utilization of drugs by patients.

We are a drug-oriented society evidenced by the increasing abuse of illegal drugs and also by our reliance on caffeine and alcohol in the habits of daily living. Even patients and physicans seem to maintain a "pill for every ill" philosophy. The pharmacist has a role in this problem and he must be utilized to his maximum potential by relating national health insurance to the problems of proper therapy and drug use. Incentives must be built around better utilization of pharmacy manpower toward increased interaction with patients and health professionals to promote comprehensive health care with the most rational drug therapy at the most reasonable cost.

Mr. Chairman, I submit that pharmacy must be included in the planning, development, and implementation of any national health insurance plan in the interest of the best utilization of all health professionals toward the good of health care in this country.

Thank you.

Mr. ROSTENKOWSKI. Thank you, Mr. Hostetler.

Mr. Waggonner?

Mr. WAGGONNER. Thank you, Mr. Chairman.

On page 3 of your statement you say:

Pharmacy students have not only performed drug related services, but they have also functioned in health screening activties to the point of making minor diagnosis on problems all the way from hearing deficiencies to hernias.

Do I take this to mean that you are advocating that pharmacists be licensed to start making diagnoses and everyday treatment?

Mr. HOSTETLER. No, sir; we are not ready, I believe, to accept a role such as in the licensure of this type of process. However, as was mentioned earlier, I think by Mr. Corman, concerning the best utilization of the health manpower, the pharmacist has a very broad education concerning health not only on drugs but we are taking courses such as anatomy, physiology, pathology, and going a lot further than just studying structures and actions of drugs.

If we are talking about supplying this need for new physicians in this great shortage of health manpower and talking about better utilization of the health professionals that we presently have, this is broader than this one specific area and I think we would alleviate some of this shortage in manpower. This is where I said the pharmacist should be utilized for the knowledge that he has. If you look at the community pharmacists, a lot of them are called Doc because they are the first person a lot of people see when they enter the health system. A lot of community pharmacists are able to provide health screening and tell the patient, "You are really sick, go to the doctor," or "You have poison ivy."

Mr. WAGGONNER. It seems to me that you have contradicted yourself in saying that you shouldn't be involved in diagnosis of cases to any extent, but then you have come along and taken an opposite position and advocated that. What I want to get at is you have made a statement which says that the role, in effect, of the pharmacist should be expanded. Tell me where you think the limits of pharmaceutical participation really ought to be. What should you do and what shouldn't you do? Should you be a dispenser or should you counsel with the patient or are you asking that the doctor counsel with you before he writes a prescription?

I seem to get this impression, too. Over on page 4 you talk about your educational experience. You say.

> It doesn't make good sense from an economic point of view if from no other that the government should follow up on this investment by fully utilizing professional pharmacists trained to at least some extent with the government's own funds.

Then you say on page 5:

> The pharmacist has the potential of taking patient drug histories in the community or those to prevent drug interaction and the adverse reaction from possible drug allergies.

I would like to know if you think the training is sufficient now or are you advocating additional training for pharmacists to do the sort of thing you advocate there. You say on page 6 that the HEW report shows that 25 percent of drug therapy is ineffective or unnecessary amounting to a value of between $1 billion and $2 billion a year in wasted funds. Is this a criticism of doctors that pharmacists could prevent if they were consulted before prescriptions were written?

I would like a little more elaboration about what you are talking about. You advocate more use of pharmacists but you haven't told us how.

Mr. HOSTETLER. I think Dr. McGhan should answer that.

Dr. MCGHAN. I just want to comment. Mr. Waggonner, on the fact that in the things presented here and the types of things that can be

done by pharmacists I don't think it is up to us today to define the ceilings or the boundaries within which pharmacy can perform. I think it only right to point out that it has not been considered in the past to utilize pharmacists fully, that there has been a great misuse and underutilization.

Mr. WAGGONNER. Let's stop right there for a minute. Where in the past have they not been fully utilized, at least to the extent that they have been to this point qualified or educated to perform?

Dr. MCGHAN. I think they are limited to some extent by the licensure and the forms of regulations that bind them to the function of distribution services. I think that there is a larger role in the health team.

Mr. WAGGONNER. Tell me what it is.

Dr. MCGHAN. In consultation and educating patients and other health practitioners on the proper utilization of drugs.

Mr. WAGGONNER. Then you are advocating that a pharmacist become a health practitioner and that doctors and patients consult the pharmacist.

Mr. HOSTETLER. Mr. Waggonner, this happens everyday across the country in many situations.

Mr. WAGGONNER. I spent some time in a drug store myself. It is not to go to see the doctor, but to say, "Doctor, I have a cold." Are you advocating that the pharmacist be allowed to issue prescriptions that until now cannot be filled except on a doctor's prescription?

Dr. MCGHAN. I think what we are saying here is that we realize that a physician does not always have the most up-to-date knowledge of pharmacology and the use of drugs. I think proper consultation in a team setting between physicians, pharmacists, nurses, and patients is necessary for the proper prescribing of drugs for rational therapy.

Mr. WAGGONNER. You are saying that when a doctor does not feel that he has sufficient information about drugs available, that he consult with the pharmacist, who does have more detailed knowledge about this drug?

Dr. MCGHAN. I believe that is the statement we are attempting to make.

Mr. WAGGONNER. Is that as far as you are attempting to go?

Dr. MCGHAN. As far as the pharmacist's role?

Mr. WAGGONNER. Yes, sir.

Dr. MCGHAN. I think it is much further than that, into the areas of drug abuse education and venereal disease prevention. Due to the pharamacist's training in physiology, he should be a sort of health advocate for the community and his role should not be limited to just pharmacology, because his training goes beyond that.

Mr. WAGGONNER. Is there anything in any legislation that you know of nationally or within any one State that prevents you from doing these things involving community activities, education, now?

Dr. MCGHAN. The problem has been that pharmacists have been forced to maintain their lives along the lines of distribution of drugs and there has not been a system developed that promotes the team approach, that promotes community involvement.

Mr. WAGGONNER. You mean restrained by law, or is it just a position that they have fallen into themselves?

Dr. MCGHAN. I think it is both a legal and financial restraint.

Mr. WAGGONNER. Is there a legal restraint in any way to prevent the pharmacist from involving himself in community education as far as health is concerned?

Dr. MCGHAN. Not necessarily in the community education role, but there are some definite things in this diagnosis of minor illnesses that we mentioned.

Mr. WAGGONNER. We are back to something that you are inconsistent on again. Are you taking the position that you ought to be able to diagnose some cases legally? You have painted yourself into a corner here.

Mr. HOSTETLER. When you talk about drawing up the legal guidelines of licensure, there is a difference between the things that the pharmacist can do now at the present time.

Mr. WAGGONNER. Are you advocating that the license now available to pharmacists be expanded to allow them some diagnostic authority?

Mr. HOSTETLER. I think we probably are, because we feel we have the training now.

Mr. WAGGONNER. Do you feel that you have sufficient training today to do that?

Mr. VANIK. Yes; of course, he has.

Mr. HOSTETLER. Personally, I am taking courses where I am making rounds of hospitals along with physicians.

Mr. WAGGONNER. Are you advocating that you do that in everyday practice?

Mr. HOSTETLER. Yes; and it is happening in hospitals across the Nation.

Mr. WAGGONNER. You are talking about being a second-grade doctor.

Mr. HOSTETLER. We at the Student American Pharmaceutical Association have already talked about physicians' assistants. I think that this is going to be a coming thing, and each of the individual States are working on it now at different levels. No telling what the final licensure provisions are going to be concerning physicians' assistants. I don't think that pharmacists really want to become physicians' assistants, because I think our knowledge in specific areas goes far beyond that of a physician's assistant.

Drugs are where we want our emphasis. Our main emphasis is on proper and rational drug therapy, which is lacking in the present system.

Mr. WAGGONNER. Does the pharmacist want to become a doctor?

Dr. MCGHAN. I think one of the practical factors is that there are various health professionals with various expertises. We don't all have to be one type of professional person, to contribute a role and work together to provide the best health care for this country.

Mr. HOSTETLER. Comparing the education of physicians and pharmacists, the pharmacists have two or three times the education of the action of drugs and how they react in the body. The pharmacist has twice as much education in this matter as the physician.

Why we are not properly utilizing this information, I can't understand. That is the role we want to assume.

Mr. WAGGONNER. Has the pharmaceutical association taken this up with the medical profession?

Mr. HOSTETLER. You mean telling the doctors they need to give their students more training in pharmacology?

Mr. WAGGONNER. Have you tried to establish a line of communication between the two associations to impress this upon them?

Dr. MCGHAN. I think these are some of the things that are very much in evidence, especially in the national student associations in the projects we have undertaken to develop effective team roles and effective interchange of expertise, ideas, and backgrounds, so that these things can be performed.

We are working with the National Student Nurses Association and the Student American Medical Association in community health projects that are demonstrating that these things can occur and will occur with young professionals. I hope this does have an affect on our parent organization.

Mr. WAGGONNER. Thank you, Mr. Chairman.

Mr. VANIK. Mr. Chairman?

Mr. ROSTENKOWSKI. Mr. Vanik.

Mr. VANIK. I just want to say that I am very pleased with the vigorous and exciting nature of the testimony presented by the witnesses on this subject. I am encouraged. I think that we are not adequately using the people that have high training in related health professions, to the extent that we should or we could.

I think that having people with your degree of training to just mix potions is ridiculous. We will have doctors mixing succotash before we finish with this health care business.

I feel that there is an underutilization of the highly trained and capable people in these health-related professions, many of whom have as much or more competence in many areas and training than doctors. The people who have become pharmacists and have gone into other related health professions have just as much qualification to go to medical school as the lucky fellows who were able to get in, and they have just as much capability.

As an individual citizen, I recommend occasionally that citizens should go to hospitals. They come into my office. They are just hardly able to breathe. I can see they have respiratory problems. I can see that they are potential heart cases. Every citizen has a right to express an opinion on his observations on either his own health or the health of another.

Mr. WAGGONNER. Will the gentleman yield?

Mr. VANIK. I will yield when I am through with my statement.

I have heard enough of this business about people invading other professional areas. I think that what we have done and what we have permitted to happen today, is to demand so much dependence on the doctor that we don't utilize any of the other related health professions to the extent that we should.

I think that it is a terrible loss to our economy, I think the health of this country is in perilous danger of plummeting downward because of the lack of doctors and the restrictions that are placed on other citizens who could help a little if only to observe, if only to tell people when they ought to go to a doctor.

It seems to me that we are reaching a point where a doctor is the only one who can say anything or make any observation on the health of a citizen. Frankly, when you analyze the health care of America, a great proportion of the health care of America is self-administered. People administer their own health care, and it is only for the small

fraction that is left over, a very important fraction, for which they consult physicians.

Professional limitations are so critical that I am hardly able to make a judgment myself whether I am well or sick today. It makes me almost feel that I have to call a doctor every morning to determine whether I am ready to go to work.

Yes, 99 percent of the health care of America is individually administered by the person himself. This is what really makes most of us well. We get into a critical problem and we need the doctor. But there are a lot of people along the way that can provide a great deal of help.

We over-use drugs today. They are counterproductive. As a judge I have sat in courtrooms and I have listened to testimony in which drugs that were producing opposite results were administered. I wasn't able to do anything more than observe, but I saw teams of doctors working against each other. I think the pharmacist knows almost as well as most doctors what drugs are beneficial. He can tell by what is ordered by the doctors in whom he has most confidence those drugs which are working and those which are not.

I think that the pharmacist has a great role. I think he is underutilized along with the other professions in this business. I think somehow we ought to utilize the vast training that these young men and women have and give them a greater role in making America healthier.

Mr. WAGGONNER. Mr. Chairman, the gentleman has finished now. Can I have the floor?

Mr. ROSTENKOWSKI. Mr. Waggonner.

Mr. WAGGONNER. The gentleman gets worked up like this very often. If he will read the record, he will find that I only asked these gentlemen what they were advocating. I did not condemn the pharmaceutical people in any way.

I asked them what it really was they were recommending, because I wanted some idea. It may well be that they are underutilized and that is exactly what I was trying to find out.

So the gentleman has gotten worked up over nothing. Thank you, Mr. Hostetler.

Mr. HOSTETLER. Thank you.

Mr. ROSTENKOWSKI. Mr. William Woods.

Would you identify yourself, Mr. Woods, for the record please, and then proceed.

STATEMENT OF WILLIAM E. WOODS, WASHINGTON REPRESENTATIVE AND ASSOCIATE GENERAL COUNSEL, NATIONAL ASSOCIATION OF RETAIL DRUGGISTS; ACCOMPANIED BY NEIL PRUITT, FOURTH VICE PRESIDENT, AND ALAN WADDLE

Mr. WOODS. Thank you, Mr. Chairman.

My name is William E. Woods, Washington representative and associate general counsel for the National Association of Retail Druggists.

For the record I would like to identify the two gentlemen with me. First, on my left, Mr. Alan Waddle from Harrisburg. Ark., a long-

time personal friend of Chairman Mills and former officer and leader in the National Association of Retail Druggists for many years. We wanted the chairman to know that he supports the NARD position expressed here today and to let him know that he appreciates the chairman's efforts to improve the national health by holding these hearings.

On my right, the second gentleman is also a pharmacy owner and vice president of the NARD from Toccoa, Ga., a personal friend of a distinguished member of this committee, Mr. Landrum of Georgia.

The National Association of Retail Druggists was established nearly a century ago to unite independent retail pharmacists and to provide a means whereby these pharmacists could contribute to their common improvement and the public good. Today the National Association of Retail Druggists represents the owners of approximately 40,000 independent pharmacies in which some 75,000 pharmacists in this country practice their profession and dispense about 75 percent of the Nation's out-of-hospital prescription needs.

The independent community pharmacist today is simultaneously a professional practitioner and a small business. NARD and its members vigorously support the American free enterprise system which provides the only meaningful climate under which a small businessman can economically survive, have the opportunity to succeed by his own efforts and perform an important and essential service to his community.

The recommendations of the Ways and Means Committee can have a profound effect on the independent pharmacists of this Nation and can, indeed, preserve or obliterate a place for the independent practice of pharmacy as an important part of the free enterprise system. Because of the singular importance of these hearings on our membership, we will focus exclusively on those provisions in the pending measures relating to drug coverage.

Mr. Chairman, I may skip a few paragraphs here in the interest of time.

Mr. ROSTENKOWSKI. Your full statement will be placed in the record without objection.

(The complete statement follows:)

STATEMENT OF WILLIAM E. WOODS, WASHINGTON REPRESENTATIVE, AND ASSOCIATE GENERAL COUNSEL, NATIONAL ASSOCIATION OF RETAIL DRUGGISTS

SUMMARY

Retail pharmacists serve the health needs principally of non-institutionalized patients. Prescribed drugs for non-institutional patients are largely a neglected benefit in private and governmental health care programs. A national health insurance program (or modification of Medicare and Medicaid) should cover drugs as part of a fundamental and basic health care benefit.

Pharmacies are widely dispersed throughout the population and in many instances represent the most accessible health care resources. Consolidation of health manpower and facilities into the most economical and efficient groupings would reduce accessibility and the quantity of actual care received for many patients. Any reorganization or reorientation of the existing health care system must be considered carefully to assure that innovations will result in improvement in health care for the Nation.

Coverage for prescribed drugs should be given a priority equal to physician, diagnostic and hospital services.

Utilization controls should be accomplished through non-economic means such as peer review, and co-payments, co-insurance and corridor deductibles should not be adopted.

Practitioner reimbursement should be set at the fair value of the service rendered. Drug wholesale costs or "acquisition costs" ought not to be set at less than the cost to the provider pharmacy.

Reimbursement to the pharmacist for his prefessional services ought to be based on any reasonable method regularly employed by an individual pharmacy, including but not limited to a prescription dispensing fee. Pharmacy reimbursement ought to be set either at a reasonable level equal to the usual and customary charges made by an individual pharmacy or at the usual and customary charges of an individual which are reasonable. However, in no case should the government be permitted to establish and adopt a flat "fixed" dispensing fee and reimburse the pharmacy either that fee or the pharmacy's usual and customary charge, whichever is the lesser.

Drug coverage ought not to be limited to therapy for chronic diseases or maintenance drugs, but should be comprehensive in scope.

National health insurance proposals should provide opportunities and a mechanism whereby the knowledge, education and training of the nation's pharmacists could be better and more fully utilized in providing health care to patients.

Drug coverage, either as a part of national health insurance or as an extension of Medicare services for home patients, ought to be provided through the vendor concept, utilizing the independent retail pharmacies of the country. Patients ought to continue to be guaranteed the freedom to choose any qualified retail pharmacy to serve their drug needs.

Any program adoped by Congress which includes drug coverage should assure that the pharmacists have an adequate voice and role in program formulation and operation. Individual provider panels are recommended to serve the function of recommending drug program design and administration concepts which may not be rejected unless demonstrably unreasonable or incompatible with other phases of the health care program.

The National Association of Retail Druggists was established nearly a century ago to unite independent retail pharmacists and to provide a means whereby these pharmacists could contribute to their common improvement and the public good. Today, the National Association of Retail Druggists represents the owners of approximately 40,000 independent pharmacies in which some 75,000 pharmacists in this country practice their profession and dispense about 75 percent of the Nation's out-of-hospital prescription needs.

The independent community pharmacists today is simultaneously a professional practitioner and a small businessman. NARD and its members vigorously support the American free enterprise system which provides the only meaningful climate under which a small businessman can economically survive, have the opportunity to succeed by his own efforts, and perform an important and essential service to his community.

The recommendations of the Ways and Means Committee can have a profound effect on the independent pharmacists of this Nation and can, indeed, preserve or obliterate a place for the independent practice of pharmacy as an important part of the free enterprise system. Because of the singular importance of these hearings on our membership, we will focus exclusively on those provisions in the pending measures relating to drug coverage.

Great emphasis has been placed upon making health care accessible to all people. Each of the proposals before the committee shares the common goal of guaranteeing greater accessibility to health care for greater numbers of our citizens or, at least, removing the financial barriers that exist for some in seeking adequate health care.

Just in humanistic terms, every citizen must support the objective of providing early and ready access to health care. And the emphasis in recent years has been on keeping patients out of high-cost institutional settings whenever possible. Obviously, if a patient can be treated without confinement in a hospital, costs of care are decreased for whoever pays the bill and ancillary costs incurred such as wage loss and other factors, are minimized for the patient and his family.

Independent community pharacies are principally involved with ambulatory patients. As such, our members share the view that any extensions of Medicare, Medicaid, or establishment of national health insurance should provide prescribed drugs for non-institutionalized patients.

Experience reveals that one of the major shortcomings of Medicare, in our view, is its continuing failure to make any provision for prescribed drugs for beneficiaries who are not confined in an institution—hospital or extended care facility. A Medicare patient can obtain a multitude of services—physician care, hospitalization, diagnostic services—but drug coverage is limited to drugs furnished during confinement in an institution.

Particularly with elderly patients, care at the earliest opportunity may avoid more serious illnesses and complications and the need for hospitalization. While a Medicare patient has coverage for physician office visits in most cases, there is no coverage of any drug therapy that generally is the key to the patient's recovery.

Since enactment of Medicare, both the Johnson and Nixon Administrations have appointed special task forces to study the advisability of adding home drugs to the Medicare program and both task forces have recommended including such drug coverage. Further support for including drug coverage for the Medicare home patient came this year in a report by the 1971 Advisory Council on Social Security which stated "Medicare should be expanded to include coverage of out-of-hospital drugs requiring a prescription."

Most frequently, illnesses require a physician visit and some form of drug therapy. Because this is not the most expensive segment of care, our thinking usually rapidly shifts to the higher costs of hospitalization or nursing home care. There is no question that the substantial costs of extended institulional stays are of concern to all our citizens. And coverage for these costs, either through public programs or through health insurance, is necessary and reassuring. But the focus here is on the health care items of greatest cost affecting the smallest segment of the population.

Unquestionably, more people visit physicians, need laboratory services for diagnostic purposes, and have drugs prescribed for their illnesses than are hospitalized or need institutional care. The physician and pharmacist are actually the first line defense in our health care system. Unfortunately, both in government programs and in private health insurance programs, coverage for prescribed drugs is given too low a priority or excluded altogether.

Prescribed drugs are not a mandatory service required in State Medicaid programs, for example. What we have said about the exclusion of prescribed durgs for Medicare is more applicable to Medicaid because this latter program covers younger persons more often bothered with acute infectious diseases for which the only therapy, particularly for children, is frequently drug therapy.

BASIC HEALTH PROGRAMS SHOULD COVER DRUGS

In the consideration of the proposals before the committee, we ask that prescribed drugs be considered as an integral part of a basic health care package which would also include medical and diagnostic services. What good is there in making the services of a physician available to diagnose an illness, and making diagnostic laboratory services available to assist the physician, if after these procedures and services are completed, the necessary drug therapy indicated to properly treat the illness is not also available. It just doesn't make sense to expend the time and resources on a diagnosis for which therapy cannot be provided. And it does not make any more sense to institutionalize a patient to assure that drug therapy indicated will be provided. However, this is the posture of the current Medicare program, most private health insurance programs, and some Medicaid programs.

HEALTH CARE SYSTEM REORGANIZATION

There is considerable interest and discussion in reorganizing our health care delivery system. A common thread through most of the proposals before the committee provides some encouragement for the organization of "health maintenance organizations" or centralized health care centers. Such organizations are not new in health care. We believe that before the Congress undertakes the cost and task of reorganizing the health care system in this country, the advantages of the current system should be carefully evaluated to assure that any reorganization will truly be an improvement.

There are advantages in some instances to what we now have compared to centralized health care centers. The independent community pharmacists of this

nation have been proud of their ready accessibility to the population. On the other hand, established health care centers with differing levels of care and facilities have their advantages, too. We are not now prepared to say that one should be preferred to the exclusion of the other.

Problems of transportation of sick patients to and from a central facility may actually decrease the accessibility of health care for some segments of our society. Today, pharmacies are widely dispersed throughout the population and are generally the most accessible health care resource. The Nation has about 7,000 hospitals while the number of pharmacies exceeds 52,000.

If we consolidate health care centers to most economically and efficiently utilize over-all health manpower and facilities, we would undoubtedly reduce the number of pharmacies. But would this improve health care of our people? We submit that it would not.

Where continuity of medication is important, the accessibility of a pharmacy may be a crucial factor in determining whether the medication is regularly taken. A patient may arrange for transportation to a health care center to see a physician, or for diagnostic testing, or for other occasional medical care attention, but not for refills of medication or other incidental health needs over protracted period of time. Proximity is a factor in assessing accessibility and continuity of drug therapy.

For example, a diabetic being maintained with oral anti-diabetic drug therapy would most likely consider the availability of a pharmacy for refills of the drug and as a source of self-administered urine testing agents as the most important aspect of health care. If the patient did not have either the drug, or the diagnostic agents to periodically evaluate therapy, a personal health crisis could readily develop. For a diabetic maintained on insulin, retail pharmacy availbility is even more critical.

We must also consider that not all areas of the country present suitable settings for health maintenance organizations. In densely populated areas, we already have clusters of health facilities and yet an apparent inaccessibility seem to be primarily a problem of the indigent segments of society, not the non-existence of facilities.

In light of this, we should consider whether the inaccessibility is a result of the existing patterns of health care coverage under public and private programs, particularly the general exclusion of coverage for prescribed drugs. What we may need is a revision in the type and scope of health care coverage and a means of better coordinating current and existing health care resources rather than a wholesale revision.

NATIONAL HEALTH INSURANCE BILLS

Coming specifically to drug coverage in some of the pending measures:

In H.R. 4349, we would concur with its objective of establishing a minimum standard of health care benefits. This is in line with our earlier general comments. However, we would urge the committee, if this approach is adopted, that the priority for prescribed drug coverage be elevated from Priority II to Priority I. NARD believes that with the experience of Medicaid, pioneering private health care plans, and the CHAMPUS program, (Civilian Health and Medical Program of the Uniformed Services), that we could readily tool up to provide drug coverage on a much broader basis than now exists.

H.R. 4349 would require a $1 co-payment for each non-institutional prescription obtained. We cannot support a co-payment principally because existing experience and studies have shown it to be a disincentive and inappropriate to controlling proper utilization. If utilization controls are found necessary, such control should be accomplished through non-economic means such as peer review. By using peer review mechanisms, utilization can be controlled by proper professional consideration rather than by economic deterence or abrogated by economic affluence.

We also would urge modification of the proposed Section 2002(e)(2)(A) for Title XX of the Social Security Act which places the maximum reimbursement as not exceeding "the seventy-fifth percentile of a low to high distribution of the actual charges made for similar services in the same locality during the preceding calendar year." While we can accept the "prevailing charge" concept as valid means of determining compensation for pharmaceutical services, we do not believe that it can be appropriately applied on a broad basis. The government, or any other health care payor, ought to be willing to pay the fair value

of the services rendered, and not 75% or some other percentage of the fair value. Further, if a national health insurance program were to have a broad impact on pharmacies, as we expect it would, the prevailing charge would progressively decrease with each annual revision.

H.R. 7741 makes no provision for home drug coverage. We believe that this bill is unsatisfactory because it perpetuates a mistake revealed by experience with existing programs. However, we do support H.R. 7741's provision which would help many of the independent community pharmacies meet the standards for health care coverage. A large proportion of the Nation's pharmacies employ less than 10 persons and hence these small businessmen would benefit from this significant assistance. We would urge that the committee consider incorporating this provision in any final legislation developed.

H.R. 4960 also makes no provision for home drug coverage and our comments relative to H.R. 7741 are equally applicable here. We urge the committee to revise the scope of the qualified health care insurance policy set forth in proposed Section 2009 to include prescribed drugs and such other drugs reasonably necessary in the treatment of illness or disease.

H.R. 22 proposes generally liberal and comprehensive benefits but places restrictive limitations on the provisions for home drug benefits. Covered drug therapy is limited to those chronic diseases and conditions for which drug therapy, because of its duration and cost, commonly imposes substantial financial hardship. Immediately, two qualifications must be met: drug therapy must be of sufficient cost to impose a substantial financial hardship and must be of sufficient duration to have such a financial effect. We believe that a drug program should be comprehensive in scope and not limited to only those chronic conditions where drug therapy would be particularly costly. A cardiac patient on digitalis needs a relatively inexpensive but vital drug to maintain proper heart function and the consequences of a break in the drug therapy regimen requires restabilization and the intervention of medical personnel. The bare economic cost of one or two breaks in therapy could equal or exceed the cost of drug therapy for the patient for an entire year.

Section 86 of H.R. 22 provides that the Health Security Board will determine product prices which shall be the maximum drug cost reimbursement levels recognized and further directs that the prices so established be set so as to encourage the acquisition of drugs in substantial quantities. This provision would place an unreasonable burden upon many pharmacies in this country and works contrary to a trend in pharmacy management. Where volume warrants, some pharmacies buy drugs in quantities but this does not automatically produce a lower cost to either the pharmacy or the patient. Inventory investment as well as costs of subdividing large quantities, storage space, breakage, and other factors may increase the final "cost" to the pharmacy substantially. Further, pharmacies with insufficient volume to purchase in quantities to achieve price levels established under these criteria would be financially penalized by participation in the program.

H.R. 22 envisions a program where the government will virtually pay for all the drugs furnished to non-institutionalized patients with certain chronic illnesses and diseases. The Congress should not deliberately establish a program which extracts a discriminatory tax from the nation's pharmacies, the amount of the tax being the difference between the fictional acquisition cost established by a government bureau and the actual higher cost paid by many small retailers. The inherent strength of the current drug distribution system in this country lies in the fact that the number of small drug stores far exceeds the high volume multi-unit operations. While the small store may purchase in smaller quantities their prescription product inventory will usually reflect a broader availability of life saving drugs.

Total reimbursement is established as the product cost (as outlined) plus a dispensing fee. NARD objects to the fixed "dispensing fee" approach apparently envisioned in Section 86. The government is directed to establish schedules of dispensing fees which may vary according to regional differences, differences in the volume of drugs dispensed, differences in services provided, and other factors deemed relevant. This provision looks toward a situation where pharmacies in a given area would be divided into three or four categories and a fee established for each category.

If a flat sum representing reimbursement for overhead, profit, labor, and other factors is essential for administrative or other purposes, it should be individ-

ually determined for each pharmacy. No two pharmacies have the same volume or product mix, labor costs, and like factors. Therefore, a flat "fixed" fee will underpay some and overpay others.

Preferably, a government program would adopt any reasonable method of determining charges employed by the individual pharmacy provider. Current Federal guidelines for pharmaceutical services in Medicaid programs provide several alternative methods for determining pharmacy provider reimbursement and we believe that this flexibility is desirable and necessary.

Section 56(a)(3) of H.R. 22 permits a health care practitioner (pharmacist) in a non-profit hospital or a participating comprehensive health service organization to perform such acts and procedures as the Health Security Board may, by regulation, permit. We believe that this concept has considerable merit and we fail to see what rationale supports permitting a pharmacist in an institutional setting to perform a function while denying a pharmacist in independent private practice the right and opportunity to perform that same function. Pharmacists have the training and ability to perform expanding professional functions and responsibilities.

In the Senate, S. 836 relates to the subject pending before the committee. Much of what has been said about drug coverage in H.R. 22 is applicable to S. 836. The pharmacy reimbursement provisions are nearly identical except for the added factor that the government payment to a pharmacy cannot exceed the "customary charge at which such dispenser of drugs sells or offers such drug to the public at the time such drug is furnished," to quote proposed Section 1818 (c)(4) of S. 836. NARD finds this provision particularly objectionable because of its inherent unfairness.

In establishing a dispensing fee in an indivdual store an average "gross profit margin" is calculated and theoretically set to equal an amount representing the difference between the average prescription charge by the pharmacy and the pharmacy's ingredient costs. Since the dispensing fee is an average margin, a pharmacy who chooses not to change his entire method of doing business, or calculating all charges to accommodate a governmental planner's concept, may have charges to the private paying public which are above and below that average figure. More concretely, a pharmacy on a 40% markup would charge a patient $2.00 for a drug costing the pharmacy $1.20 and $10 for a drug with a wholesale cost of $6. If the dispensing fee is set at $2.00, the cost to the government of each of the prescriptions would be $3.20 and $8 respectively.

Under the provision in S. 836, however, the pharmacy would not be able to charge the government more than $2.00 for the first prescription. In the first situation, the pharmacy realizes a gross profit of $4.80 for both prescriptions; in the second situation, $4; and in the third situation required by S. 836, $2.80. Obviously, a pharmacy using a 40% markup will be financially disadvantaged on every prescription dispensed under the program where his regular charge to private patients is less than $5.

VENDOR PROGRAMS AND FREEDOM OF CHOICE

Speaking generally, NARD believes that one of the major weaknesses and deficiencies in current health care programs, both public and private, is the absence of or inadequate provisions for pharmaceutical services. We believe that one of the major strengths in the health care system is the thousands of independent community pharmacies readily accessible to virtually every segment of the population. Any revisions in the Federal health care programs, or any legislation governing private health care programs should seek to correct this deficiency and capitalize on the strengths of the existing retail distribution network for drugs.

The vendor program for providing drugs has proved acceptable in Medicaid. In fact, the change to the vendor program concept in health care was established in the last decade by the Kerr-Mills program which was initiated by the distinguished chairman of this committee. While NARD members have had many complaints about the actual administration by individual states of the vendor program under first the Kerr-Mills legislation and later under the modifications made by Medicaid, the strength of the vendor concept is as valid today as it was in 1960.

Another important, indeed essential, concept that has stood the test of time in Medicare and Medicaid is the "freedom of choice" guaranteed to patients to

select any qualified provider of services to furnish needed health care services. We believe that freedom to choose the health care practitioner is a strength of the current Federal programs and should be retained in any future program.

Combined, these two concepts—vendor program and freedom of choice—permit and preserve an opportunity for the traditional forces in our competitive enterprise system to assure that the quality of care and services will not deteriorate merely because the government may be paying all or part of the costs.

PROVIDER VOICE IN PROGRAM DESIGN

None of the proposals before the committee permits or assures the providers of service an adequate roll or voice in the design, operation, and administration of the programs. This summer, at the request of the National Association of Retail Druggists, a subcommitee of the House Select Committee on Small Business held three days of hearings on the impact of third party payment programs and the record of those hearings details the problems and issues of greatest concern to independent pharmacists.

Basically, however, the complaints stem from a common cause—that of giving all interested parties in the drug program, except the pharmacists who must economically and professionally survive under them, a significant role in the design and planning. Nearly without exception, program sponsors such as big business, big insurance companies and big unions have designed and implemented a drug program from a supposedly bureaucratic vantage point in both private and government programs which program was then placed before each pharmacist on a "take it or leave it" basis. With the experience of operating under existing programs, most NARD members could contribute significantly to improving the design and administration of these programs while not detracting from the over-all program goals.

We strongly urge that the committee consider individual provider panels for each benefit area covered and charge these provider panels with the responsibility for developing the design, operation, and supervision of the administration of the benefits furnished by their provider group. What we envision here is a panel of distinguished pharmacists (who would not be fulltime government employees) to act as a Board of Directors responsible for pharmaceutical benefits. We recognize that the benefits must be coordinated and control must be vested in the responsible governmental agency, but the providers should be given the first opportunity to recommend an administrative plan compatible with existing practices and procedures and with the over-all program goals. Plans recommended by such a panel should be adopted and implemented unless the responsible governmental agency can demonstrate that the proposal is unreasonable or that the proposal is incompatible with other phases of the benefit package or program goals.

We appreciate this opportunity to appear before you on behalf of the members of the National Association of Retail Druggists. We have not commented in detail on the various National Health Insurance proposals for the reasons we have stated but we hope we might have the opportunity of furnishing the committee additional written statements and supplementary materials for the record as the committee drafts legislative recommendations concerning this important subject. We are anxious to be of continuing assistance particularly in matters concerning drug coverage.

