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Tracking Job Number	***52***	Printed: 03/18/2002
Document Title	Report of the Secretary's Review Committee of the Task Force on Prescription Drugs	
Author	Dunlop, John T., EtAl	Document Date 22-Jul-69
Document Description:	A committee of a review committee established by Secretary Finch to assist him in making the decision of the course of action he should take with respect to prescription drug coverage in the Medicare program.	

Project Specifics

SR Number	IM-203
Project Number	ORDI-IM-203
Project Title	History of a Drug Benefit Under Medicare
Awardee	
Project Officer	Delew, Nancy
Principle Investigator	
Funding Level	
Start Date	02/01/2002
End Date	02/01/2003
Project Description:	This project looks at t[illegible]mpts to develop a benefit in the Medicare program for prescription drugs.

Initiated (CMS):	sagilloway	Date:	18-Mar-02	Accepted (IQ):		Date:	
Released (IQ):		Date:		Received (Sub):		Date:	
Finished (Sub):		Date:		QC'd (IQ):		Date:	
Returned (IQ):		Date:		pproved (CMS):		Date:	

REPORT
of the
SECRETARY'S REVIEW COMMITTEE
of the
TASK FORCE ON
PRESCRIPTION DRUGS

Office of the Secretary
U. S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
Washington, D.C.

Members of the Review Committee

of the Task Force on Prescription Drugs

John T. Dunlop, Ph.D., Chairman
Professor of Political Economy
Harvard University

Morris Aarons
General Counsel and Executive Secretary
National Association of Pharmaceutical Manufacturers

John Adriani, M.D.
Chairman, Council on Drugs
American Medical Association

William S. Apple, Ph.D.
Executive Director
American Pharmaceutical Association

Leighton E. Cluff, M.D.
Professor and Chairman
Department of Medicine
University of Florida College of Medicine

Marian Wright Edelman
Attorney at Law
Washington, D.C.

Joseph F. Follmann, Jr.
Director of Information and Research
Health Insurance Association of America

Victor R. Fuchs, Ph.D.
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National Bureau of Economic Research

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Thomas H. Hayes, M.D., Ph.D.
Director, Department of Drugs
American Medical Association

William Hutton
Executive Director
National Council of Senior Citizens

George James, M.D.
Dean
Mount Sinai School of Medicine

V. D. Mattia, M.D.
President
Hoffman-LaRoche, Inc.

Margaret M. McCarron, M.D.
Assistant Medical Director
Los Angeles County
University of Southern California
Medical Center

Bert Seidman
Director, Department of Social Security
American Federation of Labor-Council of
Industrial Organizations

Willard B. Simmons
Executive Secretary
National Association of Retail Druggists

C. Joseph Stetler
President
Pharmaceutical Manufacturers Association

Warren E. Weaver, Ph.D.
Dean
School of Pharmacy
Medical College of Virginia

July 22, 1969

Report of the Secretary's Review Committee of the Task Force on Prescription Drugs

On March 24, 1969 Secretary of Health, Education and Welfare Robert H. Finch named a 17 member committee to review the findings of the Department's Task Force on Prescription Drugs (Final Report dated February 7, 1969). The committee members, all from outside government, were drawn from a wide variety of backgrounds and groups.

The Task Force on Prescription Drugs was established in May 1967 to undertake a comprehensive study of the problems of including the costs of out-of-hospital prescription drugs under Medicare. The Task Force, under the chairmanship of Dr. Philip R. Lee, Assistant Secretary for Health and Scientific Affairs, made a number of significant studies, issued a series of 10 interim reports and background papers.

This Review Committee was not established to provide a comprehensive evaluation of so extensive a series of reports and technical studies. Nor would this committee be entirely appropriate for an exhaustive review, particularly in a short period and without staff. The assignment of this Review Committee is very much more limited and specialized. Secretary Finch

charged the committee as follows: "What I now want, to assist me in determining the course of action I am to take, is the judgment of groups outside government who are directly and vitally concerned with the place of prescription drugs in health care - the medical and pharmacy professions, industry, economics, and the consumers of health services, that is the American people."

At its first meeting on April 4, 1969 this Review Committee decided that it could most effectively fulfill this limited assignment in a brief period by concentrating upon four groups of issues raised in the findings and recommendations of the Task Force.

I The question of the inclusion of out-of-hospital prescription drugs in Medicare and the major features of any such program.

II Certain pharmacological issues particularly relating to chemical, biological and clinical equivalency and to federal regulation.

III Certain economic characteristics of drug manufacturing and drug distribution particularly relating to research, product differentiation and pricing.

IV The means of improving the flow of information regarding drugs to practicing physicians.

Individual members of this Review Committee then were invited to

state their views on each of these four groups of issues. These memoranda prepared by all members of the committee, except the chairman, are attached as an appendix to this report. This appendix is an integral part of the report. It is thus readily possible to ascertain in some detail the shades of views and advice of the diverse groups represented on this Review Committee.