Mr. Woods. Since enactment of medicare, both the Johnson and Nixon administrations have appointed special task forces to study the advisability of adding home drugs to the medicare program and both task forces have recommended including such drug coverage. Further support for including drug coverage for the medicare home patient came this year in a report by the 1971 Advisory Council on Social Security which stated, "Medicare should be expanded to include coverage of out-of-hospital drugs requiring a prescription."

Most frequently illnesses require a physician visit and some form of drug therapy. Because this is not the most expensive segment of care, our thinking usually rapidly shifts to the higher costs of hospitali-

zation or nursing home care. There is no question that the substantial costs of extended institutional stays are of concern to all our citizens. And coverage for these costs, either through public programs or through health insurance, is necessary and reassuring. But the focus here is on the health care items of greatest cost affecting the smallest segment of the population.

Unquestionably more people visit physicians, need laboratory services for diagnostic purposes and have drugs prescribed for their illnesses than are hospitalized or need institutional care. The physician and pharmacist are actually the first-line defense in our health care system. Unfortunately, both in Government programs and in private health insurance programs, coverage for prescribed drugs is given too low a priority or excluded altogether.

Prescribed drugs are not a mandatory service required in State medicaid programs, for example.

BASIC HEALTH PROGRAMS SHOULD COVER DRUGS

In the consideration of the proposals before the committee, we ask that prescribed drugs be considered as an integral part of a basic health care package which would also include medical and diagnostic services. What good is there in making the services of a physician available to diagnose an illness, and making diagnostic laboratory services available to assist the physician, if after these procedures and services are completed, the necessary drug therapy indicated to properly treat the illness is not also available?

It just doesn't make sense to expend the time and resources on a diagnosis for which therapy cannot be provided. And it does not make any more sense to send a patient to a hospital to assure that drug therapy indicated will be provided. However, this is the posture of the current medicare program, most private health insurance programs, and some medicaid programs.

In our statement we have commented on the proposals. We will not read that statement now, but we will comment on three points. I offer for the record now a resolution passed at the NARD Annual Convention at New Orleans on October 14, 1971.

Mr. ROSTENKOWSKI. Without objection it will be included.

(The resolution follows:)

RESOLUTION ON NATIONAL HEALTH INSURANCE AND COMMUNITY PHARMACY PARTICIPATION ADOPTED AT THE NARD 73RD ANNUAL CONVENTION, NEW ORLEANS, LA., OCTOBER 14, 1971

Whereas, there are currently pending in the Congress of the United States a number of diverse proposals for improving the availability of health care services to all citizens; and

Whereas, most pending proposals either exclude or make inadequate provisions for home drug needs; and

Whereas, in both Medicare and Medicaid the Congress failed to recognize the vital and essential role of pharmaceutical services in any health program that attempts to provide even rudimentary medical care; and

Whereas, it is self-defeating for any program to pay for diagnostic and physician services without also assuring that indicated pharmaceutical services will be adequately provided when and as needed;

Resolved: That the National Association of Retail Druggists, in Convention assembled, urges the Congress to include pharmaceutical services as a priority and mandatory benefit in any revisions of current plans for National Health Insurance or any future Federally-funded health care program; and

Further resolved, That Congress should consider hospital, diagnostic, physician, and pharmaceutical services as comprising a single, coordinated, and interrelated unit of health care; and

Further resolved: That Congress be urged not to restrict drug coverage to those drugs provided in or by hospitals or similar institutions or in any other manner which discriminates against independent pharmacy participaton.

Mr. Woods. The second point concerns fair reimbursement for the retail pharmacist and we offer for the record a report NARD sponsored which is the most extensive analysis and study of variability in pharmacy charges for prescription drugs conducted by the R. A. Gosselin Co.

The purpose of the study was to collect and present objective and pertinent statistical data which could be used by third party reimbursement administrators and planners and others to aid in the design of fair and equitable reimbursement policies for all pharmacies commensurate with the public interest.

Mr. Chairman, this study was undertaken to assist the Ways and Means Committee in considering drug coverage in any medical care program. This would be available for the record. sir.

Mr. Rostenkowski. Without objection it will be included.

(The report referred to follows:)

VARIABILITY

ANALYSIS

PHARMACY CHARGES

FOR PRESCRIPTION DRUGS

UNDER THIRD PARTY PROGRAMS

R.A.GOSSELIN and COMPANY, Inc.

890 PROVIDENCE HIGHWAY · DEDHAM · MASSACHUSETTS 02026

Summary results of a study jointly commissioned by the National Association of Retail Druggists and the National Association of Chain Drug Stores

PREFACE

In January, 1970, the National Association of Retail Druggists and the National Association of Chain Drug Stores jointly commissioned R. A. Gosselin and Company, Inc. to conduct a comprehensive statistical study of variability in prescription charges and operating characteristics in the pharmacies of the United States.

The purpose of the study was to collect and present objective and pertinent statistical data which could be used by third party reimbursement administrators and planners and others to aid in the design of fair and equitable reimbursement policies for all pharmacies commensurate with the public interest.

Data findings in this study were obtained from a total of over 2600 retail pharmacies representative of the nation. In addition, nearly one-half million prescriptions were analysed to determine prescription charge variability.

This report is a summary of findings extracted from the 402 page technical report provided NARD/NACDS in January, 1971.

INTRODUCTION AND SUMMARY

Prescribed drugs as part of pre-paid health care programs, public or private, have been a subject of considerable controversy since the matter was first explored in depth in the HEW Task Force on Prescription Drugs during the 1960's.

The central issue has not been the question of providing needed therapy to eligible participants of one program or another, for certainly pharmacists along with their professional peers have been at least as equally desirous as program administrators to participate in the expansion and improvement of health and health care in the nation.

The issue has been fundamentally economic and fiscal in nature. Because of many misconceptions and erroneous assumptions about pharmacy practice and the systems for determining individual prescription charges by pharmacists in the more than fifty thousand retail pharmacies of the nation, program designers have tended to adopt or recommend reimbursement procedures which, at best, are foreign to the operating modes of the vast majority of pharmacy practitioners or, at worst, deprive dedicated professionals of their ability to function as important members of America's health-care team.

The causes of variability in prescription charges for identical drugs in identical quantities, so often the subject of lay press and general media "surveys," has been one of the principal misconceptions leading to restrictive reimbursement approaches to pharmacists. Not having explored and determined why such variation exists has led to the assumption that the variation should not exist to begin with. Other misconceptions and misinterpretations based upon generalizations of isolated cases or experiences or superficial reviews have helped to formulate a viewpoint that holds that low charges represent efficient pharmacy operation while higher charges represent inefficient management. Paying a "middle-ground" fixed fee to all, it has been argued, is an effective device for forcing inefficient practitioners to become efficient, even if such new efficiency means the abandonment of certain professional services required by the patrons of that pharmacy or a restriction of the scope of inventories. The fact that some dispensers of prescriptions may be overly rewarded when the fixed fee is above their normal charge is ignored.

The study which was commissioned by the National Association of Retail Druggists and the National Association of Chain Drug Stores and completed in January of 1971 has explored the matter of variations in prescription charges in well over 2000 pharmacies and has found a positive cause and effect relationship between operating characteristics and prices charged for prescriptions. It shows that prices charged by individual pharmacies reflect accurately the differences in the environmental and operating characteristics of each store. It also shows that single attributes, such as emergency service or free delivery, taken by themselves are not necessaritly indicative of the cause for price variability. Other attributes may have equal or greater effect but in the opposite direction, for example - discount policy on health and beauty items. The sum total of all the significant variables, positive and negative, establishes a Professional Services Index for each pharmacy which with remarkable precision estimates what the prices charged will be for that pharmacy.

The singular importance of the findings of the study is that a realistic alternative to the fixed or variable dispensing fee plus acquisition cost method of reimbursement is indeed reasonable, feasible and economical for providing prescribed drugs via the nation's retail pharmacies.

The study provides a considerable body of facts and evidence previously lacking to show how a reimbursement system can be based upon the regular charges the pharmacist makes to the general public, while providing the program administrator with the information he needs for cost predictability and administrative control. Speed of reimbursement would be guaranteed to all pharmacies whose charges do not exceed their established statistical norms. In public programs, taxpayers could expect efficient and harmonious programs for their tax dollars.

BACKGROUND

THE PROBLEM:

Several factors, controllable and uncontrollable, have a bearing upon the individual pharmacy's ability to employ a pricing policy to entitle a fair and equitable return on investment. Each pharmacy reacts and adjusts to a unique set of circumstances, whether they be externally or internally related factors, and the operational expenses of each store vary as a result. The present reimbursement policy of paying a standard fixed fee to those pharmacies participating in third-party programs, public or private, does not take into account the unique individual differences that exist from pharmacy to pharmacy.

STUDY OBJECTIVES:

The study was intended to establish that:

Identifiable environmental factors and individual operating characteristics cause charges for identical prescriptions to vary significantly from one pharmacy to another.

Prescription charge variance is normal and expected and can be measured in a valid statistical manner.

A reimbursement system more equitable than those currently employed could be utilized for the acceptance or rejection of prescription charges submitted by individual pharmacies.

METHODOLOGY:

The study deals with source material representative of the entire nation. It is confined to retail pharmacies, both chain and independent, and specifically excludes hospital pharmacies and other non-retail outlets.

In the statistical analysis of the factors which significantly affect the final selling cost of prescription drugs, efforts are restricted to those objective factors such as hours open per week, size of store, prescription filling volume, which can be quantified in a statistically reasonable and acceptable manner. The following research sources are employed:

Pharmacy Universe Panel (PUP)

PUP is a stratified random sample of nearly 900 pharmacies routinely employed to obtain various attitudes and opinions on numerous topical questions. A mail survey was conducted in April, 1970, with this panel in order to obtain background information about the attitudes of retail pharmacists concerning third-party programs now in existence.

National Prescription Audit (NPA)

The existing data bank of the National Prescription Audit, which is recognized by industry, government and the profession as being representative of retail prescription activity in the nation, is utilized. This ongoing research study is now nearing its nineteenth year of continuous operation. Over 400,000 prescriptions collected from a nationally representative subsample of 322 pharmacies for the six-month time period ending April, 1970, serve as the base data for this analysis.

Questionnaire Survey

A questionnaire was mailed to a randomly selected list of 10,640 retail pharmacies on June 29, 1970. Pharmacists were asked to supply their usual and customary charges by whatever pricing system they routinely use, markup or fee, or a modification of either, for a list of representative prescriptions. In addition, the pharmacist was asked to provide information on the characteristics of the pharmacy, the customer, and its area served, as well as data on services rendered, purchasing and pricing policies, utilization of personnel, etc. The average price charged was correlated by statistical means with those factors, both external and internal, to each pharmacy in order to establish the relative effect of each as a contribution to price.

SUMMARY OF SPECIFIC FINDINGS:

- There is considerable dissatisfaction among pharmacists with several factors involving the process of reimbursement now in effect under third-party pay programs and in particular the Medicaid/State Welfare Programs.

- The factors most strongly criticized by pharmacists are those coincident with reimbursement such as the amount allowed and the method utilized.

- Pharmacists are generally unhappy with claims processing as it concerns the administrative tasks and time required for claims submission and the length of waiting time for reimbursement.

- The use of the actual acquisition cost as part of the reimbursement formula is almost universally found to be difficult for pharmacists to ascertain and is considered unfair.

  The fixed fee component of the reimbursement formula fosters an inequitable return on investment for pharmacists due to environmental (over which they have little control) and operational influences.

- An uncontrollable environmental influence is the varying disease patterns within the trading area served by the pharmacy. Several socio-economic factors affecting disease incidence (therapeutic category concentration) are present in different proportions in the area served by each pharmacy. The professional services required of a pharmacist vary by the type of medical environment in which he operates.

- Beyond the pharmacist's control is the matter of drug usage patterns. Physician preference concerning length of therapy and size of prescription varies considerably. Under the fixed fee where all prescriptions, regardless of quantity dispensed and choice of therapy, each is treated identically creating disparities in return on investment between pharmacies.

- Most pharmacists (67%) are dissatisfied with the amount of time and calculation necessary for claim form submission. In addition, slow payment forced a substantial number to seek bank loans and increase their prices to regular customers.

- Regression analysis of 165 variables associated with pharmacy operations isolated 36 which were found to be statistically significant in causing prescription price variation in pharmacies.

- The relative presence or absence of each of the 36 variables within a pharmacy can be calculated and given a quantitive value which when added together provide an index, the Prescription Services Index (PSI), rating relative to the national average for all pharmacies.

- The index (PSI) for each pharmacy reflects an accurate calculation of costs involved in providing the drug product and pharmaceutical services to the patients served.

- The PSI method facilitates a means which would provide an equitable payment for each pharmacy based upon its own unique mode of operation and environmental conditions, matched against national parameters for similar operations in the country.

- A workable alternative reimbursement formula for third party prescription claims is proposed using Prescription Service Index as a means of establishing acceptable Rx price levels for individual prescriptions submitted by all pharmacies. It offers advantages over present methods for the program administrator, pharmacist, general public and taxpayer.

PROBLEMS WITH PRESENT REIMBURSEMENT METHODS

When pharmacists were asked to express their opinion via a mail survey in early 1970, there was found to be considerable dissatisfaction with several factors involving the process of reimbursement now in effect under third party pay programs and particularly the Medicaid/State Welfare Programs.

The factors most strongly criticized were those concerned with pricing such as:

- the level of reimbursement allowed
- the pricing method utilized

In addition, pharmacists were generally unhappy with claims processing as it concerned:

- the administrative tasks required of them and time involved
- the length of waiting time for reimbursement

PRICE DETERMINATION:

At the present time nearly every state has a reimbursement method which treats each vendor identically. The method generally involves, as part of the reimbursement formula, a component for product cost and another for dispensing cost. There is considerable dissatisfaction on the part of pharmacists that the system itself is too rigid in that allowances aren't made for individual pharmacy differences and,secondly, the formula for reimbursement is cumbersome and unduly involved.

Product Costs

An overwhelming majority of pharmacists (89%) responding to the survey did not favor the use of a formula which requires the calculation or determination of the actual acquisition cost. The main objection is the difficulty in determining actual acquisition cost for each prescription and, secondly, it penalizes those pharmacies that have been able to develop purchasing efficiency by employing good management skills.

A survey of 1933 pharmacies in the summer of 1970 shows that pharmacist purchasing of ethical drugs from the wholesaler or other source varies substantially:

PHARMACY PURCHASING DIFFERENCES

Ethical Drugs Purchased From Wholesaler	% Pharmacies
Less than 20%	12%
21 - 50%	39
51 - 80%	26
81 - 99%	22
100%	1
	100%

The table shows that not all pharmacies are alike with respect to purchasing. Secondly, it shows that within a given pharmacy the determination of actual acquisition cost can be different from item to item. The dilemma here is that the pharmacist finds this factor within the formula particularly difficult to cope with and the payer finds it an obstacle to efficient monitoring and control. Some programs using the acquisition cost have found it necessary to adopt the average wholesale price (AWP) whether the pharmacy purchased the ingredients below this price or not.

For certain products there is the added price difference based on larger quantity sizes. The decision to purchase, however, is often predicated upon product demand rates over which the pharmacist has no control as therapy is dependent upon disease incidence.

A study of new prescriptions dispensed for a typical drug within 322 pharmacies for a six-month time period showed the differences in the rate of sales to be as follows:

SALES OF A TYPICAL DRUG

# of Tablets Dispensed	% Pharmacies
None	13%
Less than 500	33
500 - 999	23
1000 - 1999	18
2000 or more	13
	100%

National Prescription Audit, November 1969-April 1970

The rate of purchase discount available for this product is of benefit to some pharmacies and of no benefit to others. The profile of nearly 7000 different products, brand and generic, filled in the 322 pharmacies show similar patterns; that is, some pharmacies dispense a larger volume than others and not necessarily because of total pharmacy volume. It is also an established fact that quantity purchase discounts vary considerably by product and by supplier and are subject to change over time. Pharmacists' inventories include merchandise purchased over a period of time.

The fixed fee approach requires the calculation of the actual ingredient cost or the average wholesale price, neither of which produces a realistic cost determination with the former creating an immense burden for the pharmacist and the latter, if used, superfluous for claims purposes.

Dispensing Costs

Most pharmacists (89%) are unhappy with an inflexible reimbursement system. In addition to the basic disagreement upon the method to be used, most pharmacists (67%) believe the level of reimbursement to be inadequate. The reason for the latter is that circumstances beyond the control of the pharmacist, unique to the pharmacy and its environment, frequently are responsible for variations in return on investment. As an entrepreneur he incurs considerable business risks in fulfilling the therapeutic requirements of his patrons.

Environmental Factors:

The pharmacist has little control over the disease incidence and drug usage patterns within his geographic area. Characteristics of the pharmacy clientele vary widely from one location to another. In addition, population shifts affecting socio-economic factors such as age, family concentration and per capita income are uncontrollable. This is an important consideration since the average price for prescriptions in selected therapeutic treatment areas varies considerably. Note that the average price of an Ataraxic prescription is nearly double the price of a typical prescription for a cough/cold product, ($5.34 vs. $2.76).

THERAPEUTIC CATEGORY DIFFERENCES

Therapeutic Category	% All Rx's Filled	Average Price	# Refills for Every 100 New Rx's
Antibiotics	21.4%	$4.69	34
Cough/Cold Preps	10.8	2.76	55
Analgesics	10.0	3.14	61
Hormones	8.0	3.94	161
Ataraxics	6.3	5.34	190
Sedative/Hypnotics	4.4	2.47	225
Cardiovasculars	4.3	4.58	250
Antispasmodics	2.7	3.73	153
Diuretics	2.7	4.22	199
Sulfonamides	2.3	3.63	57
All Others	27.1	3.97	110
All New Rx's	100.0%	$3.95	114

National Prescription Audit, November 1969 - April 1970

Also, the pharmacist can expect to fill an additional 190 prescriptions for every 100 Ataraxic Rx's filled. For cough/cold preparations, he can expect but nearly 1/3 as many refills. This again is beyond the control of the pharmacist - he does not create the "demand" for therapeutic agents.

Not only is the expected volume of total prescriptions filled, including new and refills, beyond the pharmacist's control, but the mix of therapeutic categories filled is left to the prevalence of disease patterns within the locale of the pharmacy. Based upon the refill factor alone, it is easily seen that programs allowing but one set formula for reimbursement would be difficult for the pharmacist to determine his return on investment nor exercise professional or management control in order to satisfy the demands of his clientele.

A study of the therapeutic category sales mix for a six months period found that no two stores were identical. Typically, where one pharmacy may fill more antibiotics as a proportion of the total prescription file, it would fill proportionately less for another treatment area.

To illustrate this product mix difference within a pharmacy, three typical pharmacies are shown as examples:

EXAMPLES OF DIFFERENCES IN THERAPEUTIC CATEGORY MIX

	% All New Rx's Filled			
Therapeutic Category	Pharmacy "A"	Pharmacy "B"	Pharmacy "C"	All Pharmacies
Antibiotics	9%	22%	34%	21.4%
Analgesics	8	10	4	10.0
Cough/Cold Preparations	4	12	19	10.8
Antispasmodics	14	2	1	2.7
Sulfonamides	1	3	4	2.3
Hormones	4	18	7	8.0
Ataraxics	8	4	4	6.3
Sedative/Hypnotics	6	3	1	4.4
Cardiovasculars	18	1	2	4.3
Diuretics	10	1	1	2.7
All Others	18	24	23	27.1

National Prescription Audit, November 1969 - April 1970

Although the ten therapeutic categories account for nearly the same proportion (77-82%) of the total prescription file within each pharmacy, there are distinct differences between each pharmacy in terms of selected categories. This table serves to point out that there are vast differences in types of therapeutic agents dispensed in each pharmacy. Pharmacies that fill a large proportion of their file for higher cost medication are allowed a much smaller return than those pharmacies that fill a high proportion of prescriptions in the lower priced therapeutic treatment areas.

As a professional, he is committed to serve the patients who come to him with the drugs they need available when they need them. The maintenance of the appropriate mix of inventory is a serious and costly obligation for which he should be reimbursed. To limit his trade to only a few fast turnover items for economic reasons is not in the best interests of his patients. A professional or dispensing fee developed by an individual pharmacy based upon its own historical and current experience with therapeutic agents, refill Rx and quantities it handles would be an appropriate one for that pharmacy.

A dispensing fee set arbitrarily for all pharmacies or even by arbitrary groups cannot possibly take the variations in therapy into consideration. Obviously, the pharmacist's regular charge to the general public does account for the uniqueness of his professional environment.

Another environmental factor over which the pharmacist has little control is the size of the prescription dispensed. Generally this decision is left to the discretion of the physician. Third-party program control and administration might well consider standard drug quantities rather than standard dispensing fees.

A study of prescription sizes for a six-month period shows that for a typical drug there may be as many as 50 different prescription sizes dispensed with the modal quantity size accounting for but less than half of all the prescriptions dispensed for the product.

To illustrate this point, the frequency distribution of quantity size for three typical products is presented:

PRESCRIPTION SIZE DIFFERENCES

	% Prescriptions Filled		
Rx Size	Drug "A"	Drug "B"	Drug "C"
9 or less	.3%	2.9%	2.6%
10 - 19	4.2	16.1	12.2
20 - 29	11.4	9.1	14.1
30 - 39	30.7	61.5	39.5
40 - 49	7.9	1.5	2.0
50 - 99	30.7	7.9	21.0
100 or more	14.8	1.0	8.5
# Rx's	(3945)	(1287)	(1569)

National Prescription Audit, November 1969-April 1970

CLAIMS PROCESSING PROBLEMS:

Claims Submission

There is considerable annoyance on the part of pharmacists with the difficulty in calculating a charge for a prescription when using a fixed fee alone or in combination with a percent markup since the average cost, whether average wholesale cost or true ingredient acquisition cost, is part of the formula and difficult to ascertain.

About two of every three (67%) pharmacists in the survey of 1933 pharmacists across the country stated that they were dissatisfied with the claim forms processing necessary for reimbursement under Federal or State supported programs. Most find it extremely time consuming.

Claims Waiting Period for Payment

Another point which creates undue financial hardship upon certain pharmacies is the matter of the length of waiting period necessary for reimbursement.

WAITING PERIOD FOR REIMBURSEMENT UNDER MEDICAID/STATE WELFARE PROGRAMS

% of Pharmacies	Waiting Period
32.3%	Over 60 days
2.5%	Over 120 days
.5%	Over 180 days

Only 19% of the pharmacies indicated that they routinely received payments in 30 days.

Private insurance programs show a much better record, with 50% of the pharmacies receiving payment in 30 days or less, and all but about 10% receiving payment in under 60 days.

Forty percent (40%) of the pharmacies indicated that the amounts owed to them under Medicaid were $1,000 or greater. Almost 6% indicated that their accounts receivable ran between $5,000 and $10,000. In those pharmacies that indicated a heavy Medicaid volume, that is 15% of their prescriptions or greater, 27.4% of them had to seek financial assistance from banks to meet their business obligations.

Surveys conducted in this study indicate a high degree of concern that pharmacists have with the development of third-party pay programs. Their opinions are based upon their experience with the various Medicaid programs which appear to be far less than 100% satisfactory in mode of operation and reimbursement in most states.

Perhaps the experience of Medicaid can serve the highly valuable purpose of indicating to third-party pay administrators that, if these programs are to be successful, all facets of this highly interactive system must be considered and systems developed which will recognize the needs and requirements of all pertinent factors.

CONSIDERATIONS IN THE DESIGN OF A METHOD:

In the final report submitted by the Task Force on Prescription Drugs of the U. S. Department of Health Education and Welfare, specific considerations are set forth in the implementation of a drug program providing direct reimbursement to the vendor. These criteria include:

- The level of payment submitted for reimbursement must be acceptable to the vendor (pharmacy).
- The reimbursement technique should minimize record-keeping and time consumed in claims submission required by the vendor.
- The method should allow the pharmacist to compute the program payment easily.
- The method should provide prompt payment.
- The method should permit a reasonable check on the accuracy or appropriateness of payments without resulting in very high auditing and accounting costs.

In view of the preceding, it is clear that the vendor reimbursement methods presently available have far from satisfied fully all of the above criteria.

It was with this background that a comprehensive statistical study focusing upon variability in prescription charges and pharmacy operating characteristics was conducted. Its purpose was to isolate more fully the factors which would aid in the design of an alternative reimbursement method which would satisfy the above requirements and result in other advantages.

RESEARCH BACKGROUND:

Earlier studies on the reimbursement problem concentrated upon determining the costs of filling a prescription by seeking detailed accounting and financial operating data about the prescription department. The difficulty with this approach is that the information required for analyses is not ordinarily available in the majority of pharmacies. To obtain it requires an inordinate amount of time on the part of the pharmacy owner or accountant, and adds to operating costs.

Data Description

Based upon this prior and unsatisfactory experience with studies involved with determining costs of filling a prescription, it was decided that the desired goal could be better achieved by obtaining extensive information about store environment and operations in as simple a form as possible and from as many pharmacies as possible. Over 10,000 randomly selected pharmacies in the country were sent a comprehensive questionnaire during the summer of 1970, and a 20% response was obtained on but one mailing, which was proportionate and representative of all types of pharmacies.

The owner or manager of each pharmacy was asked to provide data on specific areas involving the pharmacy's environment and operational characteristics. The areas involved were as follows:

Classification Data:

Location:
- Shopping Center (Plaza)
- Medical Building
- On Main Street
- Off Main Street

Area:
- Downtown Business Dist.
- Neighborhood/Residential
- Rural

Type:
- Single unit
- Multiple (2-3 units)
- Multiple (4 or more)

 # Years Store At Present Location:
- Less than 5 years
- 5-9 years
- 10-24 years
- 25 years or more

Hours Open Per Week:
- Less than 70 hours
- 70-79 hours
- 80-89 hours
- 90-99 hours
- 100 hours or more

Trading Area Served:
- Mostly within 1 mile
- Mostly within 3 miles
- Mostly within 5 miles
- Mostly within 10 miles
- Mostly beyond 10 miles

 # Competitive Pharmacies in Trading Area:
- None
- 1 or 2
- 3 or 4
- 5 to 9
- 10 or more

Size of Store: (Sq. Ft.)
- Less than 1000 sq. ft.
- 1000-1999 sq. ft.
- 2000-2999 sq. ft.
- 3000-5999 sq. ft.
- 6000-9999 sq. ft.
- 10,000 sq. ft. or more

Monthly Rent:
(If owned, estimate rent)
- Less than $250/month
- $ 250- 499/month
- $ 500- 749/month
- $ 750- 999/month
- $1000-1499/month
- $1500/month or more

Total Annual Store Sales:
- Less than $100,000
- $100-199,999
- $200-299,999
- $300-499,999
- $500-999,999
- $1,000,000 or more

Rx Sales As % Store Sales:
- Less than 25%
- 25-49%
- 50-74%
- 75% or more

Average # Rx's (new and refills) **Filled Per Day:**
- Less than 25 Rx's
- 25- 49 Rx's
- 50- 74 Rx's
- 75-149 Rx's
- 150-299 Rx's
- 300 Rx's or more

Ratio New To Refill Rx's:
- More refills than new
- New/refills about even
- More new than refills

Price Most Health & Beauty Aids At:
- Mfg. Sug. Retail Price
- 1- 9% off list
- 10-19% off list
- 20% or more off list

	Rx's Covered Under Federal/State Supported Programs	Rx's Covered Under Private Insurance Programs	Rx's By Charge Customers
% All Rx's Filled:	_____% all Rx's	_____% all Rx's	_____% all Rx's
Usual Waiting Period For Payment:	☐ Less than 1 month ☐ 1-2 months ☐ 3-4 months ☐ 5-6 months ☐ 7 months or more	☐ Less than 1 month ☐ 1-2 months ☐ 3-4 months ☐ 5-6 months ☐ 7 months or more	☐ Less than 1 month ☐ 1-2 months ☐ 3-4 months ☐ 5-6 months ☐ 7 months or more

% All Rx Drugs Purchased:

Direct ..... _____%

Wholesale ..... _____%

Coop. Buying Group ..... _____%

Central Warehouse ..... _____%

Other ..... _____%

ADDS TO: 100%

Those Which Apply To Store:

Open Sundays. # Hours _____

Open holidays. # Hours _____

Customer waiting area

Free vehicle Rx delivery

Emergency after-hour on-call service

A comprehensive drug information library

Pharmacy accepts all Rx's requiring compounding

Complete patient/family Rx record service (includes drug sensitivities)

Proportion Of Each Of The Following Activities Performed By A Pharmacist.

Purchasing Rx drugs
Checking in orders
Labeling, pricing and placing drugs into stock
Handling recalls and returns

Receiving Rx's directly from customer
Obtaining drugs from stock
Typing labels
Counting, pouring and packaging
Instructing customer on Rx use directions

Writing up charge/sales receipts
Preparing and sending bills
Reconciling accounts receivable
Selling non-legend drugs and med./surg. supplies
Selling sundries in pharmacy

Total # Hours Spent By <u>All</u> Pharmacists In Store:

Maintaining a comprehensive drug info. library

Maintaining a complete family Rx record service

Reading journals & professional publications

Reading drug company literature

Discussing drug & health care information with drug company detailmen

Attending seminars, continuing education courses & professional meetings

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Providing information on 3rd party pay programs to recipients

Providing drug & health care information and Rx use directions to customers

Providing drug & health care information to physicians, hospitals, nursing homes, ECF's

Providing drug & health care information to civic groups, local gov't. officials, local community, general public

The other key element in the study was obtaining from each pharmacy the prices charged for ten identical Rx's and a description of the pricing method employed. The ten Rx's were selected after an analysis of the National Rx Audit to obtain a representative cross section of both brand name and generic items of varying volume.

In obtaining this extensive information from each pharmacy, it was possible to allow many factors to be considered in determining the relative contribution of each to variations in price. The statistical analyses necessary in the study of the interaction of the attributes and prices were achieved using two advanced and comprehensive statistical programs and large capacity computers to handle the immense amount of data collected.

One program was obtained from the National Opinion Research Center at the University of Chicago for use in the multiple correlation and regression analyses of these data. The second came from Princeton University and was utilized for factor analysis.

Regression Analysis

It was necessary to consider all of the questionnaire variables simultaneously in order to properly measure the effect of each. To do this a mathematical technique called multiple regression was used. With the high speed computers utilized in the study there was no problem in analyzing the large number of variables over a wide range of values. Each of these variables was fitted to the "Prescription Services Index" and the slope coefficient calculated.

The "Prescription Services Index" for each pharmacy in the study was calculated by assigning the value of 100.000 to represent the grand average of all prices for the ten Rx's for all stores. The average for the ten items for each pharmacy was then compared to the national value of 100.000 to determine a relative index for each pharmacy. By converting the slopes into standard units, the questionnaire variables were ranked according to their influence on the index. A minus sign indicates a decrease in index per unit and an increase in questionnaire answering units. For example, the index over store decreases as the percentage of discount on health and beauty aids increases (increase in questionnaire answering units).

Factor Analysis

Prescription prices in 19 of the 50 states were significantly different from the national average prescription price. Each member of each group was adjusted for the average price difference of the group.

The remaining 69 variables were factor analyzed to reduce these 69 variables to the smallest meaningful dimensions. The first step was to reduce all the 1933 answers on 69 questions to 14 principal components. Each of these principal components was formed by applying a calculated weight to each of the 69 original variables. Using only 14 component factors, one is able to describe every store in relation to all other stores just as precisely as if one used the original 69 questions. That is, no loss of information has occurred. The difficulty is that all 69 question variables are present in every component.

To further simplify the questionnaire results, every one of the 69 original variables is expressed in terms of the 14 new principal components. It is as if we drew a graph with principal components as the principal axis and each variable as a point on the graph. Most of the points representing our original 69 variables will be somewhere between the 14 principal component axes. The object is to twist or rotate this system of 14 axes so as to end up with each variable as close as possible to one of the 14. We wish to express each variable as a member of one of these 14 groups rather than as a point off in space by itself.

This is easy to see in two dimensions on a simple X, Y Cartesian diagram. If a variable is one-half X and one-half Y, it could be plotted as the point (1/2, 1/2) half way between X and Y axes. If we twist or rotate the axis, the point can be made to lie exactly on X or on Y, depending on which direction we rotate. This simple process generalizes directly to the fourteen principal component coordinate axes system in the survey.

Of course, all 69 variables are not directly over each of the 14 axes, but they end up very close. We know this to be true because we have already shown that the questionnaire variables have only 14 principal components. The variables are then rearranged according to the closest axis. This gives us our final factor groupings.

All of the 69 variables were regressed or fitted to price and their statistical contribution was noted. All non-significant variables were eliminated from these groupings and the identity of the variables in the final factors was established.

The interactive nature of these variables and their identity with various types of store operation was resolved into eight principal factors by factor analysis with each including a set of variables. In total, 36 different variables were isolated as significant, as shown in the following table:

FACTORS IN THE MODEL DEVELOPMENT OF PRESCRIPTION SERVICES INDEX

		Slope Coefficient
I EXTERNAL FACTORS		
1. REGIONAL ADJUSTMENT (State Grouping)...		
GROUP A:	California, Nevada	14.04261
GROUP B:	Rhode Island	-13.97720
GROUP C:	Connecticut, New Jersey	3.98068
GROUP D:	New Mexico, Washington	4.04400
GROUP E:	Arizona, Delaware, Indiana, Vermont	- 6.56598
GROUP F:	Maryland, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Tennessee, West Virginia	- 3.25818
GROUP G:	Alabama, Arkansas, Colorado, Dist. Columbia, Florida, Georgia, Idaho Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New York, Oregon, South Carolina, South Dakota, Texas, Utah, Virginia, Wisconsin, Wyoming	- 0.76602

	Slope Coefficient
2. URBANIZATION AND INCOME LEVEL...	
a. Average per capita income for city or town	0.00073
b. Trading area served in miles	- 0.80736
c. Number competitive pharmacies in trading area	- 0.31024
d. Average hourly wage of registered pharmacist	0.85574
e. Average hourly wage of non-pharmacist	0.79579
3. STORE CHARACTERISTICS...	
a. Store under single ownership	1.40695
b. Years in present location	0.58815
c. Size in square footage	0.22980
d. Rental expense	0.46918
e. Store location (shopping center or not)	- 1.73535
f. Total hours open per week	0.50803
g. Daily prescription volume	- 2.40675
h. Health and Beauty Aid discount policy	- 3.31002
4. THIRD PARTY PAY PRESCRIPTION INVOLVEMENT...	
a. Federal/State program Rx's as % of all Rx's Rx's	0.05585
b. Private Insurance program Rx's as % of all Rx's	0.12331
c. Usual Waiting Period for payment of Third Party program prescriptions	0.60169
II INTERNAL FACTORS	
1. SPECIAL CUSTOMER SERVICES...	
a. Percent Rx's charged by customers	0.07640
b. Usual waiting period for charge customer payments	0.82979
c. Prescription sales as % total store sales	1.05402
d. Provide free vehicle delivery service	2.00840
e. Provide patient/family Rx record service	1.44448
f. Provide customer waiting area	0.63150
2. SOURCE OF DRUGS PRUCHASED...	
a. % Rx's purchased direct	- 0.04314
b. % Rx's purchased through wholesaler	0.02497
c. % Rx's obtained from central warehouse	- 0.05951

	Slope Coefficient
3. PERSONNEL DEPLOYMENT...	
a. % time typing of labels is done by R.Ph	- 0.05951
b. % time counting, pouring & packaging is done by R.Ph.	0.79975
c. % time handling recall & returns is done by R.Ph.	- 0.26869
d. % time preparing & sending bills is done by R.Ph.	- 0.29832
e. % time non-legend drugs and medical/ surgical supplies are sold by R.Ph.	- 0.38105
f. % time the instruction of customers on Rx use direction is done by R.Ph.	0.79421
4. COMMUNITY RELATIONS AND PROFESSIONAL DEVELOPMENT...	
a. Hours attending seminars, courses and professional meetings per week	1.19288
b. Hours reading journals and professional publications per week	1.08939
c. Hours reading drug company literature per week	- 0.98091
d. Hours providing drug and health care information and Rx use instruction to customers per week	0.54750

The factor analysis procedure has grouped the variables into sections or factors where interdependence exists. Reliance must not be placed upon the index weight associated with any single variable. But, since the entire factor group as a whole is included, this weight is reliable and the statistical significance of these factor increments to the prescription services index is impressive. The t-scores for the factors are displayed.

T-SCORES FOR THE EIGHT FACTOR GROUPINGS

Factor	t-score
Regional Adjustment	19.7
Urbanization and Income Level	7.3
Store Characteristics	18.3
Third Party Pay Prescription Involvement	5.9
Special Customer Services	11.4
Source of Drugs Purchased	6.7
Personnel Deployment	4.9
Community Relations and Professional Development	4.8

A t-score of 1.96 is significant at the .05 risk level. These factors are all a multiple of this threshold value. Those factors with the highest t-scores are also those with the greatest effect upon the prescription services index.

Such confidence as this illustration provides is necessary for weak factors would make interpretation difficult. Because of the very large number of respondents, the relations reported here are not only well-established statistically, but represent what are believed to be the facts of operational expenses.

For each of the variables, slope coefficient is calculated from the regression analysis. We need only multiply this slope by the score to obtain a prescription services index increment for each variable separately. The sum of all of these increments (or decrements) will be the final estimate of the prescription services index for that store.

PSI Prediction Model

The precise value for the questionnaire coding deserves discussion. In this study it is assumed that responses from 1933 pharmacies represent all the pharmacies in the country. If the average prescription services index is set at 100.00, the basis for every questionnaire variable is also the average for all stores. The advantage of this procedure is that the basic format now has a constant term of 100.00, which is incremented (or decremented) according to the pharmacy response to each question.

For instance, if a store purchases 10% direct, 90% from wholesaler and 0% from central warehouse, the following calculation would result for that store:

AN EXAMPLE OF THE CALCULATION OF THE EFFECT OF ONE VARIABLE

Variable	(1) Slope Coefficient	National Average	(2) Deviation from National Average	(1) X (2) Increment
Direct Purchase	- .04314	36.783	- 26.783	1.1554
Wholesale Purchase	.02497	53.452	36.548	.9126
Central Warehouse Purchase	- .05951	5.949	- 5.949	.3540
Total				2.4220

This pharmacy (Pharmacy A on the next page), as a result, would be expected to gain 2.4 points on its prescription services index. This, together with all other variables, would sum to the total expected prescription services index of the pharmacy.

The following pages illustrate ten typical pharmacies and the index points each would gain or lose relative to its description and activity within each of the eight groupings. The sum of the eight identifies the individual store index. Note that these ten pharmacies are quite dissimilar from one another and that one pharmacy is more than 27 points above the national average. This represented a difference of more than a $2.00 charge on each prescription between each pharmacy (one charged 71.4% more than the other). Despite these variances, the model predicted the indices for these pharmacies within four cents or one percentage point.

FACTORS DETERMINED TO BE STATISTICALLY SIGNIGICANT:

I. EXTERNAL FACTORS	STORE A	STORE B	STORE C
1. Regional Adjustment (State Grouping) ..	+14.043 (Cal)	-6.566 (Ind)	-3.258 (Pa)
2. Urbanization and Income Level ..	+2.851	-1.257	-1.662
a. Average per capita income for city or town	$3616	$2774	$2716
b. Trading area served in miles	5 miles	10 miles	10 miles
c. Number competitive pharmacies in trading area	5 - 9	3 - 4	None
d. Average hourly wage of registered pharmacist	$8.00	$5.80	$5.00
e. Average hourly wage of non-pharmacist	$3.20	$1.80	$1.40
3. Store Characteristics ..	+4.986	-9.322	-1.601
a. Store under single ownership	Yes	No	Yes
b. Years in present location	10-24 yrs.	5-9 yrs.	< 5 yrs.
c. Size in square footage	< 1000 sq.ft.	6000-9999 sq.ft.	2000-2999 sq. ft.
d. Rental expense	$250-499/mo.	$1000-1499/mo.	< $250/mo.
e. Store location (shopping center or not)	No	Yes	No
f. Total hours open per week	< 70 hrs.	90-99 hrs.	< 70 hrs.
g. Daily prescription volume	25-49 Rx's	150-299 Rx's	75-149 Rx's
h. Health and Beauty Aid discount policy	List	10-19% off list	List
4. Third Party Pay Prescription Involvement ..	+0.190	-0.379	-0.238
a. Federal/State program Rx's as % of all Rx's	10%	13%	15%
b. Private Insurance program Rx's as % of all Rx's	5%	4.5%	1%
c. Usual Waiting Period for payment of Third Party program prescriptions	3-4 months	1-2 months	3-4 months
II. INTERNAL FACTORS			
1. Special Customer Services ..	+3.967	-2.203	-3.363
a. Percent Rx's charged by customers	50%	25%	5%
b. Usual waiting period for charge customer payments	1-2 months	1-2 months	< 1 month
c. Prescription sales as % total store sales	75% or more	25-49%	50-75%
d. Provide free vehicle delivery service	Yes	No	No
e. Provide patient/family Rx record service	No	No	No
f. Provide customer waiting area	Yes	Yes	Yes
2. Source of Drugs Purchased ..	+2.422	-4.500	-0.302
a. % Rx's purchased direct	10%	0%	50%
b. % Rx's purchased through wholesaler	90%	10%	50%
c. % Rx's obtained from central warehouse	0%	90%	0%
3. Personnel Deployment ..	-1.627	-0.983	+0.194
a. % time typing of labels is done by R.Ph.	100%	100%	100%
b. % time counting, pouring & packaging is done by R.Ph.	75%	50%	100%
c. % time handling recall & returns is done by R.Ph.	75%	50%	100%
d. % time preparing & sending bills is done by R.Ph.	0%	0%	25%
e. % time non-legend drugs and medical/surgical supplies are sold by R.Ph.	50%	25%	50%
f. % time the instruction of customers on Rx use direction is done by R.Ph.	50%	75%	100%
4. Community Relations and Professional Development ..	+0.362	-0.722	-0.185
a. Hours attending seminars, courses and professional meetings per week	1-5 hours	None	1-5 hours
b. Hours reading journals and professional publications per week	1-5 hours	6-10 hours	1-5 hours
c. Hours reading drug company literature per week	1-5 hours	6-10 hours	1-5 hours
d. Hours providing drug and health care information and Rx use instruction to customers per week	6-10 hours	6-10 hours	1-5 hours
STORE PRESCRIPTION SERVICES INDEX:	127.194	74.068	89.565
NATIONAL INDEX:*	100.000	100.000	100.000
DEVIATION:	+27.194	-25.932	-10.435

* *Based upon 1,933 pharmacies surveyed*

PRESCRIPTION SERVICES INDICES FOR SELECTED STORE EXAMPLES

STORE D	STORE E	STORE F	STORE G	STORE H	STORE I	STORE J
-0.766 (Tex)	-0.766 (Ark)	+4.044 (Wash)	-0.766 (Mass)	-0.766 (Wisc)	+3.980 (NJ)	-3.258 (Tenn)
-2.014	-1.506	+1.866	+1.095	-1.083	-0.233	-3.707
$2375	$2047	$4119	$2961	$2972	$3550	$1817
10 miles	10 miles	1 mile	1 mile	10 miles	10 miles	Beyond 10 miles
10 or more	5 - 9	10 or more	1 - 2	5 - 9	5 - 9	3 - 4
$5.78	$5.78	$6.00	$5.00	$6.00	$6.50	$4.50
$2.01	$1.85-2.15	$1.75-2.25	$1.90-2.10	$2.00	$2.05	$1.80-2.00
-0.297	-7.235	+5.245	+6.420	-2.764	+2.140	+3.307
Yes	Yes	No	Yes	No	Yes	Yes
25 yrs. or more	< 5 years	25 yrs.or more	25 yrs.or more	< 5 years	5-9 yrs.	25 yrs.or more
< 1000 sq.ft.	< 1000 sq.ft.	3000-5999 sq.ft.	1000-1999 sq.ft.	6000-9999 sq.ft.	1000-1999 sq.ft.	3000-5999 sq.ft
< $250/mo.	$500-749/mo.	$500-749/mo.	$250-499/mo.	$750-999/mo.	$250-499/mo.	< $250/mo.
No	No	No	No	Yes	No	No
< 70 hrs.	70-79 hrs.	70-79 hrs.	70-79 hrs.	80-89 hrs.	70-79 hrs.	70-79 hrs.
75-149 Rx's	75-149 Rx's	25-49 Rx's	< 25 Rx's	50-74 Rx's	50-74 Rx's	50-74 Rx's
List	10-19% off list	List	List	1-9% off list	List	List
-1.669	-0.350	-1.506	-1.140	-1.060	-0.320	+0.426
0%	1%	10%	0%	5%	5%	25%
0%	1%	1%	0%	2%	8%	5%
-	1-2 months	< 1 month	-	1-2 months	1-2 months	1-2 months
+8.532	-3.669	-2.172	-5.809	+0.247	+2.671	-1.005
80%	1%	3%	0%	10%	50%	25%
3-4 months	< 1 month	< 1 month	-	1-2 months	1-2 months	1-2 months
75% or more	50-74%	< 25%	< 25%	25-49%	25-49%	50-74%
Yes	No	Yes	No	Yes	Yes	No
Yes	No	Yes	No	Yes	Yes	No
Yes	Yes	Yes	No	Yes	No	Yes
-0.302	-0.719	+2.422	0.000	-0.302	+1.740	+0.253
50%	35%	10%	37%	50%	20%	45%
50%	65%	90%	57%	50%	80%	55%
0%	0%	0%	6%	0%	0%	0%
+3.745	-0.700	+0.194	-0.281	+0.492	+0.492	-0.104
25%	100%	100%	100%	100%	100%	100%
100%	100%	100%	100%	100%	100%	100%
75%	100%	100%	100%	100%	100%	100%
0	100%	25%	0%	0%	0%	50%
50%	50%	50%	75%	50%	50%	50%
100%	100%	100%	100%	100%	100%	100%
+0.362	-0.185	+0.362	-1.378	+0.367	+1.451	-1.378
1-5 hours	1-5 hours	1-5 hours	None	1-5 hours	1-5 hours	None
1-5 hours	1-5 hours	1-5 hours	1-5 hours	None	6-10 hours	1-5 hours
1-5 hours	1-5 hours	1-5 hours	1-5 hours	1-5 hours	1-5 hours	1-5 hours
6-10 hours	1-5 hours	6-10 hours	1-5 hours	15 hrs. or more	6-10 hours	1-5 hours
107.721	86.308	110.455	98.141	95.131	111.921	94.534
100.000	100.000	100.000	100.000	100.000	100.000	100.000
+ 7.721	-13.692	+10.455	- 1.859	- 4.869	+11.921	- 5.466

Research Conclusions

- Factors causing price variability can be identified.
- The contribution to price for each factor can be quantified.
- An index relative to a national average for each pharmacy can be determined based upon the varying presence of certain factors readily available.
- The calculated index (PSI) for each pharmacy includes an accurate reflection of the costs of that pharmacy to provide the drug product and pharmaceutical services to the patients served.
- The PSI can provide the basis for the design of a reimbursement method which would provide an equitable payment for each pharmacy based upon its environmental and operational characteristics profile.

A DESCRIPTION OF THE USE OF THE PSI METHOD IN A REIMBURSEMENT SYSTEM:

The prescription Services Index (PSI) for each pharmacy is easily calculated from information supplied by the pharmacy on an annual (or semi-annual) basis. Periodic verification and spot checking of facts supplied is left to the discretion of the administrator and would require less time and work than current audit procedures.

Secondly, the current prices charged to the general public for identical prescriptions would serve as the Rx Price Reference source. Prices charged throughout the nation for nearly one million new prescriptions at various quantity levels for approximately 7000 different products are in existence and available from the National Prescription Audit (NPA) or could be obtained from a similarly designed study.

The two sets of information, the PSI and the Rx Price Reference, allow the method to work smoothly.

For example, assume two different pharmacies (Universal Pharmacy Code numbers #999999 and #999998) submit a claim for Vilox 10mg #30 (National Drug Code number XYZ-VLOX-01). One pharmacy (#999999) with a PSI of 107.00 submits a charge of $4.25 while the other pharmacy (#999998) with a PSI of 84.00 submits a charge for $3.85

The average price for the nation for XYZ-VLOX-01 (#30 tablets) shows a figure of $4.00, as shown in the National Rx Price Reference File.

An example of an acceptable claim:

(Price shown in National Rx Price Reference File)	times	(Pharmacy #999999 PSI)	equals	[Highest Acceptable Price]
$4.00	X	107.00	=	$4.28

Charge Submitted = $4.25 - Claim approved, payment made immediately

An example of an unacceptable claim:

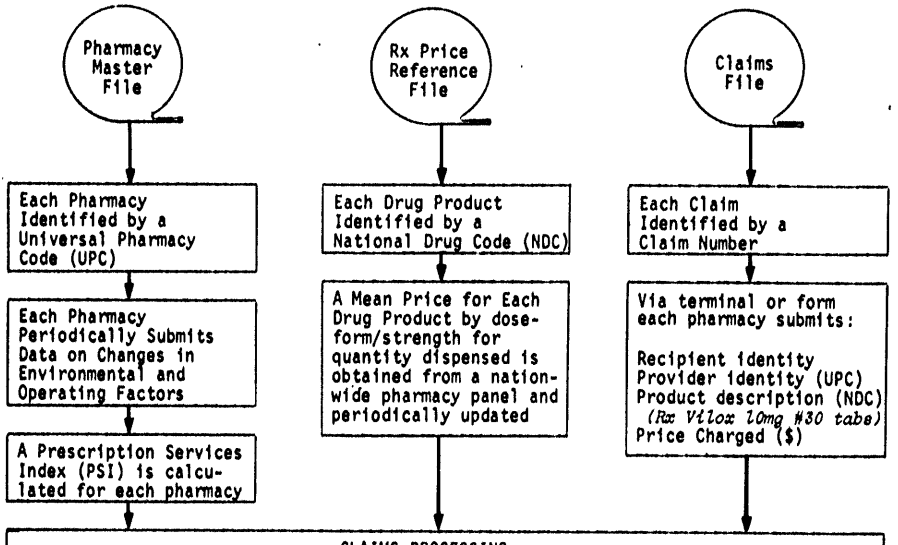
(Price shown in National Rx Price Reference File)	times	(Pharmacy #999998 PSI)	equals	[Highest Acceptable Price]
$4.00	X	84.00	=	$3.36

Charge Submitted = $3.85 - Claim disapproved, price adjustment required

To allow for minor variations in prices that might occur for pharmacies with an identical PSI number, standard deviations can be applied to the Rx Price Reference figure.

PRESCRIPTION SERVICES INDEX

Third-Party-Pay Prescription Claims System



CLAIMS PROCESSING

STEPS INVOLVED	CLAIM 1	CLAIM 2
1 Recipient Eligibility Established	Mary Smith 000-9999-11	John Doe 000-8888-22
2 Claim Record Identifies:		
Universal Pharmacy Code (UPC)	999999	999998
Prescription Services Index (PSI)	107.00	84.00
National Drug Code (NDC)	XYZ-VLOX-01	XYZ-VLOX-01
Price Charged ($)	$4.25	$3.85
3 Average Price for Nation for NDC (XYZ-VLOX-01)	$4.00	$4.00
4 An Acceptable Price Limit is Calculated (NDC AVG. PRICE X PSI)	$4.28	$3.36
5 Price on Claim with Limit of Acceptability is Determined	Acceptable Claim Paid Promptly	Non-acceptable Price Adjustment Required

Ongoing Research on Modal quantities, price variations, characteristics, drug utilization and review, price and quantity monitoring

Satisfaction of Criteria

STEPS INVOLVED WITH THE PSI METHOD:	SATISFACTION OF SPECIFIC TASK FORCE CONSIDERATIONS:
1 Pharmacy periodically fills and submits data on changes in environmental and operating factors.	. Information sought is readily available or retrievable, and is not confidential. . Eliminates need for detailed P&L or other accounting data which for the most part is not available in the form needed to establish "cost of filling an Rx."
2 Pharmacist fills and dispenses third party Rx as does all others and charges same price as he would to general public.	. Same price to all customers and patients. No double standard for professional service. . Prices respond to competitive pressures. Additional costs of 3rd party paperwork, etc., spread over full base of Rx's. . Simplified reporting for claims - only Rx price is needed - acquisition cost not essential for claim processing. AWP can be made part of computer input.
3 Pharmacist submits claim to processor via terminal or form.	. Allows for flexibility and accommodation of all pharmacies, using terminal or not. . If form used, sight draft concept is compatible.
4 Processor using national drug code and universal pharmacy code compares claim amount for quantity with national data base audit of amounts and prices and PSI for pharmacy - accepts or "rejects" claim.	. Simple, uncomplicated computer method for processing. . Eliminates unwieldy validation of actual acquisition cost for each Rx. . Speeds claim processing time, keeps cost at minimum. . Provides administration with realistic method for establishing limits for range of acceptable prices.

THE ADVANTAGES OF THE PSI METHOD:

Advantage for the Program Administrator

- Method allows the more efficient control of costs through facile review of pricing abuse.
- Method can be easily integrated into a fully automated data processing system.
- Method can easily be interfaced with other vendor systems.
- Method would allow quick data retrieval by use of single comprehensive nomenclature and National Drug Code System.
- Method works equally well with or without a scientifically designed formulary.
- Method would provide means to implement an effective utilization review as comparisons with general public Rx's easily accomplished with National Rx Price Reference source.
- Method is simple and easy to control.

Advantages for the Pharmacist

- Method does not hinder dedicated pharmacist who provides service at reasonable cost.
- Method identifies only those who are charging in excess of norm for all pharmacies operating under similar circumstances.
- Method allows competition to work on prices in private enterprise. Low price, non-service operations are paid at usual low price.
- Method allows for quicker payment and reduces claims submission time.
- Method monitors those pharmacies that are consistently over-priced or under-priced.
- Method monitors, via National Prescription Data Panel, prescription prices for all items and quantities to show shifts in price levels, up or down, allowing for constant and current revision of upper and lower limits of acceptable prices.

- Method by use of an automated data processing system would minimize time spent in claims processing.
- Method allows each pharmacy to use its normal pricing method whether fixed fee, variable fee, percent markup, or a combination of all and thereby eliminates any further disagreement on primary methodology.
- Method eliminates the difficult-to-establish acquisition cost of each drug and uses the operational expenses of the pharmacy as the reimbursement criteria.
- Method is easily implemented and simple to understand.

Advantages to the Patient and the General Public

- Method optimizes patient care and encourages continued physician prudence in the choice of medication.
- Method encourages participation in programs and provides incentives for pharmacists to assume new responsibilities in the health care of patients.
- Method eliminates double standard in pricing. It uses prices to non-beneficiaries as standard reference for pricing to beneficiaries and eliminates non-beneficiary subsidization of beneficiary costs.
- Method encourages competitive pricing and private enterprise.
- Method satisfies the taxpayer since it minimizes program costs.

Summary

A workable alternative to the present reimbursement formulas in the processing of third party prescription claims is the use of a pharmacy prescription service index rating system and the regular prices charged to the general public. For the above reasons it offers the most equitable solution for all parties while keeping costs at a minimum and satisfying all the necessary criteria for efficient administration.

Mr. WOODS. Now, I would like, in the interest of time, to discuss the vendor program and freedom of choice.

Speaking generally, NARD believes that one of the major weaknesses and deficiencies in current health care programs, both public and private, is the absence of or inadequate provisions for pharmaceutical services. We believe that one of the major strengths in the health care system is the thousands of independent community pharmacies readily accessible to virtually every segment of the population.

Any revisions in the Federal health care programs, or any legislation governing private health care programs should seek to correct this deficiency and capitalize on the strengths of the existing retail distribution network for drugs.

The vendor program for providing drugs has proved acceptable in medicaid. In fact, the change to the vendor program concept in health care was established in the last decade by the Kerr-Mills program which was initiated by the distinguished chairman of this committee. While NARD members have had many complaints about the actual administration by individual States of the vendor program under first the Kerr-Mills legislation and later under the modifications made by medicaid, the strength of the vendor concept is a valid today as it was in 1960.

Another important, indeed essential, concept that has stood the test of time in medicare and medicaid is the freedom of choice guaranteed to patients to select any qualified provider of services to furnish needed health care services. We believe that freedom to choose the health care practitioner is a strength of the current Federal programs and should be retained in any future program.

Combined, these two concepts—vendor program and freedom of choice—permit and preserve an opportunity for the traditional forces in our competitive enterprise system to assure that the quality of care and services will not deteriorate merely because the Government may be paying all or part of the costs.

PROVIDER VOICE IN PROGRAM DESIGN

None of the proposals before the committee permits or assures the providers of service an adequate role or voice in the design, operation and administration of the programs. This summer, at the request of the National Association of Retail Druggists, a subcommittee of the House Select Committee on Small Business held 3 days of hearings on the impact of third party payment programs and the record of those hearings details the problems and issues of greatest concern to independent pharmacists.

Basically, however, the complaints stem from a common cause—that of giving all interested parties in the drug program, except the pharmacists who must economically and professionally survive under them, a significant role in the design and planning. Nearly without exception, program sponsors such as big business, big insurance companies and big unions have designed and implemented a drug program from a supposedly bureaucratic vantage point in both private and Government programs which program was then placed before each pharmacist on a take it or leave it basis. With the experience of op-

erating under existing programs, most NARD members could contribute significantly to improving the design and administration of these programs while not detracting from the overall program goals.

We strongly urge that the committee consider individual provider panels for each benefit area covered and charge these provider panels with the responsibility for developing the design, operation and supervision of the administration of the benefits furnished by their provider group. We recognize that the benefits must be coordinated and control must be vested in the responsible governmental agency, but the providers should be given the first opportunity to recommend an administrative plan compatible with existing practices and procedures and with the overall program goals.

We appreciate this opportunity to appear before you on behalf of the members of the National Association of Retail Druggists. We have not commented in detail on the various national health insurance proposals for the reasons we have stated, but we hope we might have the opportunity of furnishing the committee additional written statements and supplementary materials as the committee drafts legislative recommendations concerning this important subject. We are anxious to be of continuing assistance particularly in matters concerning drug coverage.

Thank you, sir.

Mr. GREEN (presiding). Thank you very much, Mr. Woods.

I am sorry that I came in late for your testimony. As you may or may not understand, at the moment there is a quorum call going on and members have been going to the floor. We thank you for your contribution.

Mr. WOODS. That is all right. Thank you very much. We appreciate appearing.

Mr. GREEN. The next scheduled witness is Mrs. Bernice M. Hemphill. Is Mrs. Hemphill here?

Off the record.

(Discussion off the record.)

Mr. GREEN. I am going to suspend these hearings for 10 minutes and answer the quorum call myself and by then one or the other of us will be able to return. I ask your indulgence for 10 minutes.

Thank you.

(A brief recess was taken.)

Mr. ULLMAN (presiding). The committee will be in order.

Is Mr. Connelly here? In the interest of time we will move out of order and hear you, Mr. Connelly.

If you will further identify yourself and your colleague for the record, we will be happy to recognize you.

STATEMENT OF HARRELL CONNELLY, DIRECTOR, PROFESSIONAL RELATIONS, AMERICAN SOCIETY OF MEDICAL TECHNOLOGISTS; ACCOMPANIED BY MISS THELMA WILSON, IMMEDIATE PAST PRESIDENT

Mr. CONNELLY. Mr. Chairman, I am Harrell L. Connelly, director of professional relations with the American Society of Medical Tech-

nologists located in Houston, Tex. As a member of the executive office staff my responsibilities include providing consultative and resource service to the society's personnel relations committee and the government liaison committee.

I am here today representing the American Society of Medical Technologists. Accompanying me today is Miss Thelma Wilson, administrative technologist, the Appalachian Regional Hospital in Beckley, W. Va., and also immediate past-president of this organization.

Mr. ULLMAN. We are happy to have you here. You are recognized.

Mr. CONNELLY. Thank you.

The American Society of Medical Technologists is a national professional organization composed of approximately 21,000 members engaged in the supervision and the performance of clinical laboratory tests. Included in the membership are supervisors with graduate degrees, technologists with baccalaureate degrees, and technicians with education ranging from 2 years of college to on-the-job training. Our organization believes it has major responsibilities for increasing technical knowledge, providing means for members to evaluate and improve their performance, and education of students entering the various levels of clinical laboratory practice. The ultimate goal of our society is the provision of the best possible care to the patient at economically sound levels. I wish to thank you for allowing me to present our views on pertinent issues involved in the concept of national health insurance legislation.

We have not adopted a preference for any particular bill. Instead, we have compiled a set of principles regarding clinical laboratory services under federally assisted health programs. These principles should be considered for inclusion in whatever legislation the committee approves.

Dr. M. M. Brooke, of the Lavoratory Division, National Center for Disease Control, in a paper published in "Public Health Reports," states—

> With assurance of payment of laboratory bills through health programs, the development of automated laboratory procedures, the establishment of mass screening programs, and the growth of comprehensive health insurance plans, the number of laboratory tests in this country may increase from an estimated 1,800 million now to more than 8 billion by 1975.

Obviously, payment for such vast numbers of laboratory procedures will constitute a significant amount of the cost of any national health insurance program.

Dr. Brooke, in the above cited report, also states—

> (. . . tests from . . .) All types of medical laboratories—independent, hospital, and public health—are now generally recognized as subject to error, and we can therefore proceed with the task of improving laboratory services.

Already the increased number of tests being performed under medicare and medicaid has required the use of automated screening techniques. The results of screening tests are examined; those producing abnormal results are then repeated and further tests ordered to evaluate the patient's condition. In actuality, when automated equipment is used, test values are spewed out very rapidly, but proper supervision is essential to insure that these values are correct. The instruments utilized should be constantly supervised by persons who have the educational

background to fully understand the theoretical concepts upon which these instruments are based, their standardization or the limits of their capabilities. If these machines are operated by individuals who do not adequately understand the operation, the test values may be erroneous and may be abnormal—meaning the patient will be studied further. Equally possible is for the results to appear normal, when in fact they should have been abnormal. In this case, the patient is not followed up as soon as might have occurred with accurate test values. He thus can suffer irreparable harm, and the unnecessary additional costs of more lab tests and extended hospital stay.

Programs in proficiency testing to improve the quality of laboratory tests have been developed by the American Society of Clinical Pathologists, the College of American Pathologists, the American Association of Bioanalysts, Proficiency Testing Service, Inc., and several commercial companies. In addition, the College of American Pathologists has developed a program which includes not only proficiency testing, but inspection of the laboratory equipment, staffing and performance. While the quality of these programs is continually improving, participation is voluntary, thus limiting the potential benefits to laboratories which recognize the need for evaluation and improvement. With voluntary participation, there is no mandate for improvement if defects or poor performance is encountered. Even more discouraging is the fact that those who do not voluntarily participate are often those who need it most.

The Joint Commission on Accreditation of Hospitals (JCAH) conducts surveys of hospital laboratories in conjunction with their general inspection and review program. Usually the surveyor has limited knowledge in laboratory operation. He collects data which includes the number and type of personnel, procedures performed, methods of recordkeeping, and visible records of a quality control program. The only specific requirement for laboratory personnel under JCAH standards is that procedures be carried out by competent personnel with at least one qualified medical technologist on duty or available at all times. Laboratories receiving approval from the joint commission are automatically exempt from the need to comply with standards established in the medicare regulations.

A laboratory not located in an accredited hospital must meet Federal standards in order to receive payment for tests under medicare. These standards are largely concerned with qualifications for clinical laboratory personnel. Hospital laboratories, therefore, may receive payment for medicare-covered procedures, while complying with JCAH regulations, a different and far less stringent set of standards.

The Clinical Laboratory Improvement Act of 1967 provides Federal licensure of clinical laboratories engaged in interstate commerce. This act emphasizes proficiency testing and internal quality control in an effort to insure the accuracy of test results. Again, most hospital laboratories are not covered by these regulations, since they do not engage in interstate commerce.

More than half of the States in the country have some form of licensure regulations affecting clinical laboratory personnel or procedures. There is no currently accepted standard observed in State licensing

regulations, and as a result, great variation exists from State to State. Some regulate the training or evaluate the performance of laboratory personnel; others attempt to test and evaluate the quality of work performed, while others are largely ineffectual and merely maintain the status quo.

In some States laboratories which qualify for JCAH, Medicare and/or CLIA are exempt from the State law—thus, only a small portion of laboratories are covered by these State laws.

In all States laboratories operated by Federal or local government are exempt as are the laboratories maintained in a physician's office for his own patients.

Federal regulations have sometimes tended to compound confusion by attempting to achieve similar goals by widely differing methods. For example: Medicare regulations attempt to insure quality by evaluating personnel, while Clinical Laboratory Improvement Act regulations control quality by evaluating the product and the technical performance. As pointed out in the Auerbach report, there is an urgent need for the various Government agencies to bring their criteria into one set of standards.

Proficiency testing as required under medicare and the Clinical Laboratory Improvement Act is either conducted under a State Health Department or, in the latter, through the Center for Disease Control (CDC) of HEW. In this context, proficiency testing is the evaluation of test accuracy by providing a substance which the laboratory analyzes. Results are then measured against the known value—a standard quality control process.

In several bills before this Congress demonstration of proficiency is cited as a means of qualifying personnel—especially those who have not met specific educational and/or certification criteria. In some circles this is meant to be a paper and pencil examination. How successful such an examination will be remains to be seen. It should be noted that paper and pencil tests have definite limitations in the ability to measure attitudes and psychomotor skills, as well as limitations in the ability to adjust to technological change. In some States proficiency means a challenge exam which a student takes to receive academic credit for knowledge he has gained by other means. The American Society of Medical Technologists urges that those persons considering laboratory standards of performance and personnel be very careful to designate the exact meaning assigned to the term "proficiency testing." Further, we believe that all appropriate professional societies should be utilized to help develop and evaluate any proficiency testing examination prior to its adoption.

The Government, organized medicine, and the public have created a sudden surge of interest and action devoted to improvement of laboratory services. Resulting is a complicated array of confusing and often conflicting standards, rules and regulations. The second annual report of the Health Insurance Benefits Advisory Council of HEW states—

> The Council is also concerned that the emphasis on the development of mechanism for cost control may deflect interest and effort from an even more important goal—the need to relate the cost of a given health service to the substance and

quality of the service rendered. The determination of the relationship of cost to quality requires the development of more precise measurements of quality. The Council, therefore, urges that the highest priority be given to the development of such measurements.

Many concerned allied health professions are seeking to protect the patient through better definition of performance standards for practioners while also evaluating ways to delegate tasks to lesser trained individuals. This plan could reduce health costs while maintaining quality care. Personnel standards are best enforced by effective licensure regulations. Licensure efforts have been hampered this year by the national moratorium on licensure declared by the American Association and the American Hospital Association. It is indicated that a comprehensive study of the problem will be made. A mechanism for this study is under consideration, but we have not seen an acceptable means for evaluating the results of the study, nor have we seen the development of the plan for implementing recommendations. We believe the following statements summarize the present situation:

1. There is a continuing need to assure the public the highest quality laboratory performance possible.

2. Due consideration must be given to cutting the costs of laboratory service without sacrificing quality.

3. There are too many fragmented and conflicting regulations now in effect to guarantee any level of consistent performance from one laboratory to another.