This procedure has simplified the writing of this brief Report since the opinions and arguments of individual members are readily available and stated in their own terms. The brief text of this Report was developed after a discussion of the issues and the memoranda prepared by the individual members at the second meeting held on May 6, 1969. This discussion sought to identify major points of difference, to clarify misunderstandings and to achieve genuine agreement on some questions. The draft text of this Report was thereafter circulated to all members of the Review Committee before its submission and most members suggested specific comments. The chairman bears final responsibility for its formulation.

This Report has sought to indicate areas of general agreement on the four groups of issues and also points of significant difference where they remained. No attempt has been made to achieve artificial agreement. The remaining differences may often be as significant as the areas of agreement.

This approach is in accordance with Secretary Finch's request: "Let me say further that I do not seek a unanimous report nor any artificial compromise. I would, of course, like to know the points on which you are in complete agreement, but it is equally important for me to know where you differ and why."

I. Out-of-Hospital Prescription Drugs and Medicare

One of the most significant findings of the Task Force on Prescription Drugs provided: "In order to improve the access of the elderly to high quality health care, and to protect them where possible against high drug expenses which they may be unable to meet, there is need for an out-of-hospital drug insurance program under Medicare," (Finding No. 2). It further concluded that such a program would be both economically and medically feasible and should be instituted.

1. This Review Committee concludes, with only one dissent, that the Secretary of Health, Education, and Welfare should recommend an Administration decision for an out-of-hospital drug insurance program under Medicare.

The arguments which seem particularly cogent in support of this conclusion of the committee are as follows: "The requirements for appropriate prescription drug therapy by the elderly are very great - far greater, in fact, than those of any other group - and many elderly men and women are now unable to meet those needs with their limited incomes, savings, or present

insurance coverage." (Finding No. 1). Some unnecessary high cost hospital use could be reduced by the provision for out-of-hospital prescription drugs. The present inequity under Medicare between payment for in-hospital drug costs and the absence of any payments for identical out-of-hospital drug usage should be eliminated. Other advanced industrial countries have developed programs for out-of-hospital drug costs under social insurance.

2. The Review Committee recommends overwhelmingly that the Secretary authorize and direct the Commissioner, Social Security Administration in cooperation with other officers of the Department of Health, Education, and Welfare to develop more detailed plans, proposed regulations, data processing procedures and cost computations than presently available in keeping with the major features of a program outlined below, including some alternative variations. Such further details are essential for legislative consideration.

The Task Force appropriately found (Final Report, p. 44) that "considerable time would be required to develop all the necessary administrative mechanisms" and that full implementation of a program would require a substantial period after enactment of appropriate legislation. A decision to proceed with more detailed administrative planning and legislative proposals is necessary if a program is to be operative in two years or so.

3. The Task Force proposed, or suggested that consideration be given, to a variety of features in the design of an insurance program in order to constrain costs. It suggested that initially coverage should be given to prescription drugs most likely to be essential in the treatment of chronic rather than acute disease, that consideration be given to an annual deductible of $50 or $100, or that benefits might be initially restricted to those over some age such as 70 or 72, that a formulary be used in part for the purpose of constricting costs and that utilization review procedures be developed for the same purpose. (Findings No. 31, 32, 33, 18, 28). Some of these proposals such as that relating to a formulary, were advanced in part also for reasons of "high quality medical care" and "rational prescribing."

This Review Committee is well aware that costs of Medicare have greatly exceeded expectations and that the failure to design into a program effective cost constraints may well jeopardize legislative approval of any out-of-hospital prescription drug program. Nonetheless, this committee has reservations concerning a number of these Task Force suggestions. This committee has sought to develop alternative suggestions for cost control, but it recognizes the need for further work in this area with more precise cost estimates as legislative proposals and regulations are developed. It is also aware of the possibilities of increased utilization of prescription drugs, some of which may be unwarranted.

a. This Review Committee does not regard the limitation to chronic disease treatments and the exclusion of acute cases as advisable or administrable.

b. An age limitation other than over 65 is undesirable.

c. An annual deductible provision which imposes a requirement on the patient as an individual to keep records should be avoided.

d. Co-insurance provisions are less desirable than co-payment features.

e. While the value of formularies has been well established for hospitals, most members of the committee are of the view that a required national formulary is not appropriate for an out-of-hospital prescription drug insurance program. A purely advisory national formulary, with utilization review on the basis of the experience of a number of formularies developed on a locality basis, might possibly be appropriate.

4. The Review Committee would favor an out-of-hospital prescription drug program under Medicare which incorporated the following features:

a. A co-payment arrangement so that the patient would be required to pay a fixed dollar amount for each prescription. (It might be possible to incorporate into such a plan an arrangement so that the co-payment

would cease, or be reduced, or be subject to reimbursement over a certain accumulated amount during a year.)

b. A vendor reimbursement arrangement so that pharmacists and other vendors rather than beneficiaries would be reimbursed. The committee generally favors a dollar and cents, rather than a percentage, mark up or fee based upon practice in the locality by type of outlet to be added to the acquisition cost of the drug product.

c. Most of the members of the Committee favored a program under Part A of Medicare.

d. Utilization review is essential but costs are difficult to control even with post audit.