4. There is a need for national standards in order to insure consistent high quality in laboratory performance.

5. National uniform standards would provide adequate control if the following factors were included—

(*a*) minimum standard for education of personnel,

(*b*) institution of valid quality control requirements,

(*c*) standards for equipment and technical methodology,

(*d*) development of effective evaluation of laboratory performance.

The provision of national personnel regulations in conjunction with national health insurance could serve to set minimum standards for education, and could serve to enforce performance standards. As pointed out in the recent HEW Conference on Personnel Licensure and Certification (May 12 and 13, 1971), the responsibility for developing these standards should rest with the respective professional associations. To this end, the American Society of Medical Technologists has developed material which could be utilized in the preparation of minimum laboratory standards. A summary and the specific standards are attached and we would like to have this made part of the record.

Mr. ROSTENKOWSKI (presiding). Without objection, so ordered.

(The material referred to follows:)

NATIONAL MINIMUM STANDARDS FOR CLINICAL LABORATORIES

Clinical laboratories provide essential service to the medical practitioner, and through him, to the patient by furnishing vital information for the diagnosis, prevention, or treatment of any disease, or the assessment of the health of man. The Secretary shall require that all clinical laboratories be conducted, maintained, and operated without injury to the public health.

The establishment of minimum standards for clinical laboratories is vital in the public interest in order to reduce the hazard of inadequate performance.

Adherence to minimum standards does not preclude the establishment of higher standards in a laboratory or participation in any voluntary or governmental accrediting program with standards equal to, or greater than, those herein presented.

RESPONSIBLE AGENCY

These standards shall be administered through the Center for Disease Control and under the direction of the Secretary of the Department of Health, Education and Welfare. Annually, a laboratory standards advisory committee composed of appropriate representatives of the Department shall meet with a designated representative from each of the professional organizations involved in and make recommendations relative to the administration and enforcement of clinical laboratory service and representatives of the public to review, advise, these standards. A method of appeal for laboratories receiving adverse decisions shall be developed and administered by the committee.

APPLICABILITY

These standards shall apply to all clinical laboratories excet:

(*a*) those operated by an individual licensed physician for laboratory work performed on his own patients.

(*b*) a laboratory operated for teaching or research purposes only, provided that the results of any examination performed in such laboratories are not used in the health maintenance, diagnosis, or treatment of disease.

DEFINITIONS

Clinical laboratory as used in these standards means any place, establishment or institution organized or operated for the practical application of one or more of the fundamental sciences by the use of specialized apparatus, equipment and methods for the purpose of obtaining information which may be used in the diagnosis, prevention or treatment of any disease or impairment or assessment of the health of man.

Specimens means any material derived from the human body for examination or other procedure for the purpose of providing information for the diagnosis, prevention, or treatment of any disease, impairment or assessment of the health of man.

Structured training means a program planned to provide a predetermined amount of experience and in-service education in all areas of the clinical laboratory.

Acceptable laboratory means a laboratory that maintains standards equal to or greater than those set forth in this document.

Direct supervision as used in these standards shall mean the supervisor is on the premises and available immediately for consultation.

Adequacy shall be determined by authorized inspectors through the review of a quality control program, questionnaire, on-site inspection, including consultation with members of the laboratory staff.

INSPECTION

Laboratories shall have two years in which to apply for approval under these standards. Within one year following application, an initial on-site insection shall be made by an authorized representative of the administering agency. Thereafter, an inspection will be made at least bi-annually, with a comprehensive questionnaire being answered and submitted to the administering agency in the intervening years. If a laboratory is placed on probation or services are suspended in one or more areas, a request for re-inspection must be made within a six-month period to determine if corrective steps have been taken. Extenuating circumstances, as approved by the advisory committee, may be adequate reason for extending a probation for a period not to exceed 18 months following the first inspection.

COMPLIANCE

Failure to apply for aproval or failure to comply with these standards shall result in appropriate action to be taken by the Secretary. An appeal may be filed in accordance with a plan approved by the laboratory standards committee.

EXAMINATION AND REPORTS

Standard: General

The laboratory examines specimens only at the request of a licensed physician, dentist, or other person authorized by law to receive such results. The factors explaining the standard are as follows:

1. Orders or requisitions for service must clearly identify the patient, the doctor, the tests requested, special handling required, e.g., "emergency", the date and where appropriate, should specify the time when the specimen was collected. Minimum patient identification data shall include at least the name of the patient, hospital number, room number or address, age, sex, and attending physician. Requests for examination of surgical specimens should contain at least a concise statement of the reason for the examination.

2. A clinical laboratory may accept requests for tests and make reports only to persons authorized by law or to their designated representatives.

3. If the laboratory receives reference specimens from another laboratory, it reports back to the laboratory submitting the specimens. The referring laboratory must maintain a record of the name of the laboratory performing the test and the laboratory performing the test must be idenified on the patient's report by name and address or by code number.

4. Reports shall contain the identification of the person responsible for performing the procedure. Records of observation are made, concurrently with the performance, of each step in the examination of specimens. Records reflect the actual results of all control procedures. A copy of each laboratory report shall be retained for a period of at least six months.

5. Authenticated and dated laboratory reports are filed with the patient's medical record.

6. Tissue pathology reports must utilize acceptable terminology of a recognized system of disease nomenclature, and shall be cross indexed, using a system that is adequate for the hospital.

7. The pathologist shall prepare a descriptive diagnostic report of gross specimens received, which shall be a part of the patient's medical record.

8. The method of reporting should enable the physician to interpret easily the results of the test with reference to the range of usual values in health utilized by the laboratory, and with reference to the results of sequential and related tests. Reports of quantitative analyses shall include the units of concentration or activity.

9. A list or manual of analytical methods employed by the laboratory and a basis for the listed "normal" range is maintained in the laboratory. The list shall be available to the physicians.

10. If the laboratory refers specimens to another laboratory, the laboratory receiving the specimens must meet the applicable conditions under these standards. When tests are erformed in a reference laboratory, the name of the laboratory submitting the test must be maintained as part of the record.

Standard: Collection of specimens

No person other than a licensed physician or one otherwise authorized by law may manipulate a patient for collection of specimens except that qualified technical personnel of the laboratory may collect blood or remove stomach contents and collect material for smears and culture under the direction or upon the written or verbal request of a licensed physician, dentist or other person authorized by law to use the findings of laboratory examinations.

Standard: Specimen records

The laboratory should maintain for at least one month a record of the daily accession of specimens each of which is numbered or otherwise appropriately identified. The factor explaining the standard is as follows:

Records must contain the following information:

1. The laboratory number or other identification of the specimen.

2. The name or other identification of the person from whom the specimen was taken.

3. Name of the physician or other person or laboratory that submitted the specimen.

4. The date and time (if appropriate) the specimen was collected.

5. The date and time (if appropriate) the specimen was received in the laboratory.

6. The condition of any unsatisfactory specimen.
7. The type of test performed.
8. The date test was performed.
9. The result of the laboratory test or cross-reference to results and the date of reporting.
10. Cytology slides and Histology slides and blocks must be adequately identified, indexed, and stored.

LABORATORY SAFETY, PHYSICAL FACILITIES

Standard: Safety—General

There shall be adequate space, facilities, equipment and supplies within this area to perform the services offered with optimal accuracy, precision, efficiency, and safety. The factors explaining these standards are as follows:

1. There shall be a detailed laboratory safety program in operation which includes written and practical instruction for all employees in all basic areas of safety. Technical personnel shall receive special instruction in the proper use of safety equipment appropriate to their specific area of assignment.
2. Waste from all laboratory areas shall be disposed of with the closest adherence to current pollution control policies.
3. In areas where radioactive materials are used, all federal and state regulations concerning safety must be closely followed.
4. There shall be specially marked containers for disposal of broken glassware.
5. All drugs and narcotics shall be kept in locked cabinets.
6. Syringes, needles, lancets or other blood letting devices capable of transmitting infection from one person to another must not be re-used unless they are sterilized prior to each use after first having been wrapped or covered in a manner which will insure that they remain sterile until the next use.
7. All specimens suspected or known to be contaminated, icteric, or infectious shall be clearly identified and handled with due caution.
8. All contaminated glassware shall be placed in an appropriate disinfectant prior to washing.
9. Surgical and autopsy material shall be handled and disposed of so as to prevent infection.

Standard: Safety—fire

1. Emergency fire instructions, which include the number of the fire department, instructions for evacuation of patients and personnel, location of fire fighting equipment, and the date of the last fire drill shall be prominently posted.
2. A current report of inspection by the Fire Marshal shall be on file.
3. Fire extinguishers of the proper type, showing a recent date of inspection, fire blankets, and other necessary fire fighting equipment shall be readily available in all areas of the laboratory.
4. Sprinkler systems, acceptable to state standards, should be installed in all appropriate areas of the laboratory.
5. Smoking shall be prohibited in any area with flammable material and preferably confined to rest areas.
6. Flammable material shall be stored in unbreakable safety containers in well ventilated storage areas equipped with explosion proof switches and fixtures.
7. If refrigeration is required, inflammable material shall be stored only in explosion proof refrigerators.

Standard: Safety—chemical

1. All chemical containers must be clearly and permanently labeled.
2. Overhead showers, step-on eye washers, safety goggles, and other necessary equipment must be readily available.
3. Mechanical pipetting equipment shall be used for pipetting all dangerous materials.
4. Containers of acid and other highly caustic materials shall be stored at floor level as much as possible to minimize damage in the event of earthquake, storm, or other catastrophic event.
5. There shall be an adequate air control system including the use of fume hoods, ventilators, etc., to protect workers and work material from toxic and noxious fumes.

Standard: Safety—bacteriological

1. All culture materials shall be sterilized before washing or discarding. Appropriate indicators shall be included in each batch of sterilized material.
2. All refuse, including specimens and other waste, shall be free from contamination by pathogenic organisms.
3. Bacteriological safety hoods shall be available which provide an adequate flow of air and a filter system which will remove all bacteria from the exhaust flow.
4. All laboratory areas affording any possibility of contamination shall be washed daily with an appropriate disinfectant. Immediate attention shall be given to spillage of contaminants.
5. Any employee with an infectious disease shall be excluded from patient contact.
6. Disposable syringes, needles and lancets should be used wherever possible and after use be rendered useless and placed in a special, clearly identified container before destroying.

Standard: Safety—electrical

There must be a sufficient number of electrical outlets of proper voltage, adequately stabilized and all electrical equipment must be safely grounded.

PHYSICAL FACILITIES

Standard: Blood bank

1. The hospital maintains, as a minimum, proper blood storage facilities under adequate control and supervision of the qualified physician.
2. For emergency situations the hospital maintains at least a minimum blood supply in the hospital at all times, can obtain blood quickly from community blood banks or institutions, or has an up-to-date list of donors and equipment necessary to bleed them.

Standard: Clinical Laboratory

1. Out-patient areas shall be so arranged as to provide an adequate, clean area with sufficient space to draw blood or collect other specimens. In addition, there shall be an enclosed area with bed facilities for faint or ill outpatients and for patients undergoing extensive diagnostic testing.
2. Adequate, well lighted, bench top space shall be available in each work area for the performance of tests and for location of instruments. Surface areas shall be covered with material appropriate for the type of testing performed.
3. There shall be adequate space throughout the laboratory for the particular volume and type of services offered. The overall design, arrangement of equipment, and assignment of personnel shall be so carried out as to minimize transportation and communication problems.
4. There shall be adequate rest rooms and locker space for all personnel.
5. There shall be adequate library and conference room facilities located in or near the laboratory.
6. Adequate storage space shall be provided for:
(*a*) Reagents, glassware and other supplies needed for regular operations in each area.
(*b*) Easy retrieval of current and inactive records, microscope slides, paraffin blocks and wet tissue specimens.
7. There shall be an adequate forced air ventilation system providing fresh air and removing toxic fumes.
8. Adequate refrigeration space shall be provided for materials requiring refrigeration.

DIRECTION AND PERSONNEL

Standard: Laboratory director—Responsibilities

The laboratory has a qualified director who is responsible for the organizational and administrative operation of the laboratory.

1. The director serves the laboratory full-time, or on a part-time regular basis. If he serves on a regular part-time basis, he does not serve more than three laboratories or he may serve up to five laboratories providing he has a qualified associate to serve as an assistant director in not more than three of these laboratories.

2. Commensurate with the laboratory workload, the director or assistant director spends time in the clinical laboratory which is sufficient to fulfill his duties as a director or assistant director and is readily available for consultation at all other times.

3. The director is responsible for the employment of qualified laboratory personnel and the provision for a program of in-service education.

4. Appropriate delegation of responsibilities of the director shall be made in his absence.

Standard: Laboratory director—Qualifications

The laboratory director must meet one of the following qualifications:

1. He is a physician certified by the American Board of Pathology or American Board of Osteopathic Pathology. This requirement is mandatory in the area of anatomic pathology.

2. He is a physician certified by an acceptable specialty board and he must have had at least two years of experience in his area of specialty in a laboratory acceptable under these standards. He will only be considered qualified to direct a laboratory performing those tests for which he is qualified by reason of certification or experience.

3. He is a person holding an earned doctoral degree from an accredited institution with a chemical, physical, or biological science or clinical pathology as his major subject, and is certified by an acceptable specialty board and he must have had at least two years of experience in his area of specialty in a laboratory acceptable under these standards. He will only be considered qualified to direct a laboratory performing those tests for which he is qualified by reason of certification or experience.

4. He is a person holding a masters degree from an accredited institution with a chemical, physical, or biological science or clinical pathology as his major subject and is certified by an acceptable specialty board, and he must have had at least four years of experience in his area of specialty in a laboratory acceptable under these standards. He will only be considered qualified to direct a laboratory performing those tests for which he is qualified by reason of certification or experience.

Standard: Blood bank director—Qualifications

A blood transfusion service must be maintained and directed by a pathologist or a physician qualified in immunohematology and blood banking.

He may also be the laboratory director providing he meets the stated qualifications.

Standard: Supervision

The clinical laboratory is supervised by qualified personnel.

Standard: Supervisor—Duties

1. The laboratory has one or more supervisors who, under the general direction of the laboratory director, supervise technical personnel and reporting of findings, perform tests requiring special scientific skills, and with the director is jointly responsible for the proper performance of all procedures.

2. There are two categories of supervisors. The general supervisor may have responsibilities in both technical and administrative functions in all areas of the laboratory, a general supervisor may also be a technical supervisor. A technical supervisor supervises the technical performance of the staff in his specialty and is readily available for personal or telephone consultation.

Standard: General supervisor—Qualifications

He holds at least a baccalaureate degree in one of the chemical, physical, or biological sciences or medical technology and has met minimum requirements for certification in medical technology and has had two full years of experience in a laboratory acceptable under these standards.

Standard: Technical supervisor—Qualifications

He holds at least a baccalaureate degree in one of the chemical, physical, or biological sciences or medical technology, or equivalent as defined under qualifications of the technologist, and has had a minimum of one year of structured training and one year of experience in his area of specialty in a laboratory acceptable under these standards.

Standard: Technical personnel

The clinical laboratory has a sufficient number of properly qualified technical personnel to accurately perform the tests required of the laboratory and to participate in educational programs to establish or maintain competence of all personnel.

Standard: Technologist—Duties

The laboratory employs a sufficient number of clinical laboratory technologists to accurately perform under general supervision the clinical laboratory tests which require the exercise of independent judgment.

1. The clinical laboratory technologists perform tests which require the exercise of independent judgment and responsibility, with minimal supervision by the director or supervisors, in only those specialists or subspecialties in which they are qualified by education, training, and experience.

2. Clinical laboratory technologists are in sufficient number to adequately supervise the work of technicians, assistants and trainees.

Standard: Technologist—Qualifications

A clinical laboratory technologist must meet one of the following requirements:

1. He holds a baccalaureate degree in medical technology from an accredited college or university.

2. He holds a baccalaureate degree in the chemical, physical, or biological sciences, and, in addition, at least one year of structured training in a laboratory acceptable under these standards.

3. He holds an associate degree in a chemical or biological science or medical laboratory technique plus two years experience, with not less than one year of structured training, in a laboratory acceptable under these standards, and has achieved a degree of knowledge and skill commensurate with the baccalaureate degree level as demonstrated through the mechanism of educational equivalency and work proficiency examinations.

Standard: Technician—Duties

Clinical laboratory technicians are employed in sufficient number to meet the workload demands of the laboratory and they function only under direct supervision of a clinical laboratory technologist, supervisor or director.

1. Each clinical laboratory technician performs laboratory procedures which require technical skill and a minimal exercise of independent judgment.

2. No clinical laboratory technician reports test results in the absence of a clinical laboratory technologist, supervisor or director. This requirement shall not be applicable to the performance of procedures required for emergency purposes provided that the person performing the test is qualified to perform such tests, and the results of his work are reviewed by the clinical laboratory technologist, supervisor or director during his next duty period.

3. A student or trainee may perform tests only under the personal and direct supervision of a technical supervisor or clinical laboratory technologist.

Standard: Technician—Qualifications

A clinical laboratory technician must meet one of the following requirements:

1. He holds an associate degree in medical laboratory technique from an accredited institution and meets the minimal requirements for certification.

2. He holds an associate degree in a chemical or biological science from an accredited institution plus one year of structured training in a laboratory acceptable under these standards.

3. He has a high school diploma or the equivalent plus two years of experience, with not less than one year of structured training, in a laboratory acceptable under these standards and has achieved a degree of knowledge and skill commensurate with the associate degree level as demonstrated through the mechanism of educational equivalency and work proficiency examinations.

Standard: Laboratory assistant—Duties

Laboratory assistants may function only under direct supervision of a clinical laboratory technologist, supervisor, or director.

1. Each laboratory assistant performs laboratory procedures which require varying degrees of technical skill.

2. No laboratory assistant reports test results in the absence of a clinical laboratory technologist, supervisor or director.

Standard: Laboratory assistant—Qualifications

He has a high school diploma or the equivalent and training commensurate with the duties assigned.

PERSONNEL POLICIES

Standard: General

A manual of personnel policies, job descriptions, and administrative procedures must be maintained by the laboratory.

The factors explaining this standard are:

1. Current employee records are maintained that include a résumé of each employees education, experience, dates of employment, periodic review of performance and health records.
2. There is a documented program for employee orientation and inservice education.
3. Records must be maintained showing employee attendance at workshops, scientific meetings and refresher courses.
4. Current personnel policies shall be made available to all employees.

QUALITY CONTROL

Standard: General

Provision must be made for a quality control program covering all types of analyses performed by the laboratory to verification and assessment of accuracy, measurement of precision and detection of error.

Standard: Methods documentation

Blood Bank: All personnel qualifications, methods and procedures for hemotherapy conform to current "Standards for Blood Transfusion Service" published by the American Association of Blood Banks.

Clinical Laboratory: Each method must be clearly outlined including use of standards, calibration procedures, pertinent references, dates of review, sources of reagents and media. A separate record must be maintained which includes:

(*a*) The principles involved in the analytical method.
(*b*) Copies of appropriate reference manuals and other literature.
(*c*) Calibration records.
(*d*) Documentation of correction or improvement in methodology or instrumentation.
(*e*) Other pertinent information such as normals and sources of error.

Standard: Specimen collection documentation

Information must be available which includes:

(*a*) Procedure for ordering of tests.
(*b*) Precautions for special procedures.
(*c*) Procedures for the collection, identification, preservation, transportation, and storage of specimens.

Standard: Instrumentation

(*a*) The laboratory shall have a scheduled, clearly documented instrument maintenance program which includes written records for each piece of equipment indicating:

1. The date and type of service performed, including notations on repairs and recalibration.
2. The date next service is due.
3. Records of daily calibrations and/or temperature checks where appropriate.

(*b*) A copy of the manufacturer's maintenance manual must be readily available. This manual should conform to the format approved by the National Committee for Clinical Laboratory Standards.

(*c*) All blood bank refrigerators shall be monitored on a 24-hour basis and have audible and visable alarm systems.

Standard: Statistics

Each method is checked with adequate controls on each day of use. At least one standard or reference sample is included with each set of unknown specimens. Acceptable limits for standards and controls are established as well as the course of action to be instituted when these analyses are outside satisfactory

control limits. Control limits on all tests must produce results commensurate with meaningful use. If the result of the test on the reference sample is not within acceptable limits, the entire batch of analyses is repeated and control verified before reports are issued. The standard deviation or coefficient of variation shall be calculated for each quantative test performed. Positive and negative controls, when available, must be included at least once a day with the initial batch of unknown for each qualitative test performed.

Standard: Cytology

Cytologic smears shall be screened only by cytotechnologists with training and experience adequate to qualify for certification in this specialized field. The pathologist must review at least 10 percent of slides classified as normal smears by cytology screeners. All smears from sources other than the female genital tract should be reviewed by a pathologist. All abnormal or "suspicious" smears (class 2 and above) must be evaluated by a qualified pathologist.

Standard: Proficiency testing

As an adjunct to the quality control program, laboratories must demonstrate satisfactory performance in an acceptable comprehensive proficiency testing program.

Standard: Compliance with quality control

1. The "inspection" agency shall utilize as inspectors, individuals knowledgeable in the mechanisms and evaluation of quality control.
2. The quality control program in each laboratory shall be carefully reviewed, and, if found to be inadequate or incorrectly utilized, approval of the laboratory or approval for performance of specific tests shall be suspended until corrective measures are undertaken and approved.

Laboratory Standards for the American Health System

BACKGROUND

The quality of medical care practiced today is often directly related to the quality of the laboratory service utilized by the physician in diagnosing, treating, or preventing disease.

With the quality of laboratory examinations an acknowledged factor to be considered in any health care system which may be developed in this country, members of the American Society of Medical Technologists believe the system must enforce minimum standards for laboratories. Ideally, it should be the aim of every laboratory owner to operate a facility that exceeds these standards.

There are in existence today several programs for "accrediting" laboratories but each one was developed independently and in each one a different aspect of laboratory service is the primary focal point for determining quality of service. Each program is voluntary although Federal and State programs must be utilized if the laboratory serves a specified segment of the public or operates within a specified sphere.

The two Federal programs are the Social Security-Health Insurance for the Aged (Medicare), and the Clinical Laboratory Improvement Act (Interstate Commerce). Medicare approval is required for all laboratories wishing to receive payment for services rendered to Medicare patients and is administered to hospital laboratories primarily through the State Health Departments. The Clinical Laboratory Improvement Program is required for those laboratories accepting more than 100 examinations annually from outside the borders of the state in which the laboratory is located; it is administered through the Center for Disease Control in Atlanta, Ga. At least 19 states have some type of official laboratory regulations but most of them are ineffective and they vary greatly in scope and in enforcement. Some states tie their program into the Medicare program.

Three societal programs for laboratory accreditation are nationally recognized: The Joint Commission on Accreditation of Hospitals (JCAH), the College of American Pathologists, and the American Association of Bio-Analysts. The laboratory operating within a hospital approved by the Commission (JCAH) is automatically granted approval by Medicare, although there is great dissatis-

faction with the requirements and the method of survey. Approval under the College of American Pathologists program is accepted by the Clinical Laboratory Improvement program in lieu of their own on-site survey. There has been some question in regard to differences in standards of actual practice although on paper these two programs have the greatest similarity. The American Association of Bio-Analysts program is relatively new in the area of accreditation.

Representing the practitioners in the laboratories, the American Society of Medical Technologists has developed minimum operating standards to which they believe a laboratory must adhere in order to provide acceptable quality of service to the public. Whenever applicable and acceptable, existing standards from Medicare, CAP and CLIA regulations were used, with some additions and changes being made. ASMT believes there should be no standard acceptable which is lower than these and encouragement should be given to individual laboratories and to states to adopt even higher standards.

SUMMARY OF STANDARDS

The Center for Disease Control, located in Atlanta, Ga., operating under the aegis of the Secretary of HEW has the administrative experience to operate a nationwide system to improve laboratories. The strength of enforcement must rest within the province of the Secretary with assistance from a Laboratory Standards Advisory Committee which represents not only the professional group concerned with laboratory practice but also has adequate representation from the consumer and buyer of the services rendered—the public.

Unreasonable demand for the initial compliance with these standards is not intended. A time limit of 3 years for initial application and inspection should be adequate, as well as a period of 6 months in which to initiate action to correct a reason for suspension or probation. It is the privilege of the Advisory Committee to recognize extenuating circumstances which require longer periods of time. Biannual inspection, after approval, is considered feasible in a nationwide system. These standards present a workable plan, providing people knowledgable in the field are employed as inspectors.

Ordering, recording, charting, and keeping records are important parts of the efficiency and economy of the laboratory and occupy a strong place in the proposed standards. The section on laboratory safety and technical facilities is detailed, but generally follows requirements that can be adjusted to meet state or local codes while providing good working conditions for employees, which is always conducive to promoting maximum efficiency and economy. Not to be overlooked is the need for these safety requirements when the laboratory is located within the same building which houses patients and other types of health workers.

In the section dealing with direction and personnel, several points were taken into consideration. Those who work in a laboratory are most aware of the time needed for adequate direction, therefore, a limit was placed on the number of facilities which a "circuit riding" director may place under his jurisdiction. Not only should the director be responsible for the quality of personnel, but he should have the responsibility to assure the continuance of the quality through required programs of in-service and continuing education. The directorship need not be in the hands of a pathologist, but can be held by a physician with special training, or a specialist on the doctoral or masters level with an appropriate experience with direction limited to those areas in which qualifications have been earned. These requirements consider not only the Consent Decree of 1969 between the CAP and antitrust division of the U.S. Government, but also recognize the current programs in clinical pathology and specialty areas of the clinical laboratory which, when coupled with experience, provide capable directors. The only areas requiring the direction of a qualified physician are the Blood Bank and Anatomic Pathology.

Personnel qualifications follow closely those in Medicare regulations with some changes in the qualifications. The general supervisor who is responsible for the overall supervision of the laboratory and is in charge of administrative and technical direction in the absence of the director should have the background gained with an education in medical technology plus line or supervisory experience. The technical supervisor needs educational background in that specialty in which he performs plus some experience. The clinical laboratory technologist is recognized through the baccalaureate degree route or can utilize a 2-year aca-

demic program plus the mechanisms of equivalency, proficiency, and experience to qualify for this classification. The technician qualifies through the associate arts degree plus appropriate clinical training or experience; he can be a high school graduate with acceptable experience as demonstrated through the mechanism of equivalency and proficiency examinations. Duties within designed limits and qualifications of the laboratory assistants are left up to the need of the individual laboratory, with a high school education or equivalent as the only background requirements.

The standards place great emphasis on a realistic and utilized program in quality control measures, without going into minute details or requirements in every section of the laboratory. It is stressed that inspectors must be knowledgeable in the mechanisms and evaluation of the control systems and that inadequacies or incorrect utilization of the program is the basis for suspension or approval. In addition, participation in a recognized comprehensive test proficiency program is required.

GOALS

Combining a good test proficiency evaluation program, a good and properly used quality control program and a staff of accepted education and experience working under well qualified supervisors and directors in a laboratory with adequate facilities and administrative mechanisms, can earn a stamp of approval by a qualified inspector which will assure the American citizen that he and his physician can rely on the laboratory results produced in an approved laboratory in our new health care system. The members of the American Society of Medical Technologists believe the emerging health system in the United States must give this assurance to the citizen.

Quality Clinical Laboratory Services for the American People

(By M. M. Brooke, Sc. D.)

Although those close to the clinical laboratory have long recognized that laboratory errors can occur, the problem has not been openly discussed until recently. Walter Cronkite in a Columbia Broadcasting System program in 1965 focused attention on the poor performance of certain mail-order laboratories and stimulated, in part, the introduction of bills in Congress to establish performance standards for clinical laboratories engaged in interstate commerce.

In testifying before a Senate subcommittee, Dr. David J. Sencer, Director, National Communicable Disease Center (NCDC), cited proficiency testing studies that demonstrated significant degrees of unsatisfactory performance in various fields of clinical laboratory work.[1] Although the results varied from laboratory to laboratory, he concluded that "this information indicates that erroneous results are obtained in more than 25 percent of all tests analyzed by these studies." As might be expected, this statement caused great concern and, at first, certain groups challenged 25 percent as being too high a percentage or maintained that it applied to laboratories other than their own. Others have maintained that this percentage is too conservative.

Although scientists in clinical laboratories would like to be immune to error, there is no reason to expect human beings and machines to obtain perfect results in a clinical laboratory when they do not elsewhere. Additional objective evidence obtained since 1965 makes it unnecessary to belabor the point that medical laboratories can make errors or to debate the extent of the errors. All types of medical laboratories—independent, hospital, and public health—are now generally recognized to be subject to error, and we can therefore proceed with the task of improving laboratory services.

A number of significant programs and cooperative efforts have been started which should result in major improvements. Only a few can be considered in this discussion, but they illustrate what must be done to provide quality laboratory services for the American people.

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[1] U.S. Senate: Judiciary Committee, Subcommittee on Antitrust and Monopoly. Hearings on problems in medical laboratories. 90th Congress, U.S. Government Printing Office, Washington, D.C., 1967.

LEGAL AND REGULATORY EFFORTS

Until recently, there has been little or no governmental control of clinical laboratories. Beauty parlors, barber shops, and their operators are licensed in most States and cities, but the clinical laboratory and the personnel who examine blood specimens and throat swabs from patients, have been allowed to operate without control.

The first nationwide effort to establish controls for clinical laboratories came through the program of Health Insurance for the Aged (Medicare). The Medicare regulations[2] developed by the Public Health Services' Division of Health Standards established specific standards that State agencies follow in certifying laboratories as qualified to receive payment for tests under Medicare. Significantly, however, the law prohibits the application of these standards to laboratories in hospitals—although probably more than half of the laboratory tests (approximately 700 million) are performed in hospitals.

State control has evolved slowly, but it is now gathering momentum. When the Medicare program began in 1966, only six States required some form of laboratory licensure. Currently, 19 States, New York City, and Puerto Rico have laws or policies requiring the licensure of clinical laboratories and laboratory personnel, or both. Many other States have licensure legislation in various stages of consideration. Some present laws, for example, those of New York State, New York City, Kentucky, Tennessee, and Puerto Rico, provide for progressive regulations which will lead to laboratory improvement; others do little more than maintain the status quo in accordance with the vested interests of the existing laboratories.

Guidance is available to those interested in the enactment of good local laws to improve the performance of laboratories. In 1966, NCDC prepared a comprehensive guide[3] for such suggested legislation, and in 1969, the Council of State Governments published a model bill[4] to assist State legislatures in drafting licensing laws for regulating the clinical laboratory.

The Clinical Laboratory Improvement Act of 1967 (CLIA), P.L. 90–174, provided for Federal licensure of clinical laboratories (independently and by hospitals) that are engaged in interest commerce. This law is serving, even more than medicare, as an impetus to the development of local regulations. The act exempts clinical laboratories in States that enact laws establishing standards equal to, or more stringent than, those of the interstate regulations.

In addition, CLIA of 1967 is refiling still further the Federal standards for licensure of clinical laboratories. Working with several ad hoc committees whose members are clinical chemists, microbiologists, pathologists, bioanalysts, and technologists, NCDC has developed regulations[5] which are being used in the interstate licensure program.

Although until now Medicare regulations have emphasized qualifications of personnel, the CLIA regulations have emphasized the accurate performance of the tests through proficiency testing programs and internal quality control. The Division of Health Standards of the Service and NCDC are working together to make Medicare and interstate regulations as uniform as possible.

Hopefully, as new State laws are enacted, they will provide for laboratory improvement programs which will meet the CLIA requirements and the existing deficient laws will be revised to conform with Federal standards. In this way, most clinical laboratories in this country eventually would operate under comparably high standards of performance.

PRIVATE IMPROVEMENT EFFORTS

Several private professional organizations have constructive programs for regulating and improving clinical laboratories.

As stated earlier, Medicare standards for independent laboratories cannot be applied to hospital laboratories. This exemption occurred because Medicare pro-

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[2] U.S. Social Security Administration: Conditions for coverage of services of independent laboratories. Code of Federal Regulations, tit., 20, ch. 3, pt. 405, 1968.

[3] National Communicable Disease Center: A suggested guide for preparation of enabling legislation. Laboratory division, Atlanta, Georgia, 1966.

[4] Council of State Governments: Regulation of clinical laboratories and their personnel. Suggested State Legislation 28: A28–A34 (1969).

[5] U.S. Public Health Service: Clinical laboratories. Code of Federal Regulations, tit. 42, ch. 1, pt. 74, 1968.

vided that laboratories in hospitals accredited by the Joint Commission on Accreditation of Hospitals were automatically eligible to participate in Medicare and, in addition, that the laboratories in other hosptials cannot be subject to Medicare regulations that exceed the Joint Commission's standards. The laboratory requirements for the Commission's approval have been far below those of Medicare and, as a consequence, a double standard has resulted which has seemed unfair to the independent laboratories. The Commission is revising its standards, and this revision is expected to bring the standards more in line with those of Medicare. Hopefully, these improved standards will be implemented in the near future.

The College of American Pathologists (CAP) has expanded its laboratory improvement activities by initiating its "programs of excellence." These include laboratory surveys (proficiency testing programs) that cover all areas of laboratory work, laboratory inspection, and accreditation. Commendably, its proficiency testing programs are no longer limited to members of the college but are available to any laboratory which wishes to subscribe.

The laboratory accreditation program of the College has been accepted as a substitute for Federal evaluation for interstate licensure under CLIA. To date, it is the only private program to adjust its standards to comply with those established for interstate licensure.

Although exact numbers are unavailable, it is estimated that more than 300 million tests are performed in the offices of physicians in private practice. Practically all existing laws, both Federal and local, exclude from regulation those laboratories in the offices of one or two physicians who perform tests primarily for their own patients. Laboratory services performed under these circumstances are considered to be the practice of medicine.

Some of the laboratories that are presently subject to regulation are concerned over this exclusion, particularly since they reason that a comparable percentage of error may occur in these private office laboratories. Although this situation constitutes a deficiency, at this time efforts should be concentrated on making it possible for all organized laboratories—independent, hospital, and public health—to operate under comparable standards of quality.

The American Society of Internal Medicine is interested in seeing that quality laboratory service is performed in the offices of physicians in private practice. In cooperation with the Division of Health Standards of the Service, the Society has canvassed its members about participation in a 1-year proficiency testing program to determine the level of competency with tests for urea nitrogen, hemoglobin, and glucose. Recently, the American Society of Internal Medicine gave the Service a list of 500 internists who are interested in participating.

The CAP has developed a special office laboratory survey (proficiency testing) so that physicians can monitor regularly the performance of their laboratories Because of the increased complexity of laboratory work, the increased automation, and the need for specialized laboratory competencies, the amount of laboratory work performed in office laboratories will probably decrease. Nevertheless, these constructive efforts of the internists and pathologists are commendable and important because laboratory work in physicians' offices will probably continue to be excluded from regulatory legislation in the foreseeable future.

STANDARDIZING REAGENTS AND MATERIALS

One couse for variations in laboratory results is the variability of reagents used in diagnostic tests. Considering the variety of antigens, control serums, chemicals, stains, and mediums needed by the clinical laboratory and the number of companies that manufacture them, setting standards constitutes a major difficulty in laboratory improvement.

The National Bureau of Standards shortly will have available 10 standard reagent materials for clinical chemistry determinations. The Laboratory Division of the National Communicable Disease Center has described specifications for approximately 900 microbiological reagents. Reference reagents meeting these specifications have been prepared and are available to reagent manufacturers and to national and international public health agencies. Although the Federal standardization efforts of the National Bureau of Standards and the National Communicable Disease Center have been undertaken with the cooperation of manufacturers and in consultation with outside specialists, there has been a need for even greater cooperative efforts.

Recently, a significant step was made in the direction of standardization. Through the initiative of the standards committee of the College of American Pathologists, an independent National Committee on Clinical Laboratory Standards was organized in April, 1968. Membership is open to all industries, professional organizations, and government agencies that have an interest in the clinical laboratory field. Currently the membership is 50: 31 industrial representatives, 16 professional representatives, and representatives from three Government organizations. Each member appoints a representative and an alternate and submits names of persons available for assignment to area committees or working groups as experts in their areas of interest.

The objectives of this committee are to promote the development of national and international standards, such as written specifications for reagents and equipment, through a mechanism which insures that consensus has been obtained by all interested groups. Task forces and working committees have been organized to develop and propose standards for the fields of clinical chemistry, blood banking and immunohematology, microbiology, hematology, and instrumentation.

LABORATORY MANPOWER

We do not know exactly how many people are engaged in clinical laboratory work in this country, but some has estimated as many as 100,000.[6] In any event, acute shortages of well-qualified persons exist, and we anticipate greatly increased demands for trained personnel to meet expanding health needs, such as Medicare, Medicaid, mass screening programs, and the new technology. In the past there has been considerable support for research training but little for the training of persons seeking careers in the diagnostic laboratory. Fortunately, emphasis is beginning to be placed on training for services.

Through the Division of Allied Health Manpower and Regional Medical Programs, educational facilities are being established or expanded for training clinical laboratory assistants and medical technologists and for specialization to the master's degree level of medical technologists.

Training of other specialists, such as clinical chemists and microbiologists, has been neglected; however, four national conferences on training held in 1967 [7-9] recognized that the present and future clinical laboratories must be staffed by specialists. For instance, the report [10] of the conference convened by the National Institute of General Medical Sciences recommended financial support of postdoctoral residency programs to prepare the required specialists for the diagnostic laboratories.

The most encouraging feature of these current trends and programs that may bring about significant improvement in clinical laboratory performance is the extent to which the various interested groups are working cooperatively toward a common goal.

PUBLIC HEALTH SERVICE RESPONSIBILITIES

We in the Public Health Service are participating both directly and indirectly in this national effort to improve clinical laboratories. In the Public Health Service Hospitals, Indian Health Service Hospitals, outpatient clinics, and Federal prisons, we have a direct responsibility to assure that competent laboratory service is provided for the patients under our care. In 1964, the chief, Division of Hospitals, invited laboratories in Public Health Service installations to participate in the Center's proficiency testing programs. By 1967, 75 of these laboratories were participating in some phase of the program and as of now, 118 are receiving regular shipments of test specimens in one or more fields.

A number of the pathologists and technologists in the large Service installations have taken NCDC laboratory courses, but there is a definite need for

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[6] Conference on Manpower for the Medical Laboratory, sponsored by the National Committee for Careers in Medical Technology and the National Center for Chronic Disease Control, College Park, Md., Oct. 11–13, 1967.

[7] Conference on Undergraduate Training in Microbiology, sponsored by the National Registry of Microbiologists, Chicago, Ill., June 30–July 1, 1967.

[8] Third National Conference on Public Health Training sponsored by the U.S. Public Health Service, Washington, D.C., Aug. 16–18, 1967.

[9] Conference on Training of Clinical Laboratory Scientists, convened by the National Institute of General Medical Sciences, Durham, N.C., Dec. 13–15, 1967.

[10] Kinney, T. D., and Melville, R. S.: The clinical laboratory scientist—the use and organization of the clinical laboratory and the training of professional laboratory scientists of the future. Lab Invest 20:382–404, April 1969.

greater consultation and training, particularly for technicians working in the smaller hospitals and clinics. Since Federal laboratories are exempt from legal regulation, we must make certain that Public Health Service laboratories meet the standards required of others.

Indirectly, through programs associated with Medicare, Medicaid, interstate laboratory licensure, and services to States and municipalities, the Public Health Service has the responsibility to assist in improving the performance of laboratories at all levels throughout the country. The consultation and training program of the laboratory division at NCDC is dedicated to assisting the State public health laboratories to improve their diagnostic competencies and to provide the States and others with guidance and help in the training of personnel in laboratories at local levels.

Laboratory improvement, however, constitutes a tremendous undertaking requiring the cooperative efforts of Federal, State, and municipal health departments, academic institutions, professional organizations, and industry. Concerted, continuous programs are required to provide consultation, training, and other assistance needed by the 12,000 to 14,000 clinical laboratories in this country.

With assurance of payment of laboratory bills through health programs, the development of automated laboratory procedures, the establishment of mass screening programs, and the growth of comprehensive health insurance plans, the number of laboratory tests in this country may increase from an estimated 1,300 million now to more than 3 billion by 1975. Although our ultimate objective in laboratory improvement is to upgrade patient care and prevent needless human suffering, a tremendous economic savings will result as laboratory analyses become more and more accurate.

In summary, the clinical laboratories of this country have significant difficulties. Fortunately, Federal and State agencies, professional associations, and academic institutions are accepting the challenge of laboratory improvement and have made commendable strides toward desirable goals.

We in the Public Health Service must be deeply involved in this challenge. First, we need to make certain that our patients receive the highest quality of laboratory service. Second, we need to assist and support constructive programs of others that are directed toward bringing quality laboratory service to all segments of the population.

Mr. CONNELLY. Thank you.

The public's interest lies solely in the receipt of accurate laboratory services. To this end we believe uniform standards controlling both personnel and procedures are urgently required. Such standards, based on a program of careful study and evaluation, could ultimately guarantee the public reliable, low-cost laboratory service.

Thank you, Mr. Chairman.

Mr. ROSTENKOWSKI. Thank you, Mr. Connelly, for a very comprehensive statement.

Mr. CONNELLY. Thank you.

Mr. ROSTENKOWSKI. The Chair now recognizes Mrs. Bernice Hemphill.

Mrs. Hemphill, if you would identify yourself for the record and those accompanying you, we would be glad to recognize you.

STATEMENT OF MRS. BERNICE M. HEMPHILL, TREASURER, AMERICAN ASSOCIATION OF BLOOD BANKS, AND CHAIRMAN, NATIONAL COMMITTEE ON CLEARINGHOUSE PROGRAM; AND DR. WILLIAM G. BATTAILE, PRESIDENT, AMERICAN ASSOCIATION OF BLOOD BANKS

SUMMARY

1. The motivation and recruitment of sufficient voluntary blood donors to keep pace with the increasing demand for blood is the main problem facing blood

banks today. In a nation of over 200 million people, with more than 100 million individuals qualified to give blood, only 3% of the eligible population are blood donors.

2. Recent studies indicate that blood from commercial sources is 10 times more likely to transmit hepatitis through blood transfusions than from blood obtained from voluntary donors.

3. The Hepatitis Associated Antigen Test for the identification of blood that may be a carrier of serum hepatitis is estimated to be only 20–30% effective.

4. The public expects blood to be available and safe when needed for transfusion. To meet the increasing demand for quality blood, banks must get more voluntary donors. Blood is only available because of another individual's willingness to give.

5. Throughout the United States nonprofit blood banks offer to individuals, families and groups, blood assurance programs which will cover their blood and blood component requirements for a period of a year or more through voluntary blood donations.

6. To nourish voluntary replacement of blood, most blood banks place a monetary value on the blood itself—a blood replacement or blood deposit fee. This fee is kept relatively high, not to provide greater income for blood banks, but to provide a strong incentive to patients to seek blood donors. When blood replacements are made, or previously established credits are released in the patient's name, the fee is refunded or credited to the patient's account.

7. It is imperative that positive efforts be made to encourage voluntary blood donations in advance of need (predeposit and blood assurance programs), and to retain the moral and financial obligation for patients to replace blood they receive with blood, not dollars.

8. Blood banks cannot transfuse dollars. Monetary payment of the blood replacement fee by private health insurance or the Government indirectly forces blood banks to turn to the use of paid donors or commercial blood sources in many communities.

9. Providing payment for blood and components under any proposed National Health Insurance plan will result in the increased use of commercial blood and the associated risk of increased hepatitis.

10. The AABB urges the Government's support in preserving the principle of voluntary blood replacements, and strongly recommends that the payment for blood itself (replacement fee) and for blood components not be included in any National Health Insurance legislation.

Mrs. HEMPHILL. I am Bernice M. Hemphill, managing director of Irwin Memorial Blood Bank of the San Francisco Medical Society, treasurer of the American Association of Blood Banks and chairman of the national clearinghouse program.

Dr. William Battaile, president of the American Association of Blood Banks is accompanying me and I would like Dr. Battaile to introduce our presentation.

Mr. ROSTENKOWSKI. You are recognized Dr. Battaile.

Dr. BATTAILE. Thank you, Mr. Chairman.

I am Dr. William Battaile, a pathologist at Sibley Memorial Hospital in Washington, D.C. I appear here today as president of the American Association of Blood Banks. Accompanying me is Mrs. Hemphill who has already introduced herself.

The American Association of Blood Banks is a nonprofit, medical professional organization with a membership of over 5,000 including hospital and community blood banks and transfusion services throughout the United States, as well as physicians and other individuals closely allied to the field. It is the largest national organization devoted exclusively to blood banking.

Organized in 1947, the AABB's officers, board of directors, and its many committees, consist of members of the association who, like

ourselves, voluntarily contribute their knowledge and time to the improvement and advancement of blood banks and transfusion therapy at local, regional, and national levels.

We are appearing before you today not to testify for or against National Health Insurance per se, but to give testimony in opposition to the payment for blood itself or for blood components as an insurance benefit, and to urge the Government's support in preserving and furthering the principle of voluntary blood donations and replacements.

I shall be pleased to respond to any questions you may have relative to the scientific aspects of blood banking. Mrs. Hemphill will brief this committee on the overall problem of blood banking in the United States. We greatly appreciate the opportunity to present the views of the American Association of Blood Banks to the committee. We will be glad to answer any questions or furnish any additional information which will be helpful to the committee in its deliberations.

Mr. ROSTENKOWSKI. Have you concluded your statement, sir?

Dr. BATTAILE. Yes, thank you.

Mr. ROSTENKOWSKI. Mr. Betts?

Mr. BETTS. I might ask just one question for clarification. You say that you are interested in preserving the principle of voluntary blood donations.

I assume you don't want anything in the bill touching upon the subject of blood banks, is that correct?

Dr. BATTAILE. Not from the standpoint of payment for blood itself. The purpose of the presentation is to support the feeling that has been expressed recently that payment for blood generates activities that may harm the health of people in this country on the basis of transfusional hepatitis.

It has been proven that the chances of contracting hepatitis following a transfusion from paid donors or commercial donors is approximately 10 to 12 times greater than transfusions of blood from donors that are voluntary donors. So it is our purpose here to see if we can't convey to you the thought that actual payment for blood is not in the best interests of the people of the United Staes.

Mr. BETTS. Thank you.

Mr. ROSTENKOWSKI. This is consisent with your position on medicare as well, is it not?

Dr. BATTAILE. Yes.

Mr. ROSTENKOWSKI. Thank you. Mrs. Hemphill?

Mrs. HEMPHILL. I would like to add that I have been working in the blood bank field locally in San Francisco and nationally for more than 20 years.

I personally believe that blood required for transfusion to patients in the United States should come from voluntary donors. I know also that to accomplish this goal more people will have to give blood. It is within this realm that those of us working in blood banking, Congress, and other Government agencies can be most supportive by encouraging the American people to be voluntary donors.

THE PROBLEM

Today the number one problem in the United States is the motivation and recruitment of sufficient donors to keep pace with the demand for blood. The activities and programs of the American Association of Blood Banks and its members are directed toward accomplishing this goal.

More than 7 million units of blood are needed annually to meet the Nation's blood needs. The use of blood in the United States is increasing at the rate of 10 percent a year. In a Nation of over 200 million people with more than 100 million individuals qualified to give blood, only 3 percent of the eligible population are blood donors. It is obvious that not enough people are motivated to give blood.

USE OF COMMERCIAL BLOOD AND PAID DONORS

Within the last year, a great deal has been written about bad practices in blood banking, particularly with respect to commercial blood banks and the inherent risks of using paid donors.

Recent studies, as Dr. Battaile mentioned, have indicated that it is 10 times more likely to transmit hepatitis through blood transfusions provided by blood from commercial sources than from blood obtained from voluntary donors. Commercial blood programs attract donors from a population composed largely of people living on marginal incomes or less, and who generally live in crowded slum areas where addiction to alcohol and drugs are common environmental problems. Such individuals are far more likely to become exposed to hepatitis and to misrepresent their medical history to collect the payment of $5, $10 or more for their blood, than a voluntary blood donor.

Although a test for hepatitis known as the hepatitis associated antigen is now being used routinely in all blood banks, the sensitivity of this test is estimated to be only 20 to 30 percent effective. This test reduces the possibility of using infected blood, but far from eliminates the problems associated with the use of paid donors.

It is estimated that 15 to 20 percent of the blood used in the United States is obtained from commercial sources; in some parts of the country, the percentage is as high as 50 percent. In Washington, D.C., there is a commercial blood bank which draws blood from paid donors locally and ships it to Chicago and other places for use. The needs of patients in Washington hospitals are provided by the Washington Regional Red Cross Blood Center, and by hospital blood banks which are affiliated with the nonprofit Metropolitan Washington blood banks program.

The Chicago Tribune recently ran a series of articles focusing on commercialism and other bad blood banking practices. We have enclosed copies of these articles for your reading in our packets. Perhaps you saw last Friday evening's NBC program, Chronolog, on "The Business of Blood." It did not differentiate between commercialism in blood banking and the current on-going services of AABB community and hospital blood banks which depend on voluntary blood donors.

We wish to emphasize that in America today there are very good voluntary programs which must be preserved. Chronolog did not mention the scientific, technical and educational programs of the American Association of Blood Banks. The AABB standards, which its members and others follow, minimize the risks involved in the transmission of disease and to avoid transfusion reactions.

Frankly, we wish Chronolog had emphasized as a public service, the necessity for the American people to give blood voluntarily to minimize the health problems depicted. We feel sincerely and we know from experience, that commercializism in blood banking and the use of paid donors can be eliminated. More effort must be expended on public information and educational programs to depict to Americans the need for them to give blood voluntarily and keep the Nation on a voluntary system.

VOLUNTARY DONOR CONCEPT

The two principal organizations in the United States which collect blood from voluntary donors are the American Association of Blood Banks with its more than 1,300 hospital and community blood bank members, and the American National Red Cross, which, among its other activities, operates 59 regional blood centers. The two organizations each collect about half of the blood used in the United States.

In addition, member banks of the AABB are responsible for transfusing more than 6 million units of blood annually to patients. The AABB and ARC, together with the American Medical Association, American Hospital Association, and others support the concepts of voluntary blood donations.

We have also included in our packet a reprint on voluntarism and a brochure. We recommend that these publications be read by the committee. The Government itself has been a strong supporter of encouraging the voluntary donation of blood. This includes its action in providing a blood deductible under medicare.

For the past 2 years, Congress has passed a joint resolution to have the President proclaim January as "National Blood Donor Month." "Giving Blood Saves Lives" was one of the last commemorative appeals of the U.S. Post Office Department. Over 135 million of these commemorative stamps were sold. Its purpose was to encourage more generosity from the 100 million potential donors of blood.

In addition to these efforts Government can further support the voluntary blood program by not paying for blood under national health insurance. Blood is only available because of one's willingness to give it. It is imperative therefore that positive efforts be made to encourage voluntary donations in advance of need and to retain the moral and financial obligation for patients to replace the blood they receive with blood, not dollars.

VOLUNTARY BLOOD REPLACEMENTS

To nourish the voluntary replacement of blood provided for transfusion, most blood banks place a monetary value on the blood itself—a blood replacement or blood deposit fee. This fee is kept relatively

high, not to provide greater income to blood banks, but to provide a strong incentive to patients to seek blood donors from their friends or relatives or to give blood in advance of need. This fee is refunded or credited to the patient's account when blood replacements have been made or previously established blood credits have been released in the patient's name. A replacement fee is not charged within the ARC blood program; however, many individuals give to their local Red Cross centers to replace blood provided to friends and relatives because the transfusing hospital charges a blood replacement fee. People know that if they give blood they will not have to pay a replacement fee.

This fee usually does not create a financial hardship for patients since the majority have families or friends who are eligible to give blood, or belong to a business, fraternal, or social group which maintain donor club accounts with various blood banks.

Also, through the mechanism of the AABB national clearinghouse program, a voluntary system of inter-blood bank exchange of blood and blood credits, and the AABB's interorganizational agreement with the American National Red Cross, replacement donations can be recruited most anywhere in the United States and transferred to the patient's account. Patients receiving blood can have it replaced through the program in any other part of the United States. We have included a reprint of the national clearinghouse program.

As a service, most blood banks also maintain an indigent blood account to take care of the replacement needs of true hardship cases in which patients have no source of donors nor funds to pay the replacement fee.

PAYMENT FOR BLOOD ITSELF

There are an increasing number of companies that provide private health insurance plans which include payment for the blood itself in addition to blood bank and hospital fees stemming from the cost of processing and transfusing blood. The latter are legitimate cost expenses which should be provided for by health insurance. Payment of the blood replacement fee, however, defeats the very purpose for which it was established. This means that instead of voluntary blood replacements, blood banks receive monetary payment from insurance companies. Blood banks cannot transfuse dollars. Such insurance plans, therefore, indirectly force blood banks to turn to the use of paid donors or commercial sources in order to maintain adequate blood supplies to meet the needs of patients in many communities.

NATIONAL HEALTH INSURANCE

A number of bills introduced on national health insurance provide for the payment of blood or blood components. Other bills provide for a limited deduction for whole blood and red blood cells.

As with private health plans that pay for the blood itself, such plans will foster the "buying and selling" of blood and "dry up" the voluntary blood supply. Providing for the payment of blood and blood components under national health insurance can only result in the increased use of more commercial blood, bad practices, and the associ-

ated increased hepatitis risk by eliminating the patient's financial intive to solicit blood donation replacements from his friends and relatives.

The association strongly recommends, therefore, that the payment of the blood replacement fee, as it relates to whole blood and blood components, not be included in any national health insurance legislation, in order that patients receiving blood can be held responsible to obtain voluntary donors to replace the blood or components they use.

If blood is paid for, the American people have less motivation to give blood in advance of need or to give blood altruistically.

I conclude with the fact that a moral issue is also involved. Blood is living human tissue, and blood transfusions constituted the first successful transplants. As such, blood should not be bought and sold. With each advance in transplant surgery, it becomes more meaningful and more necessary for all of us to defend this principle. If this is not done, we may see price tags on hearts, kidneys, lungs, and other parts of the human body.

To meet the increasing demand for quality blood, the voluntary donor concept for blood must be preserved. To do this, we need a concerted nationwide effort of individuals and organizations involved in blood banking, as well as the cooperation of business, industry, labor unions, health professionals and the Government. It is with this goal in mind that the AABB recently announced a massive public education program to increase voluntary blood donations for the benefit of blood banks throughout the nation. A copy of the AABB news release on this proposal, dated October 28, 1971, is included in the packet.

We recognize the fact that it is not the role of the Congress to legislate morality. Conversely, the Government does not have the right to impose on its citizens legislation that would erode the quality of medical care. The public expects blood to be available and safe when needed for transfusions. Hepatitis is a serious illness any time a person contracts it. But if a patient gets hepatitis from a transfusion of bad blood, it can be fatal. If blood is to be safe, blood banks must have more volunteer donors and depend less on paid donors.

All of us then have a personal commitment to a strong voluntary blood program, for from birth to death we never know when one of us may need a blood transfusion, be it for one unit or 50 or more units. When we are in good health we should demonstrate our concern for others by giving blood ourselves and by encouraging others to make voluntary blood donations.

Finally the American Association of Blood Banks believes and is optimistic, that with more public education information and awareness that those of us in blood banking, together with government and the public at large, can convince the people of the United States to be voluntary blood donors.

We thank you for this opportunity of presenting our position, and in turn, we ask for your support in the elimination of any payment for blood itself under national health insurance.

Thank you.

(The material referred to follows:)

Chicago Tribune
THE WORLD'S GREATEST NEWSPAPER
SUNDAY, SEPT. 12

'Lifesaver' Is Potential Killer

Find Blood of Paid Donors Polluted with Hepatitis

TRIBUNE Task Force reporters spent weeks talking to medical experts and traveling in the Skid Row subculture that supplies much of the Chicago area's blood to get the story behind the blood donor dilemma in Chicago. This first report in a series was prepared by Reporters William Jones, Task Force director; Philip Caputo; Pamela Zekman; and William Currie.

The blood of 26-year-old Robert Irby is a potential killer, but that fact hasn't stopped the unemployed truck driver from selling the precious fluid a dozen times in the last two years to earn spending money.

Irby is considered a professional donor and under the rules of the blood-peddling business, his career should have ended July 22, 1970. On that date, as Irby prepared to collect another $15 for a pint of his blood, technicians at the Mount Sinai Hospital Blood Center discovered hepatitis in his blood.

The discovery meant that Irby must never again give blood because of the grave danger of infecting a recipient. The presence of hepatitis—a debilitating and sometimes fatal disease characterized by yellow skin and extensive liver damage—often tragically reverses successful surgery after the patient receives a transfusion of the tainted blood.

Bad Blood Poisons Surgery

But Irby's blood donor career was not over on that day, and what followed is yet another example of what many medical experts have warned about for years: For every step forward that medical science has taken on the operating table, it all too often falters by pumping poisoned blood back into the patient.

One blood expert estimates that nearly one out of every four persons over the age of 40 who contact hepatitis from blood transfusions will die. And it is the over-40 age group that receives 60 per cent of all blood transfusions.

In Irby's case, his name was stricken forever from the list of potential paid donors at Mount Sinai. A brief form letter was mailed to Irby suggesting that he see his doctor, and that was the end of it. Irby claims he didn't understand why his blood was rejected, and the 26 other blood donor stations in Cook County were never notified.

Since he was never paid for that last pint at Mount Sinai, Irby wasn't about to do business there again even if the center wanted his blood. Instead, he went to the Michael Reese Hospital Blood Center two months later, where the only existing test for hepatitis [an admittedly ineffective process that weeds out only one of four potentially infectious donors] failed to detect the presence of the deadly virus in his blood.

Reporters Follow His Trail

He sold a pint on Sept. 8, 1970, on Nov. 23, 1970, and on Feb. 1, 1971. He again sold blood on April 1.

Task Force reporters were able to document what happened to some of Irby's blood once it was sold and began moving into the medical community.

Three of the four pints were used for research, but a hospital official conceded they could just as well have been used in a transfusion following major surgery. The fourth pint was routed to another hospital, where officials are still attempting to determine how it was used.

According to the American Medical Association, the majority of the nation's blood supply comes from paid donors like Irby—in Chicago they account for as much as 60 per cent of the 250,000 pints drawn annually—and the paid donor is most likely to be an alcoholic or drug addict who needs the money for a bottle of cheap wine or a bag of heroin.

Chicago's four commercial blood operations cater to the blood peddler. They set up their drawing stations in neighborhoods like Uptown and West Madison Street and candidly concede that this is where most of their donors live.

And, health experts say, the thousands of gallons drawn from their veins each year are polluted with hepatitis because most paid donors live in the wretched conditions where the virus thrives.

Live in Unsanitary Conditions

Dr. J. Garrott Allen, professor of surgery at Stanford University School of Medicine and an authority on blood, puts it this way:

"The paid donor is often a cloistered resident of Skid Row, where he and his colleagues are alleged to enjoy frequently the practice of the communal use of unsterile needles and syringes for the self-administration of drugs. . . . There are also other unsanitary practices that prevail among this kind of population

which favor repeated exposures to infectious hepatitis as well. . . . Still another contributing factor is alcoholism, which appears to make such individuals more susceptible to an initial attack of either infectious or serum hepatitis."

And all too frequently, little attention is paid to the blood seller by those who work in commercial blood shops. Tasi Force reporters posing as drifters discovered they could give blood several times a week if they were willing to run the health risk. After selling a pint at one commercial operation, for example, a reporter was quickly accepted the next day at another location, even tho the scab on his arm was still fresh from the day before. Common medical practice is for donors to wait eight weeks between donations.

Hepatitis Near Epidemic Stage

"Hepatitis is reaching epidemic proportions in America," notes Dr. Bernard F. Clowdus II, chief of gastroenterology and liver disease at Mount Sinai Hospital.

"The figures from blood bank testing and from the Martin Luther King Health Center indicate that it is reaching epidemic proportions in Chicago. It is presently epidemic among people in Lawndale and of the middle class drug culture."

Clowdus underscored the problem by disclosing that beginning Oct. 1, Mount Sinai will reserve 21 beds for the exclusive use of hepatitis victims.

Dr. Mitchell Spellberg, a gastroenterologist at Michael Reese Hospital, considers blood from paid donors so lethal that in a recent operation he used blood that didn't match that of the patient rather than risk using blood that may have come from a paid donor.

Doctors at Michael Reese now face an added burden in getting blood for transfusions because the facility has banned the use of blood from paid donors.

Sees Less Risk in Mismatch

"I had to give the man blood that didn't quite match. I just decided I had to take the risk, and it just happened to work out okay," Dr. Spellberg said. "It is an added risk, but less of a risk, in my mind, than using paid donor blood, which we can't use at Reese anyway."

Dr. Aaron Josephson, director of the Michael Reese Blood Center, said the ban on paid blood resulted from "overwhelming evidence that the type of paid donor we have in Chicago had a high incidence of hepatitis."

Dr. Josephson and other authorities in blood research note that the hepatitis rate in paid donors is at least 10 times higher than that in volunteers. Other studies show that the ratio in Chicago is 11 to 1.

And when paid donors like Robert Irby and thousands of others like him continue to sell their blood again and again, the statistics can spiral to nightmare proportions.

Howard Schmid, a 57-year-old La Grange factory worker, underwent successful heart surgery in November and was making plans to return to work when the statistics caught up with him.

3 Months Later, Hepatitis

Mrs. Rosebud Schmid described her husband's delicate operation as a "huge success" and said her husband was making plans in February to return to work in June. Then, three months later his release, Schmid's eyes and skin began turning yellow, he felt weak, and his temperature soared to 101 degrees, Mrs. Schmid recalled.

Medical records show that Schmid received 22 pints of blood costing $750 during surgery in Rush-Presbyterian-St. Luke's Hospital.

Twelve of the pints came from the Interstate Blood Bank, a Tennessee corporation which operates three donor stations in Chicago and sells blood to hospitals.

Schmid was taken to Berwyn's MacNeal Memorial Hospital, where he languished for two weeks before Mrs. Schmid received a call.

"They said I'd better come down there because Howard was dying," she recalled. "He died the next day."

Schmid's death certificate lists serum hepatitis as the cause of death, and Mrs. Schmid has filed a $250,000 suit against Rush-St. Luke's.

Didn't Know the Risk, She Says

"No one ever told us when he was operated on that that was the risk he was going to take. That's the part that hurt us the most. If they had just told us, maybe we could have done something," said Mrs. Schmid. "We could have all gotten together, and we could have had good blood given to him."

Richard M. Titmuss, an internationally known authority on the relationship between blood transfusion and hepatitis, has described the blood recipient as a little more than a guinea pig.

The ultimate test of the quality of a unit of blood is whether the recipient contracts hepatitis, Titmuss said, noting that the patient is "in effect the laboratory for testing the quality of blood."

"Blood, like milk, may be bought and sold," Dr. Allen of Stanford points out. "But unlike milk, not all sources of blood are Grade A. The dairy industry is better regulated and is subject to quality control. Milk is a product that carries an implied warranty."

Allen claims that the least that should be done at this point is to label paid donor blood as "high risk" and other volunteer blood as "low risk" in its relationship to hepatitis.

He points out that the laws of 25 states, including Illinois, define blood as a service, not a product, and therefore blood is not subject to warranty. Many hospitals and physicians favor such a legislative definition because it protects them from lawsuits if a patient contracts hepatitis from blood transfusions.

Not Enough Unpaid Volunteers

The obvious answer to the problem, of course, is to obtain all blood from volunteer sources. But under the current operating policies of volunteer blood drives, according to Dr. Richard Sassetti, director of the Rush-Presbyterian-St. Luke's Blood Bank, "the demand would soon outstrip the supply. Right now we're in a situation where if a patient in need of transfusions lives long enough to contract hepatitis, we feel we've done him a favor."

Complicating the hepatitis problem is a lack of reliable statistics, a situation which frequently results from poor reporting of the disease. Last year, for example, Chicago hospitals reported only 758 cases of hepatitis to the Chicago Board of Health.

Edward King, assistant city health commissioner, pointed out that his investigators then discovered an additional 648 cases which had gone unreported.

Tomorrow: The men who sell their blood.

Chicago Tribune
THE WORLD'S GREATEST NEWSPAPER
MONDAY, SEPT. 13

Meet the Men Selling Blood to Buy Wine

There is a crisis in the quality of blood being used in Chicago and the nation and THE TRIBUNE Task Force spent weeks investigating the problem. This second part in a series deals with those who sell their blood and was prepared by William Jones, Task Force director; and reporters Philip Caputo, William Currie and Pamela Zekman.

Philip D. Testard is a peddler and his product is his blood.

He makes his sales calls at any one of several Chicago commercial blood banks and the $5 he receives in exchange for each pint is enough t keep him in cheap wine for a week. When times are hard, he drinks canned heat by cutting it with water and soft drinks.

"I'm on the wine now and I'll be on the wine till I die," said the 41-year-old Testard, an unshaven, toothless ex-convict.

Testard lives in the city's sink—Skid Row. His home is the street, and he sleeps on benches and in abandoned buildings. His diet consists of food scraps filched from garbage. Mostly, tho, he subsists on wine, going on drinking binges that last as long as five days.

He is one of the thousands of derelicts, drug addicts and alcoholics in Chicago who regularly peddle their blood for a few dollars to spend on the binge or the next supply of drugs. Their product carries no guarantee, no warning that it might be poison, even tho it is 10 times more likely to be teeming with potentially lethal hepatitis virus than the blood from a volunteer, an unpaid donor.

Cites Hepatitis Odds

Some day, blood from men like Testard may be in your veins. It is being used right now and is causing medical nightmares for surgeons and public health officials alike.

As much as 60 per cent of the 250,000 pints of blood needed in Chicago every year is drawn from the paid professional donor. Hospital blood bank directors report that 1 out of every

▶Task Force Report

20 patients who receive this blood will contract hepatitis, but only 1 out of every 200 recipients who are given volunteer blood will be infected with the disease.

The possibility that their product might kill or debilitate someone does not concern the blood peddlers. Most are so desperate for money to support their habits that they endanger their own health by selling blood—two, three and as many as four times a month.

Some peddlers, like Testard, do not even know what hepatitis is, altho they must profess they never had the disease to be allowed to trade a pint for a few dollars. And the only medical test ever devised to spot hepatitis in a potential donor is effective in only one out of four cases according to medical experts.

Blood His Livelihood

"What is hepatitis, anyway?" Testard asked a reporter as he waited to donate at the Beverly Blood Center, 4420 N. Broadway. He had just been told to return later because the center did not immediately need his blood type. The wait relieved Testard because it would give him time to have a few more drinks to compose himself before donating.

Testard said he was worried about being turned down because a rejection would mean the loss of his only source of income. He employs a number of tricks of the blood peddlers' trade to avoid being turned away.

One of the rules of the blood buying business limits donations to once every two months. Nevertheless, Testard is able to donate every two weeks—largely because there is virtually no communication between the various blood centers and hospitals that draw blood.

"Sure I give blood every two weeks," Testard said. "It takes five days to a week to get rid of that needle mark and then I'm good for another blood bank."

Occasionally, Testard sells blood twice within two weeks

[Continued on page 2, col. 5]

[TRIBUNE Staff Photo: By Ovie Carter]

Philip Testard . . . "I'm on the wine now and I'll be on the wine till I die."

MONDAY, SEPT. 13

The Skid Row Derelict: Chances Are His Blood Just Might Kill You

at the same donor station, skirting the rule by using false identification, he said.

Testard said he maintains his strength thru this gruelling schedule by eating garbage.

"You heard of the National Tea, you heard of the A & P, you heard of the Jewel?" Testard asked. "Well, that's how I eat. They throw out-of-date food into the garbage cans in back of the stores and I pick it up. It's tough, tougher than working, but the food isn't bad. I eat the pies and the cakes and the cold cuts. The meat that needs to be cooked I sell to the pizza joints up here [in Uptown] for a few bucks."

Recalls Payoffs

Such eating habits account for the most common hurdle faced by Testard and most other professional donors. Their diet causes them to suffer from a low blood iron level. To qualify for a donation, the donor's iron count must be 41, but many blood peddlers register counts as low as 35.

Testard also knows his commercial blood banks. Some have tough rules while others will overlook a low iron count, especially if they are behind in their monthly quota. He claims that some technicians will pass a donor with low iron in exchange for a cut of his fee.

"There used to be a nurse over there at [a commercial blood firm] who'd pass you if you gave her a buck," Testard said. "What you'd do is tell her that you needed the money real bad and that you'd give her a buck for passing you. She'd pass you and then you'd take your voucher and cash it at the currency exchange. Then you'd go back to the blood bank and drop the dollar in a wastebasket next to her desk."

When bribes fail, the donor simply barters his blood at a station where the rules aren't strictly enforced.

Ray Armour has been a blood peddler for 30 of his 50 years and claims he is frequently rejected for a low iron count. Armour describes himself as a vagabond and drunk. On the day he was interviewed, Armour had just been turned down at the Chicago Blood Donor Center, 2320 N. Clark St., but was not discouraged. He said he planned to make the rounds that day and was certain he would find a station that would buy his blood.

"Like Butcher Shops"

"Some of 'em are like butcher shops," Armour said. "They don't care, just as long as you walk in breathing."

A companion of Armour, who identified himself only as John, said it is possible to sell blood twice in one day, simply by offering your other arm for the second sale. John has sold blood so many times that scar tissue has formed on both arms. Like Testard, Armour and John make their homes in flophouses and under viaducts, using phony addresses on their donor cards.

The practice of using false identification and addresses makes it virtually impossible to track down paid donors who are hepatitis carriers.

Task Force reporters made this discovery when they attempted to find 10 professional donors whose blood was found to be infected with the disease. None were found and their addresses turned out to be vacant lots, park benches, abandoned buildings and warehouses.

Perhaps one or more of them was the peddler whose blood infected Richard S. with hepatitis. A hemophiliac, he asked that his real name not be used because he feared he would lose his job if his employers knew of his condition.

To stay alive, a person suffering from hemophilia often must take numerous transfusions each month of blood products drawn from the blood of several donors.

Risk Is Astronomical

Considering that the ordinary patient has an 11 to 1 chance of contracting hepatitis from a paid donor, the chances of the disease's striking a hemophiliac are astronomical.

In October, 1970, it struck Richard S., who has to transfuse blood products from seven different pints every three weeks.

"It was a real blow to me," he recalled. The doctor said it might take me the rest of my life to recover. Hepatitis on top of hemophilia was almost too much. Two chronic illnesses—it just didn't seem fair."

He has words for the Philip Testards and Ray Armours and the other blood peddlers whom he believes to be imperiling his life for a bottle of wine.

"I'd think that people who sell blood should think about it a little more and realize what might happen if they lie about their condition. It doesn't seem at all fair. Why can't they take someone else into consideration instead of that lousy money? I'll give them the money if they need it, but don't put my life on the line for it."

Tomorrow: Inside the commercial blood banks.

Chicago Tribune
THE WORLD'S GREATEST NEWSPAPER
TUESDAY, SEPT. 14

Blood Banks: Pay Stations of Winos, Addicts

The young man was unshaven and dirty, his breath reeked of cheap liquor and there was a needle mark on his left arm.

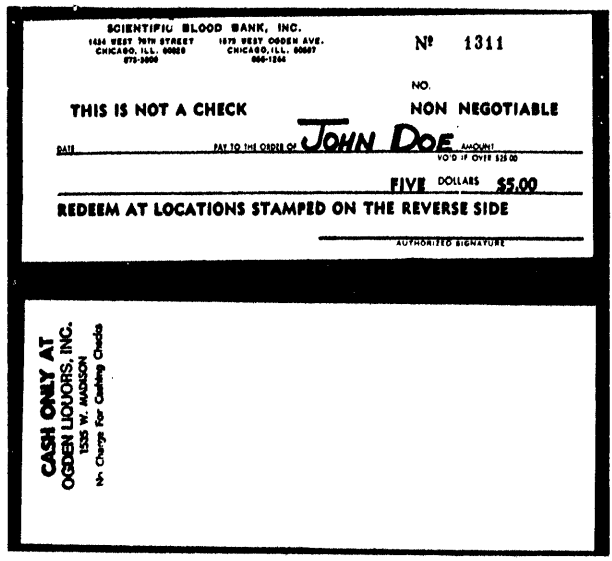
In the opinion of many medical authorities and blood experts, he was a classic example of a walking health hazard. Living from drink to drink, he pays for his binges by peddling his blood as often as he can.

On the surface it appears to be a harmless transaction. But if his blood is crawling with hepatitis—and there is no sure way of telling for certain—another bottle of poison will be on its way to a hospital operating room where it may ruin or destroy another life.

2d Day of Giving Blood

On this morning the scruffy blood peddler is preparing to do business in the Interstate Blood Center, 2543 W. North Av. Less than 24 hours earlier he had sold a pint of blood at a North Side commercial blood bank and under the rules of giving blood should have waited at least another eight weeks before selling another pint.

He is the kind of donor that is giving the nation's medical community nightmares. The blood of these donors is 11 times more likely to be infected with hepatitis, a disease that attacks the liver, than the blood of the unpaid donor.


SCIENTIFIC BLOOD BANK, INC.
1484 WEST 76TH STREET CHICAGO, ILL. 60620 873-3000
1870 WEST OGDEN AVE. CHICAGO, ILL. 60607 666-1266
№ 1311
NO.
THIS IS NOT A CHECK
NON NEGOTIABLE
DATE
PAY TO THE ORDER OF JOHN DOE AMOUNT
VOID IF OVER $25.00
FIVE DOLLARS $5.00
REDEEM AT LOCATIONS STAMPED ON THE REVERSE SIDE
AUTHORIZED SIGNATURE
CASH ONLY AT
OGDEN LIQUORS, INC.
1535 W. MADISON
No Charge For Cashing Checks

(TRIBUNE Staff Photo)

Voucher issued to donors by Scientific Blood Bank, which can only be redeemed at nearby liquor store.

THE TRIBUNE Task Force has spent weeks investigating how and why a bad quality of blood has become available to the public. This third part in a series examines the commercial blood banks and was prepared by William Jones, Task Force director, and Reporters Philip Caputo, Pamela Zekman and William Currie.

The transaction at Interstate was not unusual. What was unusual is that the donor was Philip Caputo, a Task Force reporter, and his report of the incident underscores the laxity in some of Chicago's commercial blood banks:

Stops Asking Questions

"The technician took down my phony name and address, then he started going down the list of illnesses. After I had replied 'no' to the first half dozen diseases, he stopped asking questions and just marked 'no' down the rest of the list. That done, he sent me into the back of the building, where a female technician tested my blood pressure, pulse, blood type, etc."

This exchange followed:

"Is that a needle mark?" the employe asked.

"Yeah, I had a blood test yesterday when I was looking for a job," Caputo replied.

Cautions the Response

"You know you're not supposed to give blood more than every eight weeks," she cautioned, apparently suspicious of

TUESDAY, SEPT. 14

Blood Banks: Pay Stations on Skid Row

the response. "A lot of people try to do that."

Caputo protested that he had not given blood recently, and the employe then told him to lie down on a couch so the blood could be drawn. As they prepared to take the blood, he was forced to make an excuse to leave in order to avoid giving blood twice in 48 hours.

A blood bank technician who worked closely with Task Force reporters said he learned on his first day at work how easily some unqualified derelicts can sell their blood.

Clientele of Winos, Addicts

The Scientific Blood Donor station is located at 1573 W. Ogden Av., and almost all of its clientele are the drifters, winos, and drug addicts who live in the flophouses along West Madison Street.

"The very first day I worked there some guy came in whose iron count tested at 38. My supervisor told me to write in phony numbers. He told me to go ahead and pass him and put down a 41 [acceptable iron count for donors] on the card," the technician recalled.

He said he quickly learned that falsifying records and passing unfit donors was a regular practice at Scientific. He said the practice extended from prospective blood sellers with low iron counts to those with high blood pressure.

"One guy came in. Everything else was all right with him, but his blood pressure was 196 over 152 [normal is 120 over 80], but my supervisor passed him," he said.

The technician said he suspected that the pressures of filling a daily quota forced employes to ease up on screening donors.

"But I wouldn't accept any of them," he said. "I would reject everybody, with all their drinking and wrecking themselves with malnutrition."

But even basic standards of cleanliness are sometimes laid aside, according to the technician. He said he became aware of this one day when he accidentally dropped a needle on the floor as he was attempting to correct its position in the arm of a paid donor.

Takes Needle from Floor

As blood spurted from the arm of the donor, his supervisor picked the needle up and prepared to reinsert it because the blood bag was only three-quarters full.

"That's a dirty needle," the technician said he warned the supervisor. But he said the supervisor reinserted the needle.

"What he should have done was paid the donor and scratched the blood sample since it wasn't a full pint," the technician said.

Brig. Roland W. Quinn, officer in charge of the Salvation Army's Harbor Light Center, 654 W. Madison St., accused commercial blood banks of "exploiting" men in search of liquor.

Lie to Get Money

"The drive for the next drink is just so great that they will lie to get the money," said Quinn.

The Scientific Blood Bank makes it easy for donors to spend their fee on alcohol. Instead of cash or a check, donors are paid with a voucher that can be redeemed only at a nearby liquor store. The liquor store requires them to make a purchase. And if the donor makes a small purchase, he is charged a dime as a voucher cashing fee.

Robert Gallagher, president and owner of Scientific, explains the voucher system this way:

"There is a currency exchange three blocks away, but some of these guys [paid donors] would have a hard time finding it."

Scientific is one of 11 commercial blood drawing stations in Chicago. Five are located in Skid Row or low income neighborhoods. The 11 stations dominate the blood market in Chicago, supplying the city with 60 per cent of its blood needs every year.

Have Network of Stations

And two of the commercial operations—Scientific and Interstate—have a network of donor stations in slum and Skid Row neighborhoods in Washington, Cincinnatti, Detroit and Milwaukee. Blood from these cities is frequently used in Chicago.

An officer of the Beverly Blood Center, Inc., 9944 S. Western Av., admitted that his company operates a donor station in Uptown because it puts them closer to their customers.

"At present? there simply aren't enough people volunteering blood, so you have to pick an area where low income people live," said Roger Sullivan, who manages Beverly's four drawing stations. "They use the money to buy a dress or augment their salaries. We hope it's not used to buy alcohol, but you can't control that."

Dr. J. Garrot Allen, an expert in blood research and professor of surgery at Stanford University, Palo Alto, Cal., takes a different view of the commercial donor. He contends that the fees paid for blood guarantee that more bad bl will enter the medical co munity.

"The pay scale [generally between $5 and $15 a pint] is all that is necessary to attract addicts and Skid Row people," said Allen. "It will not attract others."

The owners of some commercial blood banks dispute the statistics of people like Dr. Allen.

Dr. Coye C. Mason, owner of the Chicago Blood Donor Service, 2050 N. Clark St., labeled Allen's figures as "a lot of hogwash."

"Anyone who lies down to give his blood is a volunteer," said Dr. Mason. "We pay the donor for the time he takes to come and give his blood."

Result of Bad Blood

Richard Frame, a 68-year-old civil engineer, doesn't care who wins the verbal battle. He received two units of blood during neck surgery in Wesley Memorial Hospital in April, 1969, and four months later he was back in the hospital with hepatitis.

Frame said his doctor told him the disease was a result of bad blood received during surgery. Frame has suffered 15 per cent permanent liver damage.

Frame is suing the hospital for $100,000 and the hospital in turn has sued Chicago Blood Donor Service, alleging that it was the source of the blood.

Frame describes his experience this way:

"It's agony. Agony and a lot of turmoil. It was like the bottom had dropped out of everything."

Tomorrow: What Can Be Done?

Chicago Tribune
THE WORLD'S GREATEST NEWSPAPER
WEDNESDAY, SEPT. 15

Volunteers Can End Our Blood Dilemma

The TRIBUNE Task Force spent weeks documenting the problems of bad blood and how it is reaching hospital operating rooms. This last part in a series outlines some of the suggested solutions to the crisis and was prepared by William Jones, Task Force director, and Reporters William Currie, Philip Caputo and Pamela Zekman.

It was to be a routine medical operation, and Dr. Richard Sassetti was determined to keep the patient out of danger.

Sassetti is director of the blood bank at Rush Presbyterian St. Luke's Medical Center Hospital, 1753 W. Congress St. While he had nothing to do with the surgery scheduled for that morning, his decision could mean life or death for the patient.

Only hours before the operation was scheduled, Sassetti was confronted by an enraged surgeon who wanted to get started early and needed blood. But Sassetti was reluctant because his volunteer donor blood supply was low and an early operation meant he would have to rely on the blood from paid donors.

Blood Is "High Risk"

Sassetti and his colleagues in the hospital blood bank business describe the blood from paid donors as "high risk" and for years they have been desperately trying to avoid using it. All too often, they claim, the paid donor is a wino or drug addict whose way of life means that his blood may well be teeming with hepatitis virus, a debilitating disease that attacks the liver and can become a killer in the operating room.

"Where's the blood," demanded the surgeon. "What's the problem. Why can't you find a donor?"

Sassetti responded to the dilema in the only way he knew. First, he made the rounds of the hospital searching for suitable donors. When that failed, he and an intern each gave a pint. But they still needed two more pints. Sassetti still was reluctant to call a commercial blood outlet and run the risk of gettitng "high risk" blood.

"How about you doctor?" Sassetti finally said to the surgeon. "You're carrying it in your veins."

Surgeon Walks Away

Sassetti recalls that the surgeon reacted with a shocked look, then turned on his heel and walked away. Several hours later Sassetti succeeded in getting two more volunteer pints, bu he points to the incident as a classic case of what is happening more and more as the medical community shrinks from using the blood of paid donors.

"I guess he [the surgeon] didn't realize what kind of a problem we've got," Sassetti said. "Too many doctors think that blood can be obtained as easily as aspirin. They just scribble out 'transfusion' on the patient's card and think all you have to do is go to the corner drugstore and pick it off the shelf."

But concern has been growing among physicians in the last 18 months since the discovery of the first test to detect some heatitis tainted blood. The test known as the Australian Antigen Test, is effective in showing the virus in only one out of four cases. It can show positive in one test and negative in the next when the same person is being tested.

Tests Prove Danger

Many medical experts say the test proves that there is a very real danger from the quality of blood being used in transfusions. It is of such proportions that some experts consider it a matter of life and death for one out of every four patients over the age of 40 who receive transfusions.

"As the [hepatitis] situation now stands it is reminiscent of Upton Sinclair's "The Jungle," a book in which he exposed the lack of sanitary conditions in the meat industry in 1906," said Dr. J. Garrott Allen, professor of surgery at the Stanford University School of Medicine and an authority on blood. "The question is will the federal government act and when? Or must this be action brought about by a consumer revolt?"

Allen, Sassetti and a growing number of others in the medical community are convinced that the only answer is a sweeping, well organized volunteer blood doonr program that would eliminate the use of paid donors. Even some of the commercial blood bank operators conced ethis is the only solution and q···kly point out that they could play a part in the program. Somebody has to d r a w the blood, the ysay, and they are set up to do the job.

Dr. J. Garrott Allen

Allen explains the problem and a possible solution this way in an unpublished paper entitled "Hucksters in Blood":

"Most agree that we could reduce our incidence of transfusion hepatitis by nearly 90 per cent i fwe used only a volunteer system. This should eliminate the use of prisoner, Skid Row and addict populations as donors, because m o n e y is the urgent need of thee speople for more drugs, more alcohol and sometimes food. It [the United States] is the only country in the western hemisphere and in Western Europe in which a national volunteer blood program does not exist."

"It follows that, if 7 million units of blood will meet the nation's annual needs of our population of 200 million, only 3.5 per cent of the people need to contribute blood," Allen said. "However, there are 65 million peopfe ineligible to d o n a t e blood because they are either too old or too young. Possibly

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Volunteers Can End Blood Dilemma

another 35 million, for major or minor reasons, may not be eligible. With these crude and rather generous estimates, the nation's needs could still be met if 7 per cent of the eligible population contributed blood annually . . . If each of the 100 million eligible blood donors contributed three units [pints] of blood during his lifetime, the problem would be solved."

In Chicago at this time, 60 per cent of the 250,000 pints of blood used each year are supplied by paid donors who received from $5 to $15 a pint. Michael Reese and Mt. Sinai have acted in recent months to cut off paid blood, however. They believe they have reduced the hepatitis risk to their patients.

Dr. Richard Aster, executive director of the Milwaukee Blood Center, said Wisconsin embarked on a successful volunteer blood program several years ago. He attributes the success to the use of a centrally located blood center with satellite mobile units. This has eliminated the competition for blood among several agencies.

Public Relations Program

This means that only one public relations program is needed and it can be more effective, Aster said. A problem faced by any donor recruiting program, is that blood spoils after 21 days, so all programs must be constantly publicized and cannot be successful with only one or two well-publicized campaigns a year, Aster said.

Several other large metropolitan areas, including New York City, have established similar central donor services. New York operates an entirely volunteer program which supplies 300,000 pints of blood a year to 17 counties.

Dr. Morris Schaefer, assistant commissioner of the city's Public Health Department characterizes the center as "the best system we have at the present time, but it is not good enough. We still have a large demand for commercial blood and it must be lessened."

Except for a 20-hospital computer system set up at Michael Reese Hospital with help from the American Red Cross, there is no such central service in Chicago.

Set Up Offices

Last month the Metropolitan Chicago Blood Council organized a staff and set up offices on Michigan Avenue to begin a program to help meet the need for volunteer blood.

According to Dan Helsdingen, executive director of the council, the council's objectives are to assist in recruiting donors, provide a computer inventory of all available blood and volunteer donors in the metropolitan area, and to carry on a public education program.

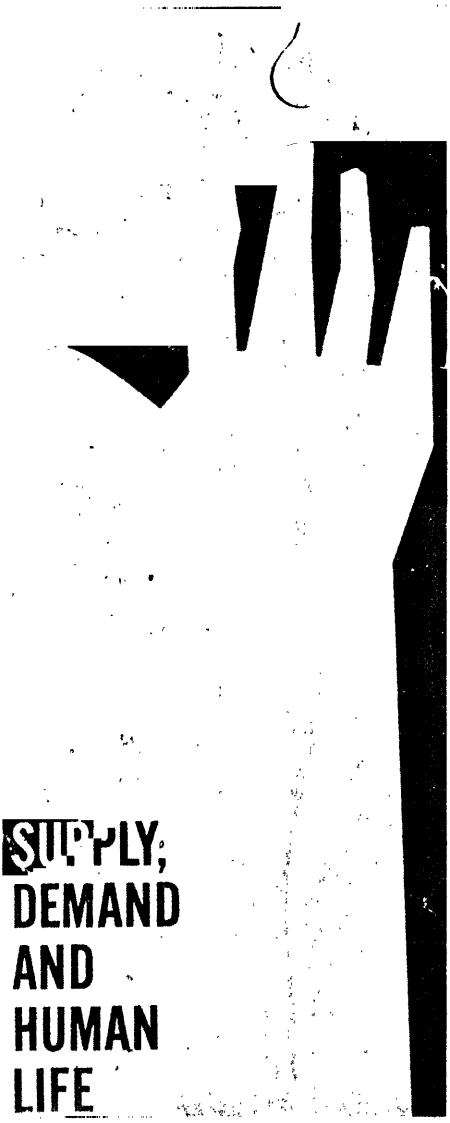
Experts in the blood field, including the most severe critics of paid donors, acknowledge that an immediate prohibition of paid donors would leave most hospitals without blood. But gradual change-over to all-volunteer blood can be accomplished, they say, pointing to successes in individual hospitals and several large communities. Even then, paid donors may be used, if their blood is used for research purposes, not transfusions.

Meanwhile, Dr. Aaron Josephson, director of the Michael Reese Research Foundation Blood Bank, said that a central registry is needed in the Chicago area to catalog the names of all donors who at one time tested positive for the hepatitis associated antigen. Josephson said that the Red Cross operates such a computerized reference nationally which is available to any blood bank but is rarely used in Chicago.

"Make City Responsible"

Robert Gallagher, president of the Scientific Blood Bank, 1434 W. 79th St., suggested that the state or the city be responsible for registering and testing all donor applicants and that they issue identification cards certifying that they meet all qualifications to sell their blood.

In another development, an attorney for Dr. Coye C. Mason, president of Chicago Blood Donor Service, Inc., 2050 N. Clark St., a commercial blood bank, objected to a reference in yesterday's Task Force article about paid blood donors which described Mason as an owner of the operation. The attorney said Mason was an owner at one time, but the blood bank has since become a not-for-profit corporation and is controlled by a board of directors.



WILL BLOOD BE AVAILABLE WHEN YOU NEED IT?

The next person to need blood could be you! You may use 20 pints. You may use two. Regardless, your need is just as great.

If you believe that your immediate need for blood is remote, consider that each and every day more than 13,000 units of blood are transfused in the United States—nearly 6,000,000 units per year.

The demand for blood increases, yet it is estimated that the annual blood requirements of the nation are provided by less than 3% of the eligible donor population of the United States—approximately 3,000,000 donors.

The nature of blood is such that it must be transfused in its whole state within 21 days after being drawn, and the blood given to a patient must be compatible with his own blood group and type.

Unless more people become donors, the *supply* will not keep pace with the growing *demand* for blood. Someday your *life* may depend on its availability.

To assure that blood will be there when you need it, give blood now and encourage others to become voluntary blood donors.

Artist Charles Lewis uses the symbol of a patient's outstretched arm seeking life-saving blood to depict the great need throughout the United States for more voluntary blood donors.

BLOOD BANKS

A blood bank is a medical facility which draws, processes, stores and distributes human whole blood and its derivatives. Some blood banks also perform other services and administer blood transfusions.

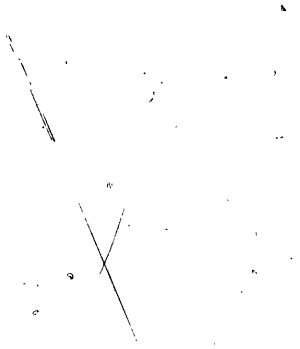
Hospital blood banks are self-operated and function primarily to meet the blood needs of their own patients. Many hospital banks depend on other facilities to supplement their blood supplies.

Community blood banks are usually locally organized and operated to serve the blood needs of a majority or all hospitals in a community.

Most hospital and community banks are members of the American Association of Blood Banks. These banks supply about half of the blood used each year in the United States. The other half comes from regional blood centers of the American National Red Cross. A very small percentage of blood is supplied by commercial banks which are privately owned. With the exception of the latter, most blood banks are nonprofit and depend primarily on voluntary blood donors.

Through a National Clearinghouse Program of the American Association of Blood Banks and a reciprocal agreement between the AABB and the American National Red Cross, banks can exchange supplies from one area to another to balance blood surpluses or shortages. The clearinghouse program also enables a blood donor to replace blood for a patient receiving a transfusion in most any area of the country. For example, you can donate a unit of blood in Hawaii for someone undergoing surgery in New York and have the credit transferred through the program to the patient's account.

These facilities operate to protect you against the unexpected. Support your local bank by giving blood.



THE VOLUNTARY DONOR

You cannot put a price tag on the life of someone you love. Money, the best medical skills and all the newest, most spectacular drugs often are not enough to save a life without the gift of blood which can only come from another human being.

Most banks obtain blood from persons who give voluntarily to replace blood used by a relative or friend, to establish protection against future blood needs for themselves and their families, or to fulfill a community responsibility. Some banks also obtain blood from paid donors. A few banks sponsor plans which provide future blood protection for an annual blood donation or cash premium. Cash payments, however, cannot assure a safe, adequate and economical supply. **Therefore, the voluntary blood donor is still considered the backbone of blood banking today.**

The following organizations know the importance of voluntary donations and urge healthy people to be blood donors:

American Association of Blood Banks
American Hospital Association
American Medical Association
American National Red Cross
Blue Cross Association
Health Insurance Council
National Association of Blue Shield Plans
Public Health Service, U.S. Department of Health, Education and Welfare.

WHAT IS BLOOD AND WHY IS IT SO IMPORTANT?

Blood can do wonderful things. It is composed of trillions of tiny cells suspended in a watery fluid called plasma. Red cells carry oxygen from the lungs to all parts of the body. White cells fight off disease and infection. Platelets help blood to clot when bleeding occurs. The plasma also contains proteins, required to control bleeding, and other essential materials.

To fully meet the needs of physicians and surgeons, blood of every group and type must be available at all times. Donors often respond when there is a special need or emergency. *But blood banks depend much more on donors who are willing to give to meet day-by-day blood needs.* Banks throughout the country must rely on a constant stream of donors to keep a "river of blood" flowing each day.

No substitute for blood has ever been developed. The only source is still the human body. As long as blood cannot be manufactured, blood banks must depend upon people like you to assure an adequate blood supply.

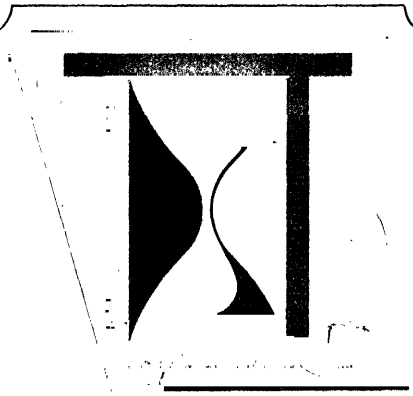
GIVING IS SAFE AND SIMPLE

Nature makes it easy to give blood. An average person has about 10 to 12 pints in his body. A normal donation is about one pint. Medical authorities say that donating a unit of blood quickly stimulates a healthy person's bone marrow and his blood count is as normal after the donation as before.

Under medical supervision, the collection of blood is made by a medical technologist or a nurse. The procedure is simple and safe. The entire process takes less than an hour.

After you have given blood, you receive a card which lists your blood group and Rh type. This is important as the blood of every human being is almost as distinctive as his fingerprint.

The giving of blood can be a satisfying and rewarding experience for you.



DON'T WAIT—DONATE!

Although most people have blood to share, many are not blood donors because they have not experienced the need for blood or they are apprehensive about the needle. However, millions of individuals are living today because of donors who have overcome their fears and realize the importance of giving blood. Blood donors are *special people.*

The need for blood increases daily. The balance between *supply, demand and human life* depends on blood donors. Your physician, hospital or local blood bank can give you more information and answer any questions about blood and blood donations.

Make a date with your local blood bank now. Don't wait—donate!

This brochure is made available as a public service by the

AMERICAN ASSOCIATION OF BLOOD BANKS
30 North Michigan Avenue
Chicago, Illinois 60602

Dedication to Voluntarism in Blood Banking

Bernice M. Hemphill

Mrs. Hemphill, Managing Director of Irwin Memorial Blood Bank of the San Francisco Medical Society, has given more than 20 years of volunteer service to the American Association of Blood Banks. She is currently AABB Treasurer and Chairman, National Clearinghouse Program

The spirit of voluntarism is deeply rooted in American tradition. During his visit to the United States in 1831, Alexis deTocqueville, the French writer, was impressed by a remarkable phenomenon — people in all walks of life giving of their time, their talents and energies to further causes they believed in. The spirit of individual volunteering — or giving of oneself to help others — and of collective, or group voluntary action for the common good, has been a source of national strength throughout our history. As we face the complexities of today's society, the spirit of volunteering becomes more meaningful and more needed than ever before.

A volunteer is defined as one who enters into any service of his own free will without constraint or guarantee of reward. In no other field does voluntarism play as important a role as in blood banking. We depend on community support, volunteer blood donors, monetary contributions for research and volunteer services of public spirited citizens and professionals who give time and skills to advance our life-saving service.

A voluntary blood donation by one person for another is an act of "caring and sharing" which has no parallel. There is no substitute for the unique chemistry which comprises the vital living human tissue — blood. The composition of blood is the same for all peoples of the world, therefore, all mankind is united by this common bond.

During the span of years I have been in blood banking many millions of people have willingly given of themselves to help others by making voluntary blood donations. These are people from all walks of life...students, housewives, laborers and skilled tradesmen, professionals...people of all ethnic backgrounds and religions...people who are willing to spend less than an hour of their time, as often as every two months, to share the "gift of life." Through their acts of giving blood, for patients close to them or for strangers in need, in war and peacetime, volunteer blood donors have demonstrated, in a very personal way, a love of God, of family, of neighbor and of country.

In meeting the nation's growing need for adequate and safe blood supplies, there is no single magic answer to balancing supply and demand. We, in blood banking, have the constant challenge of counteracting fear, apathy, myths and misunderstanding about blood and blood donation.

We constantly endeavor to sponsor educational programs to convince all segments of our society that it is easy and safe for people in good health to be blood donors. We make it convenient for people to give blood by extending blood bank hours, and by sending mobile units to groups of blood donors. We carry on aggressive efforts to impress upon families and friends of patients that they have the moral responsibility for replacing blood used with *blood itself*, either by making blood donations in the name of the patient, or by encouraging donors to deposit blood in advance of possible need.

Our member blood banks work unceasingly to conserve available blood supplies. Through the National Clearinghouse Program of the American Association of Blood Banks, over 1,000,000 units of blood have been borrowed and loaned between banks to provide blood of the right types, in the right amounts at the right place and time for those who need it. In addition, over 2,000,000 blood donor replacement credits have been exchanged, saving patients millions of dollars in blood transfusion fees.

Yet with all these measures, some commercialism does exist, but in America it does not dominate the field. Inasmuch as blood is living tissue, and blood transfusions were the first human tissue transplants, blood should not be paid for by cash or by insurance. If we allow such a system to prevail, we will subsequently see a price tag placed on hearts, kidneys and other human organs. The

Presented at First Day of Issue Ceremony for the commemorative stamp honoring America's volunteer blood donors, New York, New York, March 11, 1971.

provision of blood is a *service* and it is important that this principle be preserved through voluntary blood donations, lest we see the human body "bartered and sold" to the highest bidder.

Voluntary blood donations are important from an economic aspect. Even with general inflation and rising medical costs, blood bank services can be made available to patients at lower cost if we recruit greater numbers of volunteer donors. Money, which is now spent to buy blood or to pay donors, should be channeled into research and improved services to patients. The problems we face in balancing "blood supply and demand" are many and complex. Blood banks, the nation's "Guardians of Life" in the words of the AABB motto, have the responsibility for providing patients with safe blood. Blood donors, however, hold the ultimate answer to the quality and quantity of our nation's blood lifelines.

We are a nation of 200 million people. Over 100 million persons are eligible to be blood donors. If the annual need for blood in the United States is approximately 7 million units, how can one assume it is not feasible to keep blood banking in America on a voluntary basis! To meet the increasing demand for blood, the volunteer donor concept can and must be preserved. This will be achieved only if we reach out further and convince more people to be blood donors. To do this, we need a concerted nationwide effort of individuals and organizations involved in blood banking, as well as the cooperation of business, industry, labor unions, health professionals and the government. Above all, blood banks must have continual and emphatic support from the communications media — television, radio and the press, locally and nationally.

We welcome the handsome new blood donor stamp as a timely messenger for our cause, and we hope that millions will use it on their mail to help stamp out blood shortages and assure safe blood for all who need it.

In my years as a "blood banker," I have never ceased to be awed and inspired by the unselfish generosity and fundamental goodness of those legions of Very Special People who daily walk through our doors. Volunteer blood donors are noble Americans and we need more of them.

All of us should have a personal commitment to a strong voluntary blood program, for from birth to death we never know when one of us may need a blood transfusion, be it for one unit, for 100 units, or more. When we are in good health we should demonstrate our concern for others by giving blood and recruiting donors.

It is in this spirit of "giving and receiving" that I close with one of my favorite passages from *The Prophet:* "You give but little of yourself when you give of your possessions; it is when you give of yourself that you truly give."

Reprinted from Medical Times
August 1970, Vol. 98, No. 8, Page 101

Bernice M. Hemphill

Managing Director of Irwin Memorial Blood Bank of the San Francisco Medical Society

MEDICAL EDUCATION

AABB National Clearinghouse Blood Program

IN Montreal, Canada, a 41 year old father of three with a super-rare blood type—Group A Vel Negative—occurring in one person in 90,000, was scheduled for vascular surgery following an accident. Not a single compatible blood donor was found in Canada.

Through the Canadian Red Cross, the hospital appealed for help from the American Association of Blood Banks' Central File for Rare Donors. This round-the-clock, no-fee service, located in Chicago, includes the names of some 4,500 persons with rare blood. Donors with the Group A Vel Negative blood needed by the patient were located in San Mateo, Calif., Portland, Ore., Charlotte, N. C., and Casper, Wyo. Each donor gave a unit of blood at a nearby blood bank, and the blood, packed in refrigerated boxes, was flown to Montreal, where it was instrumental in saving the patient's life.

In Austin, Texas, a 26-year-old hemophiliac (bleeder), now studying for his Doctorate in Biochemistry at the University of Texas, has used hundreds of units of plasma for transfusion therapy during the past few years. To offset the cost of these transfusions—representing thousands of dollars in replacement fees for the blood used—the patient's father, who lives in Washington, D. C., has obtained blood donations from scores of co-workers in the United States Weather Bureau. The blood was donated in the Nation's Capital and the credits transferred to the patient's medical account in Austin.

In San Francisco, a 35-year-old physician, received two transplanted kidneys during 1969, both of which were subsequently rejected by his body. The patient, who received over 40 units of blood during the surgery, is currently

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The author conceived the original idea for a blood bank clearinghouse for the exchange of blood and donor replacement credits and coordinated the first clearinghouse program, sponsored by the California Blood Bank System in 1951. She has served as chairman of the American Association of Blood Banks National Committee on Clearinghouse since its inception and directs the program on a volunteer basis.

AABB National Clearinghouse Blood Program

dependent on a kidney machine while waiting for his third transplant. He continues to receive transfusions of packed red blood cells to fight anemia. One of his colleagues, learning of his plight, appealed to the local medical society, and another physician wrote to the patient's former classmates pointing out the need for blood replacements. The response was spontaneous and blood donations made by physicians throughout the country were credited to the patient's account.

These three patients are among thousands who have benefited from the exchange of blood or blood replacement credits through the American Association of Blood Banks' National Clearinghouse Program . . . a service which has been called "one of the Nation's most valuable banking systems."

Day after day, this "nationwide pipeline" helps communities to supply lifesaving blood of the right types and in the right amounts to patients needing transfusions.

The program makes it possible for a person in one part of the country to donate blood for another person receiving transfusions, regardless of residence. It enables a traveler, needing blood almost anywhere in the United States to draw on blood credits "banked at home in advance of need" by himself or by associates who share the benefits of an employees' or fraternal blood donor club plan.

Most significantly, it permits blood banks with *surpluses* to lend to those with *shortages* as a means of preventing outdating of whole blood, which has a refrigerator life of only 21 days.

To conserve blood supplies—a vital national resource—it is the responsibility of blood banks to "care and share" . . . to keep close watch on each day's inventory of the various blood groups and Rh types, to borrow blood when needed through the clearinghouse, and to lend blood when called upon to help other blood banks in short supply.

Nearly 6,500,000 units of blood are transfused in the United States each year and the demand for blood is growing along with its increasing use in surgery and therapy. In spite of the soaring need, only three per cent of those persons eligible to donate blood actually do so. For these reasons, the original purposes of the National Clearinghouse Program—to encourage voluntary blood replacements, to keep transfusion costs at a minimum, and to utilize available blood supplies as effectively as possible—are more meaningful than ever.

At present, more than 800 blood banks and drawing centers share the benefits of reciprocity under the National Clearinghouse Program which serves more than 3,000 hospitals and transfusion services. During 1969, more than 700,000 blood and blood credit exchanges were handled through the national program.

No formal system of reciprocity existed among blood banks prior to 1951. However, when shortages occurred in those days, blood was often rushed refrigerated from one blood bank to another—a complicated procedure which required numerous phone calls and the need for blood banks to maintain separate accounts with one another.

The idea for solving this problem was based on our monetary clearinghouse system. Since it was possible for a person to write a check on a bank in one area and withdraw the money in another, why couldn't "paper credits" representing units of blood be exchanged in the same way? From this germ of an idea evolved the clearinghouse system for blood banks, which has been patterned from its inception on the national fiscal clearinghouse system.

Originally, nine community blood banks joined forces in 1951 to form the California Blood Bank System, and set up a central book-

keeping agency—the original clearinghouse office in San Francisco—through which all transactions among the participating blood banks were channeled.

Each participating blood bank had a single account with the clearinghouse, rather than maintaining many separate accounts with other blood banks. The clearinghouse had no direct responsibility for recruiting donors, procuring or processing blood. It functioned primarily as a "locator" of blood, and as a bookkeeping agency for the blood banks.

A donor in one community wishing to give blood for a patient in another would donate a pint of blood at his local blood bank. A paper credit (I. O. U.) would then be transferred through the clearinghouse to the blood bank supplying blood for transfusion. The blood bank, in turn, would credit the blood replacement to the patient's account, thereby cancelling the replacement fee which the blood bank charges when donor replacement cannot be obtained for blood used.

The clearinghouse maintained daily records of each bank's exchanges, balanced the accounts at the end of each month, and arranged for any necessary shipment of blood to cancel indebtedness between the blood banks.

These same procedures were adopted when the American Association of Blood Banks, a voluntary organization of community and hospital blood banks, initiated the *National* Clearinghouse Program in 1953.

Five District Clearinghouse Offices were established, each serving participating blood banks in a designated area. (Illustration) Although the original District Clearinghouses were separately incorporated, the AABB took over ownership of all five clearinghouses by 1961, and the National Clearinghouse Office was established in San Francisco to coordinate the overall program.

In 1961 also, the American Association of Blood Banks and the American National Red Cross, which between them supply more than 80 per cent of the blood used in the United States entered into a nationwide agreement for the exchange of blood credits between AABB blood banks and the Red Cross's own network of Regional Blood Centers.

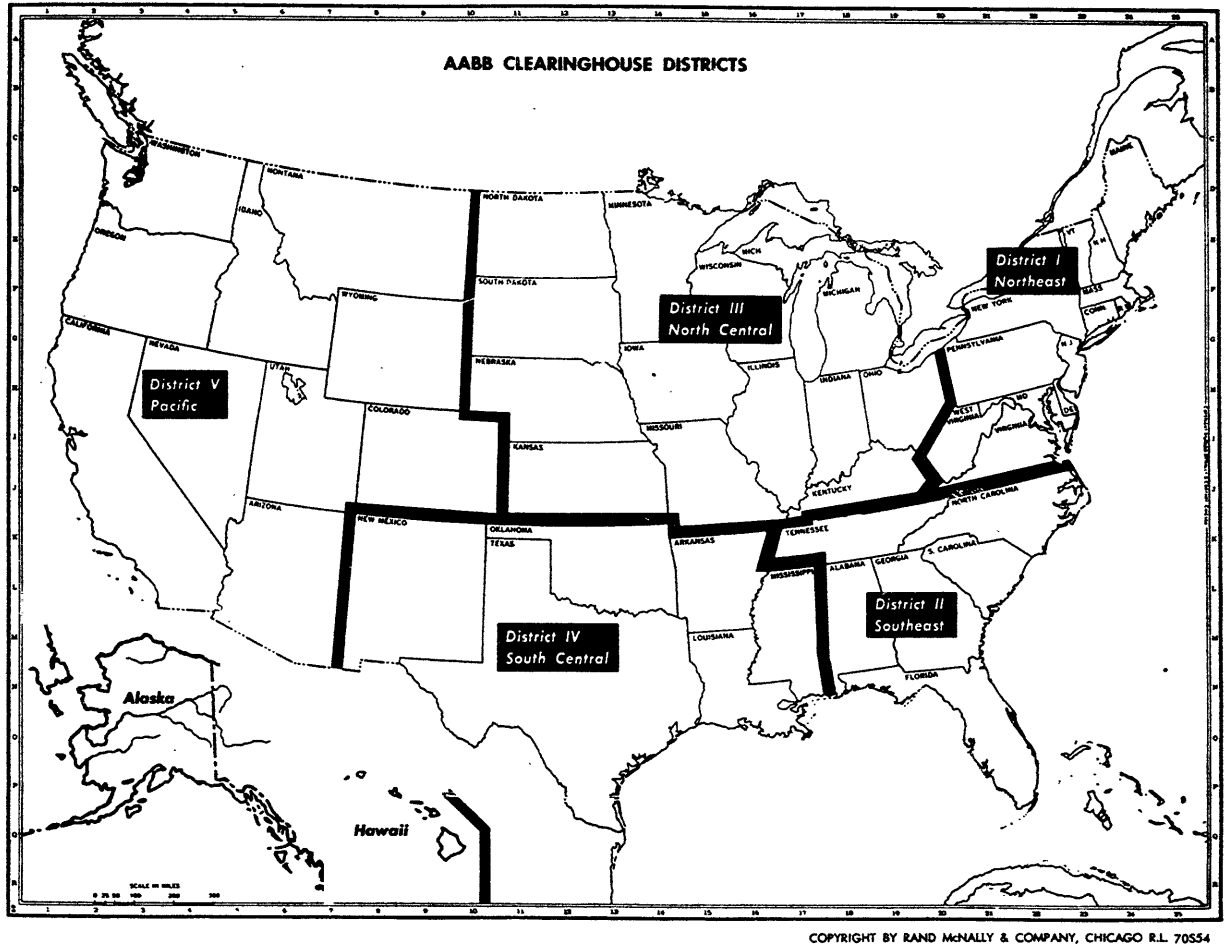
The advantages of the National Clearinghouse Program in emergencies was dramatically illustrated during the Chicago blizzard of 1967 when the program was instrumental in averting a serious local blood shortage.

On the morning of February 1, a record 23 inch snowfall halted transportation preventing blood donors from reaching local blood banks. When it was learned that another seven inches of snow was due before evening, the director of the University of Illinois Blood Bank appealed for assistance from the AABB District Clearinghouse in Chicago.

The appeal was relayed by the Telex communication system which links the clearinghouse offices across the United States.

Within minutes, four community blood banks in California, 2,000 miles away had agreed to provide most of the needed units. The blood was flown from these communities to Los Angeles International Airport and from Los Angeles to Chicago, where all shipments —181 units in all—arrived by 7 p. m. and were rushed by the Chicago Police Department to Michael Reese Hospital for distribution.

Another example of the effectiveness of the clearinghouse was demonstrated also during the New York transit strike in 1966. Coupled with the added difficulties in making normal blood collections was the depletion of the New York Blood Center's blood inventory due to the long New Year holiday. A call for assistance was sent out, and through the efforts of the district clearinghouses, 572 units of blood



were shipped from 24 blood banks in all parts of the country.

The significance of the National Clearinghouse Program also has grown with the advancement of surgical techniques. For example, in 1956, Irwin Memorial Blood Bank of the San Francisco Medical Society, supplied the blood needed for *ten* open heart operations performed that year. Today, the blood bank provides blood for approximately 16 open heart surgery cases a week, or *over 800 cases* a year, each operation requiring from six to 15 units of fresh blood.

Although the fresh, specially processed type-specific blood needed to prime the heart-lung machines and to provide post-operative transfusions must be obtained locally, a large proportion of the patients come to the San Francisco area for surgery from communities outside the areas served by the blood bank. Many come from distant States.

To encourage blood replacement, a letter is sent by the blood bank to the patient's next-of-kin, informing him of the replacement responsibility and giving the name of the nearest blood procurement facility. By availing themselves of the services of the Clearinghouse Program, resourceful families can help to assure that blood will be available for others needing it, and they may save hundreds—even thousands—of dollars in replacement fees which would otherwise be charged to the patient.

One such instance involved the wife of a former official of the California State Department of Industrial Relations, who needed 58 units of blood to control bleeding after open heart surgery.

Although the couple had lived in California for many years, they had moved to Washington, D. C. The patient has returned, however, for her third heart operation at the West Coast's famed cardiac center, Presbyterian Hospital of Pacific Medical Center in San Francisco.

Without the blood supplied for her locally, the patient could not have survived.

Her husband had numerous contacts with statewide labor and employee and professional organizations. To obtain replacements for the blood received by his wife, he arranged to have announcements published in the publications of these organizations, appeals made at membership meetings, and by word of mouth. The response was heartwarming. Blood donations for the patient were made at seven widely scattered California blood banks, and credits "deposited in advance of need" were generously released by various organizations. As a result, replacement credits were obtained through the Clearinghouse Program for every one of the 58 units of blood the patient had used.

The spirit of "caring and sharing" which is so necessary to the success of the National Clearinghouse Program, was demonstrated recently when eleven Florida blood banks joined in a search for rare blood needed for vascular surgery on a 47-year-old retired manufacturer's representative, in Clearwater.

The search began when the hospital ordered six units of blood from R. E. Hunter Memorial Blood Bank in Clearwater, to be crossmatched and available for the surgery, scheduled the following day. The patient was found to have Group O, Rh negative blood, which occurs in one person out of 15 and in addition, antibody studies demonstrated that he had an Fy^a (Duffy) antibody, which further limited the number of prospective donors who could be recruited. (Approximately 35 per cent of those individuals having O negative blood have the Fy^a antibody.)

Although the patient's blood was not so rare as to warrant a search by the Rare Donor File

in Chicago, it was sufficiently rare that no units could be found locally.

The blood bank's laboratory supervisor, Mrs. Alice B. Miller, phoned the AABB Southeast District Clearinghouse in Jacksonville, which issued an immediate appeal for compatible blood in the Jacksonville area and Orlando. Mease Hospital Blood Bank at Dunedin, near Clearwater, screened all available Group O, Rh negative units and found two compatible ones, which were shipped that morning to Clearwater. The Community Blood Bank and St. Anthony's Hospital Blood Bank in St. Petersburg found three units each of the rare blood and these, too, were promptly shipped. The response from more distant Florida blood banks was equally successful. Blood Banks in Miami, Orlando, Gainesville, West Palm Beach and Tallahassee also shipped units. In all, 19 units of the rare blood were made available.

Commending the teamwork of the technologists in the various blood bank laboratories, Mrs. Miller said, "They took time from their busy routines to do the screening test for the Fy^a antibody, which required a minimum of 30 to 60 minutes per unit. Also the blood banks cheerfully depleted their own supplies of hard-to-obtain O negative blood to share the rare blood units needed by the Clearwater patient.

According to physicians, the successful surgery could not have been performed without available blood.

Two AABB-sponsored programs which are helping to conserve local blood supplies are the Maryland Blood Exchange and the New Jersey Blood Exchange.

The Maryland Blood Exchange, established in 1963 at the request of pathologists in the Baltimore area, now includes 15 participating hospitals. From a central office, a daily inventory is taken by telephone of all available blood in these hospitals and arrangements are made to transfer blood among them when shortages occur. All transactions are channeled through the Northeast District Clearinghouse in New York. This exchange service is available 24 hours a day, seven days a week, and since its inception has been able to move more than 12, 300 units of blood fulfilling 80 per cent of all requests received.

The New Jersey Blood Exchange, operating in the same manner, was established in 1965 with seven participating Passaic County hospitals, and is now being coordinated through the North Jersey Community Blood Bank Program in cooperation with the American Association of Blood Banks' Northeast District Clearinghouse Office.

The AABB National Clearinghouse Program has continued its sponsorship of these programs which are demonstrating their value by preventing units of blood from outdating by rotating them, and by saving lives as they share blood in emergencies.

Another special program, made possible by the AABB National Clearinghouse system, is the National Blood Reserve program established in 1967 by the Nobles of the Mystic Shrine. Through this program, Shriners and their families in all parts of the country may donate blood for the Shrine Orthopedic Hospitals and Burns Institutes. A master account of all donations is maintained by the Association's National Clearinghouse Office, and credits or blood are transferred as needed to help orthopedically handicapped or badly burned children. Since the inception of this program, more than 3,000 blood donations have been made for this purpose.

Through the overall National Clearinghouse Program more than 2,000,000 blood replacement credits have been exchanged to date and

close to 1,000,000 units of blood have been shipped nationwide to alleviate shortages or in settlement of clearinghouse indebtedness. The program is guided by a volunteer committee of professionals, is self-supporting, and operates with the total paid staff of 12 full-time and three part-time employees.

In addition to the exchange of blood and blood credits, other services in the public interest are carried on through the blood bank network established under the National Clearinghouse system. For instance, by requiring that banks making blood shipments under the clearinghouse system be inspected and accredited by the AABB, the National Clearinghouse Program is helping to raise the standards of blood banks and improve the quality of blood transfusion. By promoting the voluntary donor concept and minimizing the need for blood banks to turn to commercial sources, it is helping to assure a safer, more economical blood supply.

The potential of the AABB National Clearinghouse network for expediting the distribution of blood for national defense or in a national emergency has been formally recognized by the federal government.

A Defense Mobilization Order, adopted in April, 1967, provides that "the blood collection activities of federal agencies shall be administered so as to make maximum efficient use of available sources while assuring minimum impact on provision of normal blood supplies for the civilian community."

The order was a prelude to the signing, in October, 1968, of a standby agreement between the government and the AABB for the procurement of blood in the event of a national emergency, or if a need should arise to recruit civilian donors to provide supplementary blood supplies for Vietnam and other overseas military needs, now the sole responsibility of military donors. A similar agreement was made between the government and the American Red Cross, and a joint statement of cooperation was issued by the AABB and the Red Cross.

Future goals of the AABB National Committee on Clearinghouse Program include working toward greater standardization of replacement fees and transfusion charges, and the development of new methods of recruiting voluntary blood donors so that the nation's blood-lifeline, through the National Clearinghouse Program, may render even-greater life-saving service.

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NEWS RELEASE

October 18, 1971 FOR IMMEDIATE RELEASE

LAUNCH PUBLIC EDUCATION PROGRAM TO RECRUIT VOLUNTARY BLOOD DONORS, ELIMINATE HEPATITIS RISKS

The American Association of Blood Banks (AABB), the nation's largest voluntary organization devoted exclusively to blood banking, is launching a massive nationwide public education program to recruit more voluntary blood donors. A major purpose of the effort is to eliminate the high risks of hepatitis or other infections associated with the use of blood obtained from paid donors.

The new program was announced by Dr. William G. Battaile, AABB President, and Mrs. Bernice M. Hemphill, AABB Treasurer, and chairman of its National Clearinghouse Program, which was established in 1951 as the first cooperative system for the exchange of blood and blood donor replacement credits between blood banks throughout the United States.

"So much has been written about the bad practices associated with paying donors that the public has a distorted picture of blood banking in the United States," said Dr. Battaile. "We must convince people that only they can eradicate bad practices and paid donors through volunteering to give blood. We want to eradicate the paid donor as quickly as possible. Paying for blood not only increases the chance of transmitting hepatitis through transfusions, but it also discourages voluntary donations." Dr. Battaile stated that blood is living, human tissue, and blood transfusions in that respect were the first human tissue transplants." "If we continue to allow for the payment for blood," he said, "we will eventually have to put price tags on hearts, kidneys, and lungs, and permit human bodies to be bartered to the highest bidder."

The new public information program, recently approved by the AABB Board of Directors at its annual meeting in Chicago, will utilize communications media and public information tools on a national, state, and local basis to increase voluntary blood donations for the benefit of all blood banks. Donors will be urged to give to the nonprofit blood collection facility most convenient to them; i.e., hospital, community blood bank, or Red Cross Center.

"Currently only about 3% of the 100 million medically fit adults in the U.S. voluntarily give blood each year," Mrs. Hemphill stated. "The

nation's blood needs have been rising about 12% a year, and blood banks need 7 million pints this year. We believe that this vital health need for our people can be met on an all-volunteer basis if we achieve proper coordination, motivation, and communication with the public," she said, "and the AABB plans to continue to lead the way."

The AABB has created a special monetary fund, raised from charitable contributions and membership dues, to help pay for supplies and materials for the public education program. "We are a nonprofit organization, and our member banks can't pay the whole bill for the nationwide program that's needed," Mrs. Hemphill stated. "But hopefully, large advertising agencies will volunteer manpower and guidance to support the effort which is in the public interest."

She noted the Federal government has been a strong supporter of encouraging the voluntary donation of blood. For the past two years the Congress has passed a Joint Resolution to have the President proclaim January as "National Blood Donor Month." "Giving Blood Saves Lives" was one of the last commemorative appeals of the old U.S. Post Office Department. The purpose of last March's special postage stamp was to encourage more generosity from the 100 million potential blood donors.

There are two major nonprofit blood banking organizations in the United States--the AABB with its more than 1,500 hospital and community blood bank members, and the American National Red Cross which, among its other activities, operates 59 regional blood centers. The two organizations, through their members and centers, each supply about half of the blood used in the United States that isn't purchased from commercial blood banks. The AABB has invited the American Red Cross to participate in the new public education program as a joint effort of the AABB and the Red Cross. Both groups have been working cooperatively since 1960 under an interorganizational agreement for the exchange of blood and blood replacement credits between AABB banks and ARC centers.

The AABB also will call on government and national organizations to help implement an effective program of public education to arouse and recruit volunteer blood donors on a nationwide basis. Among the groups and agencies whose help is being sought are the National Advertising Council, the American Medical Association, the American Hospital Association, the Blue Cross Association, the National Association of Blue Shield Plans, and the Health Insurance Council.

# # #

Mr. ROSTENKOWSKI. Thank you Dr. Battaile and Mrs. Hemphill for a very informative statement.

Mr. Schneebeli?

Mr. SCHNEEBELI. I have no questions.

Mr. ROSTENKOWSKI. Thank you.

Mrs. HEMPHILL. Thank you.

Mr. ROSTENKOWSKI. Prof. Robert Mahoney, would you identify yourself for the record and then proceed with your statement.

STATEMENT OF ROBERT P. MAHONEY, ASSOCIATE PROFESSOR OF BIOLOGY, SKIDMORE COLLEGE, SARATOGA SPRINGS, N.Y.

Professor MAHONEY. My name is Robert P. Mahoney, and I am an associate professor of biology, at Skidmore College, in Saratoga Springs, N.Y. I appear here today as a concerned citizen and taxpayer and I appreciate the opportunity to speak before you today on H.R. 853, which proposes to allow blood donations to be considered as charitable contributions deductible from gross income.

I am asking that the written statement that I have already supplied you be entered into the record and also that the extemporaneous remarks which I am about to make be recorded as well.

Mr. ROSTENKOWSKI. Without objection, so ordered.

(The complete statement follows:)

STATEMENT OF DR. ROBERT P. MAHONEY, ASSOCIATE PROFESSOR OF BIOLOGY, SKIDMORE COLLEGE, SARATOGA SPRINGS, N.Y.

SUMMARY

I favor HR 853 which would allow "that blood donations shall be considered as charitable contributions deductible from gross income."

Volunteer giving of blood is currently classified as a "service donated" rather than a gift of "property," and I believe this is wrong.

The IRS tax law is contradictory—if you sell blood to a commercial blood bank, you must claim the proceeds as taxable income, and yet, when you give the blood to a non-profit organization, the blood has no deductible value.

A tax deduction for blood donations could serve as a meaningful donor motivator to get many non-participating but potential donors to become regular contributors.

Donor motivation studies appear to have questioned only those individuals who are already participating—those who already have a commitment. It might be helpful to have a psychological study (motivation study) on individuals who have never volunteered to give blood.

The danger of hepatitis is much less from volunteer blood than from commercial blood. I believe HR 853, if passed, would decrease our dependence on commercial blood (Judas Medicine).

Historically, the Red Cross and the Treasury Department have been against the idea of tax deductions for volunteer blood donations.

The proposed allowed deduction of $25 a pint, not to exceed $125 a year in an individual is a modest sum and would not result in a substantial loss of revenue.

HR 853 and increased volunteer blood donations would help relieve the suffering of hemophiliacs.

The late Representative John E. Fogarty of Rhode Island, who is well remembered for his interest in medicine, introduced a similar bill in 1962.

UNREALISTIC CLASSIFICATION OF BLOOD DONATIONS

My interest in this issue dates back to December of 1968 when, in conjunction with instituting volunteer blood drives on the Skidmore College campus, I became aware of the position taken by the Internal Revenue Service as regards

the classification of blood donations. The IRS does not allow deductions for volunteer giving of blood as they consider this a "service donated" rather than a gift of "property." This position dates back to the 1939 Internal Revenue Code and a 1920 Office Decision OD712, CB3, 188. Thus, blood donations have been classified as non-deductible, along with a carpenter's time to construct a civil defense observation post, and a radio station's providing free air time for religious and public affairs programs. Surely this is an unrealistic grouping of markedly dissimilar items!

Too, the position long held by the IRS on blood donations and tax deduction is blatantly contradictory, for uniquely—

> The IRS holds that if one sells blood, he or she must claim as taxable income monies received from such sale, and yet, when one voluntarily gives the blood to a non-profit organization, such as the Red Cross, the blood has no deductible value!

(However, blood purchased from a private blood bank and then donated is allowed as a deductible contribution.)

The Koch bill, HR 853, stands to correct this contradictory and unjust position by amending the Internal Revenue Code "to provide that blood donations shall be considered as charitable contributions (and thus) deductible from gross income."

IS "YOUR" BLOOD YOUR PROPERTY?

Surely the blood pulsing through our arteries and veins belongs to the body (the individual) which produced this substance and serves as its living vessel! This life-supporting fluid is synthesized by the individual at his or her expense, and yet when he or she chooses to contribute this tangible, physical property, it becomes a "service donated." It does not seem unreasonable to me that we question the sanctity of an Office Decision (OD 712) which was made more than 50 years ago!

Also, if Mr. Joe Thomas, a resident of the state of Michigan, who sells his rare high concentrate anti-Lewis B blood for as much as $40,000 a year must, *by law*, pay taxes on sale of his *property*, then those who willingly give their blood to no-profit organizations should be allowed to legally consider their donations "charitable contributions."

DONOR MOTIVATION

While HR 853 is laudible alone for what technical wrong it stands to correct, I believe a far more important benefit to humanity is possible with the aid of this bill. I believe that passage of this bill might serve as a new, meaningful incentive to encourage more of the potential volunteer donor population to become regular blood donors. Indeed, I am optimistic that the allowance of a tax deduction will *help* to solve the problem of chronic shortages of quality transfusable human blood.

A study on "The Motivations of Blood Donors" by Perry London and Bernice M. Hemphill (Transfusion *5*:559-568, 1965), revealed that of the 5581 donors sampled, 62 per cent were in the middle income range. This becomes more meaningful when one considers the some 36 million Federal income tax returns were filed with itemized deductions in 1969! Regretfully, only three per cent of the potential donor population now donates blood, and this means a great dependence on questionable quality commercial blood.

To the best of my knowledge, no psychological study has ever been made where non-donors were questioned as to why they have never donated blood or what factors might cause them to become blood donors. All donor motivation studies appear to have used as subjects those individuals who have given blood, and these people already have some commitment (replacement, humanitarian, relative needs transfusion, etc.), so that past studies are of little value in predicting the possible effectiveness of the tax deduction as a motivator.

COMMERCIAL BLOOD AND HEPATITIS

This tax deduction allowance has the added advantage of not appealing to those seeking on-the-spot cash (winos, dope addicts), for the tax benefit would not become available until income tax filing time in the year following that in

which the blood was donated. Too, an increase in volunteer blood donations will decrease society's dependence on commercial blood, where the incidence of hepatitis is 10 times that of non-profit blood.

The importance of nonprofit blood in the scheme of general health care was correctly stated in an editorial "The Judas Medicine" which appeared in the New York Times on February 22, 1971. The Times stated that "the annual toll of sickness and death from serum hepatitis in this country could be drastically reduced if all blood transfusions were performed with volunteered blood." It is estimated that at least 3000 patients die each year from hepatitis contracted by transfusions of infected blood. An alteration of the Internal Revenue Code, such as is suggested by H.R. 853, could conceivable stimulate greater awareness and involvement by the public, with the resultant yield of more, quality volunteer blood.

POSITION OF THE RED CROSS

While the American National Red Cross has been cool to the idea of a tax deduction for volunteer blood donations, I find it hard to accept the logic behind their thinking. Red Cross Vice-President Frederic S. Laise stated (1/31/69) the fear that "Red Cross could be accused, for example, of discrimination by individuals unable to meet (our) medical criteria, but desirous of earning tax exemption." That fear would appear to me to be largely unfounded, for as with any charitable contribution, the donor must have only the desire to be charitable, but the means to do so, whether those means be money, skilled labor, executive ability, or any number of other possibilities. Since anybody who can pass standard and universally respected standards for donors may contribute, there seems little chance that anyone would rebard such health precautions as prejudicial.

POSITION OF THE TREASURY DEPARTMENT

The position of the Treasury Department on this issue has been that "on the basis of general tax principles, it would be difficult to justify the allowance of a deduction for blood donations . . . (and) these concessions would bring about a major shift in the distribution of tax burdens and would involve a substantial loss of revenue.

It is frustrating to have the Internal Revenue Service stand in the way of this blood and tax suggestion which is intended to benefit all people, and yet realize that the IRS has been willing to be quite generous with public money to a privileged few. Thus, research and background reading revealed to me that the IRS issued Revenue Ruling 64-224, on August 17, 1964, which allowed deductions of fines levied as treble damage payments for antitrust violations! I doubt very much that a $25 tax deduction for a donation of a pint of blood would cause a "major shift" in the distribution of tax burdens or a "substantial loss of revenue."

HELP FOR HEMOPHILIACS

It is evident that some new approach to donor motivation is required; the needs of the future can scarcely be fulfilled by methods which have hitherto not provided adequate supplies. Population pressures and medical advances indicate a continuing, heavier demand for blood. Indeed, only this past year The National Hemophilia Foundation announced that a prophylactic regimen of intravenous injection of a lyophilized cryoprecipitate had become available for those who could afford the $22,000 per year cost. Imagine, prophylactic treatment of hemophilia is a possibility if only enough volunteer blood could be obtained! Presently, it is estimated that 100 of the approximately 100,000 hemophiliacs in the United States are receiving this treatment.

URGE PASSAGE OF H.R. 853

I urge the Committee to take affirmative action on H.R. 853, to correct the injustice of the present tax law, and to correct the situation whereby a mere technicality of classification (calling blood donations a "service" rather than of "gift of property") is all that prevents this humanitarian proposal from aiding the blood donation program.

Finally, while you consider this bill and the more complex National Health Insurance Proposals, I urge you to recall the late Representative John E. Fogarty.

of Rhode Island, who always championed the cause of medicine. Some time after I had suggested the idea to Representative Koch, I became aware that Mr. Fogarty had introduced a similar bill during the second Session of the 87th Congress on August 15, 1962! Thus in addition to the reasons previously cited, passage of this bill would be a fitting memorial to the late Representative Fogarty.

Professor MAHONEY. Thank you.

My involvement with this problem dates back 3 years to the time when I was trying to establish volunteer blood donation programs on the Skidmore College campus and I became aware of the problem of donor motivation. It wasn't difficult to motivate the students. They are very idealistic and very readily motivated to help their fellow man, to really show their love for their fellow man.

Then I became aware of the larger problem of donor motivation on a national level. So I thought that, perhaps, a tax deduction incentive would be a good motivator, really meaningful motivator. When I went and studied the tax laws, I was amazed to find that one could not deduct the value of a pint of blood donated to a nonprofit organization as this blood was considered a "service donated" rather than a gift of one's "property."

So I suggested to Representative Edward Koch of the 17th Congressional District of New York that this would be a legislative matter if one wanted to correct this. Thus to correct the situation one would need legislation to say that from this day forward blood donations to nonprofit organizations should be considered as charitable contributions and thus deductible from gross income.

In fact, the IRS on this is to me blatantly contradictory in that if one sells blood, one must claim as taxable income moneys obtained from the sale of one's blood and yet when one gives blood, the same blood has no deductible value. How can this be two things at the same time?

It is surely one's property which is pulsing through one's arteries and veins. It is synthesized by the individual at his expense or her expense. It certainly is his or her property. So that is why I asked Representative Koch to introduce this bill. Too, I do think that this would be a meaningful donor motivator. I am interested, however, also in correcting what I think is this injustice of the Internal Revenue Service law and so the bill is before the House Ways and Means Committee now.

That the tax deduction allowance would be a meaningful motivator, I believe, is evident in the fact that according to one study, approximately 62 percent of nonprofit blood was donated by middle-income individuals, and we realize there were 36 million Federal income tax forms filed with itemized deductions in 1969. Thus, there is a large pool of middle-income people whom we could draw upon for these noprofit donations.

These are people who are concerned with having good health. They are not the commercial donors who were alluded to in the previous testimony (of Hemphill and Battaile), and we would agree that commercial blood is very dangerous. The estimate given, of 10 to 12 times the danger of contracting hepatitis from commercial blood, is conservative.

It was stated in the New York Times yesterday, October 27, that 15 times is more nearly the correct figure.

I would also like to just recount to the committee a case where a physician in New York, Dr. Howard Rusk, who formely wrote for the Times, described in the December 21, 1969, issue of the Times, his experience with a commercial blood donor.

He fell in step with a fellow, who was walking, I believe, along 14th Street. The fellow told him he was on the way to sell blood "to get money to buy a gallon of cheap wine," and Dr. Rush asked him, "How often do you sell blood?" And the fellow gave him a figure.

Dr. Rusk stated, "Don't they check up on your social security number?" and the fellow said, "Yes." And he pulled out nine social security cards.

Dr. Rusk said, "Don't you feel poorly from too frequent selling of your blood?" And the fellow said, "When he did he went to the hospital and they gave him a blood transfusion."

Here is a guy who is, perhaps, a walking hepatitis bomb, who will sell blood that may be passed on to a hospital. There is no chance to check on where the blood came from. The fellow selling his blood, laden with hepatitis, is getting good quality blood in return.

That is what we are up against right now, in reliance upon commercial blood (probably free if he is indigent).

I think that a proper allowance—it is just correcting a technical wrong, is not asking for any great kindness. If this wrong is corrected, and blood donations are allowed as charitable contributions, we would increase both the quantity and quality of the blood available to the American public.

I would like to point out also a quote from something which Dr. Garrett Allen of the Stanford University Medical School had to say. He said: "That approximately 90 percent of all of the outbreaks of hepatitis are from commercial blood." And he further pointed out that this causes a hospitalization of the people who get the blood, of approximately 450,000 days. Now, that is 1,232 years, and it also is, at $50 a day, hospital day, just for the bed, $22.5 million.

So I agree with the previous witnesses on this, that we should not pay for blood under national health insurance programs. I got the analysis of the health insurance proposals introduced in the 92d Congress only last Friday, and the only one that I was able to really find this spelled out specifically on was H.R. 4960, the Fulton-Broyhill bill, where it said that under catastrophic benefits, blood in excess of 3 pints would be paid for.

I think that what this would do, the effect would be anomalous in that you are trying to solve one health problem and you are going to create a much more serious health problem.

I would also state that the insurance coverage for blood gives the public a false sense of security. They think that because there is this insurance policy covering them, they are guaranteed blood. They are not! The money may be there, but the good quality blood that is required to keep them alive certainly is not guaranteed to be there. And this is certainly pointed out by the previous witnesses, as well.

Blood needs are increasing. There is increased surgery. The hemophiliacs are in desperate need of treatment. There is a new prophy-

lactic regimen for hemophilia. It is a concentrated material which is available, and the cost is $22,000 a year for the 100 out of approximately 100,000 hemophiliacs in the United States who can afford it.

Now, if there were enough voluntary blood given, perhaps more of the hemophiliacs would be able to get onto this sort of treatment.

Blood is needed for cancer and leukemia patients, of that there is no question.

Only in yesterday's Washington Evening Star (Oct. 27, 1971), District Delegate Walter E. Fauntroy pointed out the sickle cell crisis which is now perhaps coming to the forefront, that the blacks have this problem, and it is a very painful, excruciating problem. One of the new treatments for it in the last couple of years has been partial exchange transfusion, and the results have been a great lessening of the pain (M. Kaplan, NE. J. of Medicine *284:* 138–82, 1971).

Now, for those who say that this would serve as an incentive, and they are against incentives, I say this is just giving to the individual what is his or her due—that he or she is making this charitable contribution and deserves to be allowed to take a tax deduction for it.

As regards incentives, I would point out that many incentives have been given, and I will quote from the New York Times of October 30, 1966, Dr. E. A. Dreskin, then the president of the American Association of Blood Banks. He states, in Los Angeles, at the time:

> The shortage of blood in some parts of the country, particularly the East Coast, was so acute that blood banks offered trading stamps and tickets to movies or baseball games as inducements to give blood.

Weekend passes have been offered to the military to encourage them to give blood. In my home community, the Saratoga Performing Arts Center gives tickets to a ballet once a year, to try to encourage people to give blood.

I would like to make it clear that it is not the Red Cross which is giving the incentive. It is whichever organization is sponsoring the particular blood drive at the time.

And I would further like to quote from Dr. Dreskin in a July 18, 1969, letter to me. He said that the "proposal to promote blood donations by means of an income tax credit could be of great value in promoting blood donations."

I think that if you have this kind of incentive for individuals, you would get more quality blood, and there would be less dependence upon commercial blood.

As a concluding statement, I would say that this bill deserves your very serious consideration for the reasons I have cited, and also because a bill similar to it was introduced in 1962 by the late great Representative John Fogarty of Rhode Island. I didn't know that until I did considerable research on this, and as you all know, I am sure, Mr. Fogarty was a great friend of medicine and health.

Thank you, and I would be pleased to answer any questions you might have.

Mr. ROSTENKOWSKI. No questions.

Thank you.

Dr. August Groeschel? [No response.]

Bernard I. Diamond?

STATEMENT OF BERNARD I. DIAMOND, CHAIRMAN, GOVERNMENT AND PROFESSIONAL RELATIONS COUNCIL, AMERICAN ASSOCIATION OF BIOANALYSTS; ACCOMPANIED BY RICHARD HOLZWARTH, IMMEDIATE PAST PRESIDENT

Mr. ROSTENKOWSKI. Would you identify yourself?

Mr. DIAMOND. I am Bernard I. Diamond, accompanied by Richard Holzwarth, immediate past president of our organization.

We appreciate this opportunity to present our views on National Health Insurance legislation.

I am a bioanalyst, director of Biomedical Laboratories, an independent bioanalytical laboratory in King of Prussia, Pa. I am chairman of the committee on governmental and professional relations of the American Association of Bioanalysts, which is affiliated with the American Institute of Biological Sciences and the American Association for the Advancement of Science.

Mr. Richard Holzwarth, accompanying me, is immediate past president of our organization and director, Eastern Hills Laboratories, Cincinnati, Ohio.

We appear before you at the request of and representing the following organizations:

The American Association of Bioanalysts.
The Arizona Medical Laboratory Association.
The California Association of Bioanalysts.
The Connecticut Association of Clinical Laboratories.
The Florida Association of Medical Laboratories.
The Illinois Association of Clinical Laboratories.
The Maryland Association of Bioanalysts.
The Massachusets Association of Clinical Laboratories.
The Michigan Association of Bioanalysts.
The New Jersey Association of Clinical Laboratory Directors.
The New York State Association of Clinical Laboratories.
The New York State Chapter, American Association of Bioanalysts.
The Ohio Association of Bioanalysts.
The Oklahoma Association of Bioanalysts.
The Oregon Association of Independent Laboratories.
The Pennsylvania Association of Clinical Laboratories.
The Rhode Island Association of Clinical Laboratories.

The membership of the American Association of Bioanalysts is composed of individuals who have devoted their talents to the direction and application of the life sciences to clinical laboratory analyses, those who teach such curricula, and those who hold similar commissions in the armed services or governmental laboratories.

We were privileged to appear before Chairman Mills, in March of 1967, during committee hearings on the Social Security Amendments of 1967, related to the participation of the independent laboratory under medicare. Your committee at that time aided in the establishment of improved standards of laboratory performance for the citizens of this country. Bioanalysts are certain of your continuing desire to provide quality laboratory services in the future. We offer every assistance in implementing the best health services delivery system available.

In passing, we may also note our formal presentations on independent laboratory matters in 1965 and 1967 before the Senate Committee on Finance; in June 1967 before the House Committee on Interstate and Foreign Commerce; and in September 1967 before the Senate Committee on Labor and Public Welfare.

PRESENT STATUS OF HEALTH CARE

A review of many bills for national health insurance indicates that:

(*a*) The provision and delivery of quality health services is of critical importance, and of the highest national priority.

(*b*) Present programs do not provide for continuing, efficient, comprehensive, low-cost health services to all citizens.

(*c*) There is not adequate emphasis on preventive medicine. There must be maintenance of good health, rather than the more expensive alternative treatment of illness.

(*d*) The physician must retain the right to order tests he deems medically necessary. He and his patient must have free choice of qualified, available laboratory facilities.

(*e*) A way must be found to provide services outside the hospital, where medically indicated, as a less expensive alternative to inhospital care. While the delivery of high-quality laboratory services is not the largest sector of health care cost, it is, in our opinion, a significant part of the physician's armamentarium in diagnosing and treating his patient.

FEDERAL AND STATE LEGISLATION

As recently as 1965, there were relatively few States with laboratory licensing laws. At present, approximately 22 States have some form of laboratory legislation. A recent summary available from the Center for Disease Control indicates that approximately 100 bills have been introduced in the various State legislatures for the purpose of establishing quality standards in personnel, facilities, and laboratory performance. The Federal Government under the medicare law and the Clinical Laboratory Improvement Act of 1967 has set very high standards for clinical laboratory operations.

Bioanalysts in every State have made significant contributions in raising the quality of laboratory services to the citizens of the United States.

We recommend that representatives of the independent laboratories—both physicians and nonphysicians—be invited, at the outset, and set after the fact, to participate in the deliberations of ad hoc and advisory committees which will draw up the rules and regulations which carry out congressional intent with respect to health security. We welcome the opportunity to serve in this capacity with other professionals and with consumer and community representatives.

THE CHANGING ROLE OF THE INDEPENDENT LABORATORY

Independent laboratories are fully integrated into the health services system, and provide services to physicians, hospitals, nursing homes, extended care facilities, Veterans' Administration facilities, Blue Cross and Blue Shield plans, the Armed Forces, private insur-

ance companies, and innumerable health and welfare agencies. All of these rely upon the testing and home visit services of independent laboratories.

In many States, licensed, certified, or approved laboratories are classified as community health facilities, and are undertaking public health duties which have previously burdened State health laboratory facilities. These involve broad ecologic relationships of the human and his environment.

We recommend that there should be due consideration in any national health security program for the expanded role of the community laboratory provider of health services in full participation with the State public health laboratories. With the State tax dollar already overburdened, it is logical to expect the independent laboratory to provide new services.

We recommend further that Congress implement the earned right of the independent laboratory to continue to provide reimbursable services under whatever new system the Congress develops.

EQUALITY OF APPLIED STANDARDS

As of this moment, only independent laboratories are subject to the stringent Federal standard of medicare and the interstate laws in terms of personnel qualifications, onsite inspections, compulsory proficiency testing, and adequacy of facilities.

The Health Insurance Benefits Advisory Council, in its first report to Congress, made note of a "double standard" where hospital laboratories and doctors' office laboratories are not under equal control.

We are pleased to report that HEW has developed medicare hospital laboratory standards which will appear in the Federal Register some time next year.

The doctors' office laboratories continue to operate under no constraint of Federal or State control.

We recommend that under any new system of health services, the same standards apply to all who perform laboratory tests and who are reimbursed for such services by any governmental or private health insurance program. Consistent with that recommendation, we recommend that the Congress consider the following amendatory legislation:

Following the words, "No diagnostic tests performed in any laboratory," after subparagraph (g) of section 1861(s), of title XVIII, Public Law 89–97, page 37, strike out the following: "which is independent of a physician's office—".

CLARIFICATION OF THE TERM "LABORATORY"

Since the development of the conditions for participation for independent laboratories under medicare, in 1965, the term "independent laboratories not associated with hospitals or doctors' offices. In reviewing current legislation, we note use of the terms, "diagnostic laboratory" services, "pathology laboratory" services, and occasionally, "laboratory" services. Bioanalysts may construe some of these designations as restrictive and discriminatory.

We recommend that in all legislative language, the term "laboratory services" be routinely used to cover all qualified facilities and personnel in the respective laboratory disciplines.

DECREASED COSTS OF INDEPENDENT LABORATORY SERVICES

Independent laboratories do not receive or request public funds and grants for equipment and facilities. They are taxpaying organizations and therefore carry their fair share of the burden of government.

In spite of the economic and competitive disadvantages imposed upon a majority of our members, as compared to the hospital laboratory facilities which under medicare could purchase expensive equipment and apportion the cost to medicare and other carriers, the independent laboratory was able to lower prices in the marketplace. Hospital laboratory fees, on the other hand, increased steadily with the retention of a captive (patient) market.

Many independent laboratories have instituted advanced systems for cost control, management, automated analysis, and electronic data processing. Much more data is available to the doctor today for the patient's test dollar than was available 10, or even 5, years ago.

We recommend that every effort should be expended by Congress to insure fair competition in the marketplace. The independent laboratory director is confident of his ability to provide quality service at reasonable cost.

THE HEALTH MAINTENANCE ORGANIZATION

The Social Security Amendments of 1971, and the numerous House and Senate bills on health security, promote the development of health maintenance organizations (HMO) as a less expensive alternative to our present system.

We believe there is great potential in this approach. In developing the HMO concept, attention should be directed to:

1. Providing comprehensive prevention of specific disease, the early detection of persons at special health risk, the treatment of active disorders, the maintenance of optimum status in long-term conditions, and the rehabilitation of the disabled.
2. All the above fully accessible to all, when and where they require services.
3. The benefit package should include out-of-hospital testing, multiphasic screening procedures, together with physician-ordered laboratory studies.
4. Significant emphasis must be placed on outpatient care in nursing homes, rehabilitation centers, and extended care facilities.
5. The HMO must be publicly accountable and should have on its governing boards consumer and community representatives.
6. The HMO must be subject to ongoing quality control at all levels: Services, costs, and management.
7. The HMO must utilize the full range of manpower available in the community.

We recommend that Congress take note of the many presently existing laboratory facilities, so that HMO's will not needlessly expend

taxpayers' funds in the planning and developing of new laboratory facilities where qualified facilities already exist. We recommend further that the HMO decisionmaking bodies include representatives of the independent laboratory.

CONTINUING EDUCATION AND TRAINING

The rapidly moving front of laboratory technology has doubled the number of tests performed in the last 5 years. This number will probably double again in less than 5 more years. New systems of analysis, new tests, computerization of data, have created many new problems for all levels of laboratory personnel.

It is essential that programs and grants in continuing education be developed, not only for those presently licensed in the fields, but also for those supportive personnel whose number is legion, and without whom the laboratory could not operate. There must be full exploration of State and/or Federal licensing, means for vertical mobility of degreed and nondegreed personnel, and development of equivalency examinations at all levels, to meet the demands of the next decade.

We recommend that Congress insure the continuing participation of all interested groups in the important deliberations which have already been initiated in the above area, a participation which the bioanalyst has earned through his service in the laboratory field.

CONCLUSION

We join Chairman Mills, members of this committee, the Congress, and the Secretary of Health, Education, and Welfare in their efforts to provide a comprehensive, low-cost, high-quality system of health care to all citizens of this great country. We join all members of the health team in our deep concern for the health and safety of the public. Thank you.

Mr. ROSTENKOWSKI. Thank you, Mr. Diamond.

Mr. Schneebeli?

Mr. SCHNEEBELI. Mr. Diamond, welcome to this committee, I am particularly interested in the specific recommendations that you make. It is quite obvious that your group, your association, has much to offer in this very broad analysis that we are trying to make.

Do you feel that these community health planning groups could be effective in trying to avoid duplication between your services and the hospital laboratories et cetera? It seems that you put quite a bit of emphasis on this, and it seems to me that some group has to be established to make this determination.

Mr. DIAMOND. I certainly would agree with you, Mr. Schneebeli, there is no question what the hospitals' contribution needs to be in the program. As you probably know, there are many hospitals of 200 beds and under, that are presently discussing the possibility of outside laboratory services providing the total service.

Yes; we feel that we have a right to sit in on these comprehensive planning groups, and this is part of the thing we are asking Congress to insure for us.

Mr. SCHNEEBELI. I agree with you. Thank you very much for your splendid statement.

Mr. DIAMOND. Thank you very much.

Mr. ROSTENKOWSKI. Thank you very much, Mr. Diamond.

Arthur Sherman?

STATEMENT OF ARTHUR SHERMAN, Ph. D., PRESIDENT, MEDICAL DIAGNOSTIC CENTERS, NORRISTOWN, PA.

SUMMARY

Multiphasic Health Screening is a new approach to the delivery of health services using automation and paramedical personnel. With proper organization of the system a superior health examination can be carried out less expensively and more conveniently. Many physicians view this new approach with concern, but with exposure tend to find it acceptable.

One major application for this service is for Outpatient Diagnostic workups. Substantial barriers exist limiting its use, but there should be lowered with a new National Health Insurance program.

The second use for this service is in conjunction with the routine annual physical. Although this should be the cornerstone of a Preventive Medicine system, to date this is happening to only a limited degree. Again, National Health Insurance should encourage the routine physical examination to assess health and prevent disease.

Mr. ROSTENKOWSKI. Dr. Sherman, would you identify yourself for the record, please, and then proceed with your testimony.

Dr. SHERMAN. Dr. Arthur Sherman, president of the Medical Diagnostic Centers, in Norristown, Pa.

Sir, Iwould like to read the comments, if I may, and then add some extemporaneous remarks.

Mr. ROSTENKOWSKI. You may do so.

Dr. SHERMAN. Thank you.

MULTIPHASIC SCREENING—OUTPATIENT SERVICES USING PARAMEDICAL PERSONNEL

For many years now, the medical service industry has operated as a "cottage industry"; the physician has functioned as an individual entrepreneur, and all aspects of the delivery of medical service has revolved around this fact. I believe that this is a major reason why systematic approaches to the delivery of medical services as well as the extended use of paramedical personnel have been slow to be developed.

Today this "cottage industry" system is faced with an inflationary crisis, and will continue to be, until new approaches can be developed and implemented. The danger is that new approaches can be developed, but if they are not implemented correctly they will amount to no more than a repackaging of the existing cumbersome system.

Along with other organizations around the country, we have been operating a multiphasic health screening center for some time now. The original work in this area has been done by the Kaiser health plan in California, and our operation is similar to theirs in principle. An individual can contact us for an appointment, provided there is a physician to whom the results of the examination may be sent. The individual then arrives at our facility for an hour and a half visit.

During this time, registered nurses and technicians obtain a medical history and carry out tests on his eyes, hearing, lung capacity, heart, chest (X-ray), and blood and urine.

Our experience has been that people find this to be quite pleasant and convenient. After all data has been processed, a report is mailed several days later to the individual's personal physician, and he is encouraged to make an appointment to complete the physical examination.

PARAMEDICAL OPERATION

The key to carrying out a program such as ours is that there is no need for a physician to lay hands on the person being screened. At the same time, the examination is of excellent medical quality. This seemingly contradictory situation is achieved in the following way. First of all, we have a medical advisory board which reviews our medical protocol from time to time. Our present board is listed below, and I would note that they are a distinguished and responsible group:

Thomas Clark, M.D., medical director, All Saints Hospital, Philadelphia, Pa.;

Robert Corley, M.D., specialist, internal medicine and cardiology, Charlotte, N.C.;

Stanley Gottlieb, M.D., medical director, General Electric Co., Missile and Space Center, Valley Forge, Pa.;

Johannes Ipsen, M.D., professor of epidemiology and medical statistics, University of Pennsylvania School of Medicine, Philadelphia, Pa.;

Arthur D. Nelson, M.D. associate vice president, Temple University Health Sciences Center, Philadelphia, Pa.;

Robert Ravdin, M.D., professor of surgical research, School of Medicine, University of Pennsylvania Hospital, Philadelphia, Pa.;

Frank Tometta, M.D., chief of anesthesiology, Montgomery Hospital, Norristown, Pa.;

Manrico Troncelliti, M.D., attending surgeon, Sacred Heart Hospital, Norristown, Pa.

Second, we have a group of medical consultants that help us train our paramedical personnel and are available for any problems that arise in their own specialty. These men are all board certified in their specialties.

Finally, after a person has gone through the multiphasic process, his electrocardiogram is read by a cardiologist, his chest X-ray is read by a radiologist, and his blood and urine are analyzed in our own laboratory, which has a pathologist as codirector.

When all of the data have been collected, they are computer-processed and compared to normal-abnormal ranges obtained from a number of sources. Any out-of-range values are noted. Then, when the computer report has been prepared, our medical director, Salvatore C. Carfagno, M.D., a board certified internist, reviews it and correlates all aspects of the examination and includes his comments. Then the entire report is forwarded to the family doctor.

Again, no physician has seen this individual as part of our multiphasic screening examination. All of the work has been done by paramedicals. Yet a very thorough examination has been achieved.

INTERFACE WITH EXISTING MEDICAL PRACTICE

Most physicians in the Delaware Valley operate in solo practice, so most of the people we see return to their private family doctor for the completion of the examination. In general, relatively few physicians make direct referrals.

This is evidently caused by the conservative nature of this group, and the caution with which they embrace new approaches. Also, anything which is not physician-owned is viewed with suspicion. Of course, we do in general make their job much easier, but this fact has not as yet overbalanced the objections.

Of those physicians who see people that have chosen to go through our system on their own initiative, many are quite negative at first. Apparently, they object to any other organization seeing their patient. With time, this response has moderated, and most physicians that are familiar with our work are accepting it for what it is.

OUTPATIENT DIAGNOSTIC SERVICE

There are two ways to make use of the multiphasic service described above. One has been published widely; that is, the annual routine physical. The second is as an outpatient diagnostic service, and I would like to say a few words about this.

Outpatient diagnostic services are traditionally available either in a physician's office or in the outpatient department of a hospital. In either case, the costs are high and the inconvenience is considerable. Using the multiphasic approach with paramedicals, we find ourselves able to provide the routine diagnostic services, that is, chest X-rays, electrocardiograms, laboratory analysis, at much lower cost and with far more convenience.

For example, a patient referred to us by a physician for a diagnostic workup is put through the same complete multiphasic program described earlier, at a cost of only $50. The visit is to one location only, and takes an hour and a half.

As well, many additional procedures are carried out beyond the chest X-ray, the electrocardiogram, and the laboratory analysis. If just these three were done in the traditional way, the coust would exceed $50, and the inconvenience would be considerable.

The basic difficulty in providing this service as an outpatient diagnostic service is that we are neither a physician (where Blue Shield might pay) or a hospital (where Blue Cross would pay). Therefore, in most cases, the health insurance carrier will not reimburse us for these services, apparently preferring that they continue to be provided by the present expensive, inefficient, and inconvenient system.

For example, medicare will not reimburse us for a diagnostic chest X-ray although our equipment is modern, and our procedures are controlled by a broad certified radiologist. I understand, however, that if our X-ray facility were portable, such reimbursement would be acceptable. This is just one example of the patchwork nature of the present system. As far as Blue Cross is concerned in the Delaware Valley, all approaches have failed and they will not reimburse us for any of our services.

It makes no sense to deny payment for such valid services, especially when hospitalization for diagnostic workups can be avoided. I am encouraged to see that many of the proposals for national health insurance would include payment for such services.

PREVENTIVE MEDICINE

Most decisions relative to multiphasic screening has considered its ability to make the routine annual physical possible for large numbers of people. There simply would not be enough physicians available if we attempted to examine all adults annually. If one questions the value of multiphasic screening on a routine basis, then we are questioning, in reality, the value of routine physical examinations. Clearly, if routine examinations are done, we will find much undetected or a symptomatic disease. Many of these people, if left unattended, would end up in a hospital bed when the disease becomes serious enough to be evident.

Therefore, money will be saved by reducing hospitalization costs more than offsetting the cost of these examinations (preliminary statistical evidence of the reduction in hospitalization has been published recently by Dr. Collen of Kaiser at the October 11, 1971, annual meeting of the American Public Health Association).

I might interject that I have a copy of the paper, and I can leave it for the committee files.

Mr. ROSTENKOWSKI. Without objection, so ordered.

Dr. SHERMAN. Since such a program of annual physicals will save money if done in the way we suggest, I think any national health insurance program should allow reimbursement for such examinations. In this way people would be encouraged to practice preventive medicine and maintain good health.

Another program which is being actively promoted by HEW are health maintenance organizations. By their very name, and certainly with the concept behind them, one would assume that all such organizations would have a program of annual multiphasic examinations. In my limited experience, such does not seem to be the case. Even within Kaiser, not all facilities include multiphasic services. This situation appears to exist as a consequence of the attitude of the individual HMO medical group. As I noted earlier, physicians have generally been cool to this type of service.

It would seem to me that any HMO being organized with Federal funds should be required to establish an active preventive medicine program and include multiphasic services as part of this program.

Thank you. I want to add just a brief comment. If we would truly like to implement preventive medicine in this country and set up our health care system on a long-range basis, what we really ought to be doing is screening children.

We have begun a program of this on our own in Norristown, and it is quite feasible to do a very careful, thorough examination on children all the way down to the infant—on children from zero to 6.

This can be done efficiently, it can be done with paramedicals, and in reality it ought to be compulsory. In this country, if we had such a compulsory examination on these children, so many of the medical problems we have today would not exist.

Thank you.

Mr. ROSTENKOWSKI. Thank you.

Mr. Betts will inquire.

Mr. BETTS. Just one question, doctor.

Are the persons who perform the services in your groups—are the services such that they have to be licensed by the State, or are licensed?

Dr. SHERMAN. No; the services they provide do not generally require licensure. We do, however, use registered nurses, and on occasion, a trained technician for X-ray, for example, but by and large they are registered nurses.

Mr. BETTS. Are the paramedics ever retired service corpsmen?

Dr. SHERMAN. This would be an excellent source of paramedicals. We have not pursued that at this time, but we have very much got it in mind.

Mr. BETTS. I was wondering if some of the problems you have in connection with not being paid by the Government go to the fact that many of the services aren't licensed services. Do you think that has anything to do with it?

Dr. SHERMAN. No. For example, the difficulty with Blue Shield—we do an electrocardiogram and it is done by a trained nurse, who is trained by a cardiologist. The electrocardiogram is interpreted by a cardiologist, and as such, Blue Shield would, on its present plan, reimburse the cardiologist, but not our company. There are all sorts of difficulties such as this.

Mr. BETTS. You have answered my question.

Conversely, the licensing doesn't help you one bit. The nurses are licensed, and yet——

Dr. SHERMAN. That is right. We are, in fact, reimbursed by one nonprofit health insurance plan, which is the Inter-County Hospitalization Plan in eastern Pennsylvania. They do reimburse us for our entire range of services on an outpatient basis.

Mr. BETTS. Thank you.

Mr. ROSTENKOWSKI. Mr. Schneebeli?

Mr. SCHNEEBELI. Dr. Sherman, noting some of the men on your advisory board, it is evident your center is highly qualified. But how do you deal with a center that might spring up in the next county that is not qualified? If you have no State licensing or evidence of your degree of professionalism, how do you differentiate here? You could have a lot of "shysters" set up; couldn't you?

Dr. SHERMAN. Yes. We don't want any used car salesmen in this business.

Mr. SCHNEEBELI. How do you operate?

Dr. SHERMAN. We operate the laboratory, which is licensed by the State.

Mr. SCHNEEBELI. I am not criticizing your operation, but I think you recognize what I am driving at.

Dr. SHERMAN. We are concerned with the question. We would like to see licensure or regulations. We feel we are doing it in a very good way and it should be done this way.

By the way, I am not a physician, I am an engineer, and we have a medical director who is my vice president and who has complete control of anything we do in the screening center.

Mr. SCHNEEBELI. I agree there should be farming out of a lot of medical services now performed by the highly trained professional. The previous witness was of the same idea.

In your instance here, I agree, you have a lot to contribute, but there are limitations, without licensure.

Dr. SHERMAN. Yes.

Mr. SCHNEEBELI. I am wondering what we do to overcome this, because there is a lot of benefit that can be derived from your type of operation.

Dr. SHERMAN. I think we can very readily develop the protocol.

Mr. SCHNEEBELI. Does a State have to set up guidelines and approve them before the Federal Government can come in for reimbursement? Don't forget, we are spending taxpayers' money in reimbursement, and we can't pay out the money to people who don't know what they are doing in this rather sensitive field.

Dr. SHERMAN. In the laboratory area, we are licensed by the State, and we are reimbursed by medicare.

Mr. SCHNEEBELI. But you go beyond that?

Dr. SHERMAN. We go beyond that. Through medicare we are reimbursed for the electrocardiogram.

Mr. SCHNEEBELI. Are there many such diagnostic centers in the State?

Dr. SHERMAN. In the State of Pennsylvania there may be one or two others. I have heard of one or two others—but as far as I know, we are the only one.

Mr. SCHNEEBELI. Have you tried to get approval through State licensing?

Dr. SHERMAN. We are accepted by the State health department. They have no complaint as far as what we do.

Mr. SCHNEEBELI. You have no official stamp?

Dr. SHERMAN. No. We have been to the county medical society. They were concerned, but they have not opposed us.

Mr. SCHNEEBELI. Don't you think that gradually they are going to recognize that people like you can be of material assistance to them, assuming a lot of detail from them?

Dr. SHERMAN. Yes.

Mr. SCHNEEBELI. How about hospitals that do this type of work?

Dr. SHERMAN. We are an outpatient facility and we are not loved by hospitals.

Mr. SCHNEEBELI. I would think they would have second thoughts, because they derive a lot of their money from this same type of laboratory work.

Dr. SHERMAN. We do laboratory work for hospitals.

We maintain there is no point, really, for a hospital, an acute care hospital, to be in this business. This is the kind of thing there is no need for them to be in. We can do it so much more efficiently since we deal with presumably well people, and they deal with sick people.

Mr. SCHNEEBELI. What work do you do beyond the work that was described by Mr. Diamond? What is the difference between your types of work?

Dr. SHERMAN. The work that Mr. Diamond described related to analyses of blood and urine. We go much beyond that to do an exami-

nation, a screening examination, where we take a history, and we do electrocardiograms, and other procedures.

Mr. SCHNEEBELI. What we call a "physical exam," an annual physical.

Dr. SHERMAN. Yes; it is an annual physical when the physician wraps it up.

Mr. ROSTENKOWSKI. Thank you, Doctor.

Dr. August Groeschel?

STATEMENT OF DR. AUGUST H. GROESCHEL, PRESIDENT, COMMUNITY BLOOD COUNCIL OF GREATER NEW YORK; ACCOMPANIED BY HARRY WELKER, DIRECTOR OF INFORMATION

Mr. ROSTENKOWSKI. Identify yourself for the record, Doctor, and the gentleman who is accompanying you, and then proceed into your testimoy.

Dr. GROESCHEL. I am Dr. August H. Groeschel, president of the Community Blood Council of Greater New York, chairman of the Committee on Blood of the Greater New York Hospital Association, and vice president of the New York Hospital-Cornell Medical Center.

Mr. ROSTENKOWSKI. Continue, Doctor.

Dr. GROESCHEL. Mr. Chairman, the Community Blood Council of Greater New York, which is the parent body of the Greater New York blood program, wishes to go on record—strongly—as supporting H.R. 853.

We support Congressman Koch's bill because it will work for the direct benefit of the patients with blood needs not only in the New York metropolitan area but all over the country.

You should understand, gentlemen, that only about 3 percent of the U.S. population voluntarily donates its blood toward a reserve upon which any one of us might have to call at some time.

That's not enough. But, if just 1 percent more of the population could be induced to donate blood on a regular basis, hospital blood needs for their patients could be met with volunteer blood.

Why volunteer blood? What is so special about volunteer blood?

Volunteer blood donors are not paid a penny. Their motivations are healthy ones. They want to provide a health resource for their communities. They want to insure blood coverage for their families in case of medical emergencies. They want to donate blood to help a friend who needs it.

Whatever their reasons, they are not doing it for personal gains. They are good, concerned citizens. Ninety-nine percent of them are healthy. They have no reason to falsify their medical histories—which every licensed blood bank must record.

The Center for Disease Control of the Department of Health, Education, and Welfare noted a sharp rise in the incidence of serum hepatitis last year. It is estimated that at least 150,000 persons will contract the disease this year—the majority of them as a result of blood transfusions.

This is a very serious disease. The mortality rate is 10 percent, and much higher for persons over the age of 40.

Medical authorities, both research and clinical, agree that there is a 12 times greater risk of contracting hepatitis from commercial or purchased blood than there is from volunteer blood. Probably one of the prime reasons is the source of donors to commercial blood banks.

Many of them, especially in densely populated areas, are drifters, narcotics addicts, alcoholics, or other unfortunates who sell their blood to get money. Some, using a variety of names, sell their blood as often as once a week. Such people feel no obligation to be truthful about their medical histories. And such blood, even if it is free of disease, leaves a lot to be desired in its capacity to benefit a sick person.

These are some of the reasons why we feel such a need for voluntary donated blood.

In times of emergency when there is an areawide blood shortage, thousands of people who are not regular donors will turn out to give their blood, asking no reward. Here is that vital additional 1 percent of the population that could be converted into regular donors. We believe the government, indeed public, recognition, as provided for in Congressman Koch's bill, could be just the incentive needed to get that additional 1 percent.

After all, the Internal Revenue Code allows certain deductions for charitable contributions in dollars. Who among us can construct an equation between dollars and blood? I know I wouldn't even try.

Let us rather look upon the deductions provided for in Congressman Koch's bill as our Government's way of recognizing good citizenship and responsible community service to those who deserve it.

Thank you for this opportunity to speak to this committee. I shall be happy to try to answer any questions if you have any.

Mr. ROSTENKOWSKI. Thank you, Dr. Groeschel.

Mr. Schneebeli will inquire.

Mr. SCHNEEBELI. How do you transfer blood to a tax credit? Specifically, what do you do—give $25 a pint, or what?

Dr. GROESCHEL. $25 a unit.

Mr. SCHNEEBELI. What if you get paid, you don't get any credit?

Dr. GROESCHEL. No, he wouldn't, because it would not be a volunteer donation.

Mr. SCHNEEBELI. Then some of these "gallon" people would get pretty good deductions, wouldn't they? We have 10-gallon people at home.

Dr. GROESCHEL. I will be very happy to set your broken leg, but I can't give you the intricate details of matters relating to the Internal Revenue Service and tax credits.

Mr. SCHNEEBELI. I haven't seen any details of translating blood into money.

Dr. GROESCHEL. I would like to make the point that the matter of tax credit dollars is important. I know it is, and certainly it is of great importance to this committee. But the matter of illness, and what is on the other side, the offsetting factors in medical expense dollars is also important—the number of people who get serum hepatitis largely from commercial blood—they require health care, they require hospital care. Many of them die. You have a lot of them who are disabled for periods of weeks and months. The cost there is substantial.

They are not producing income when they are sick. They generate expenses when they are in hospitals, for care. For example, in the New York Hospital at New York, a large medical center, approximately half of all the patients are being paid for out of Federal funds.

So there is an offset on the other side for those tax credit dollars.

Mr. SCHNEEBELI. I think in addition to the dollar credit, there is a recognition of a psychological credit—"My contribution is being recognized in some form"—and I think the psychological recognition might be as important as the dollars.

Dr. GROESCHEL. You hit it right an the head. We think it would give the volunteer donor a feeling that his contribution is appreciated like nothing else.

Mr. SCHNEEBELI. Thank you.

Mr. ROSTENKOWSKI. Thank you, Doctor.

This concludes the witnesses for today. The committee will stand adjourned until 10 o'clock tomorrow morning.

(Whereupon, at 2:12 p.m. the committee adjourned, to reconvene at 10 a.m., Friday, October 29, 1971.)