5. The Review Committee has made no attempt to compare the relative benefits of an out-of-hospital prescription drug program under Medicare with the benefits of other possible medical programs or other possible alternative expenditures of public funds.

II Pharmacological Issues

There was general agreement that the establishment of biologic or therapeutic equivalency for generic drug products would result in decreased drug costs for the consumer. Minor variations between different products of the same drugs with low potent pharmacologic action are of less concern,

but biologic or therapeutic equivalency in this group of drug products could also result in some reduction of costs for consumers.

The Committee recommends:

1. The Food and Drug Administration continue to develop Reference Standards for generic drugs to assure biologic equivalency among drug products.

2. The Secretary of the Department of Health, Education, and Welfare be assisted by appropriate Advisory Committees to evaluate drug costs and biologic and therapeutic equivalency.

The Committee supports the Task Force Report on the need for effective regulation of quality control in manufacturing of drugs through improved regulations related to the registration or licensing of manufacturers.

III Economic Features of Drug Manufacturing and Drug Distribution

1. Drug industry research. There seems to be general agreement that the Task Force finding concerning duplicative and wasteful research by drug manufacturers was not adequately documented in the Task Force Report. Beyond that, some members of the Review Committee believe that the finding could not be documented because it is essentially incorrect. Others are prepared to give more credence to the charge while still others suggest that it might have been true in the 1950's and early 1960's, but is not true of current drug industry research.

2. Drug industry profits. There is general agreement that drug industry profits have been and are high compared with other industries, and that this situation requires careful study to determine its causes and implications.

3. Physician-owned repackaging companies. There is general agreement with the finding that products marketed by physician-owned repackaging companies should be considered unacceptable for reimbursement except in those instances in which the Secretary or Health, Education, and Welfare determines that the availability of products marketed by such companies is in the public interest.

4. Pharmacy research. There is general agreement with the recommendation that the National Center for Health Services Research and Development should develop and support research to improve the efficiency and effectiveness of community and hospital pharmacy operations.

5. Price differences. The subject was not discussed at the committee meeting, but in the written statements of committee members there is broad support for the recommendation of a study to consider the substantial differences in the prices at which drug products are offered to community pharmacies and to hospitals and government agencies.

6. Price information. This subject was not discussed by the committee, but in the written statements there is broad support for the finding

of a need for medical associations, pharmacy associations, and consumer groups to develop, at the local level, mechanisms whereby patients may obtain information on local prescription prices.

IV Information and Identification

The Committee addressed itself most particularly to the flow of information on drugs to physicians. Most of the Committee generally concurred with the Task Force recommendation No. 10 regarding a publication providing up-to-date information and guidelines on drug therapy. Most felt that the Department of Health, Education, and Welfare should support this effort which should preferably be the work of non-government drug experts. In general the Committee concurred with recommendation No. 12, regarding a compendium, except that there is not uniformity on the question of authorship. Those members expressing an opinion in the majority favored an authoritative compendium which would be supported by government but published by a non-government authority. It might be useful to pre-test any compendium.

Recommendations concerned with continuing education of physicians and courses in clinical pharmacology in medical schools all relate to the potential long range effects of kind of information that affect the prescribing habits of physicians. Time did not permit full and complete discussion of

these issues but those commenting favor a constructive approach to these problems. In a similar way, recommendations relating to education of pharmacists and pharmacist aides evoke a response indicating that need for pharmacist aides is not clearly demonstrated at this time and should await a more definitive study of the role of the pharmacist in the dissemination of drug information and in drug distribution. Those commenting favor a study that would bring the dimensions of the problem into clearer focus, as recommended in part by the Task Force.

APPENDIX A

Views of Individual Members of the Secretary's Review Committee of the Task Force on Prescription Drugs

TO: Dr. John T. Dunlop, Chairman
Review Committee of the Task Force
on Prescription Drugs

CONSIDERATION: Report of the Task Force

Insurance Plan

The major issue is whether the recommendation by the Task Force to extend the Medicare Program to include out-of-hospital prescription drugs should be supported.

There are many obstacles which will have to be hurdled before implementing such recommendation.

The following will probably be accepted by the majority of the Committee:

1) that the health care of the elderly is the responsibility of the government; and

2) that the health of the elderly will be improved by receiving needed prescription drugs out-of-hospital.

Thus, it should be recommended that improvement of the quality of health care for the elderly be achieved by extending the Medicare Program to cover out-of-hospital prescription drugs.

Putting aside for the moment the question of cost, manifestly, the most advantageous program for the elderly would be comprehensive coverage and this should be sought as the ultimate goal after

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Morris Aarons

a trial and error period. It would appear that low rate co-insurance would, initially, be preferable.

Record keeping might be too burdensome for the elderly particularly in view of the finding that a large percentage are at or near poverty level.

In a federally sponsored program, the greatest consideration, after need, is cost and financing. The determination of this issue is of prime importance. If it can be resolved, all other factors--administration methods and otherwise--are, by comparison, incidental.

The question then is, how can a fair program under Medicare providing for out-of-hospital prescription drugs with the maximum needed utilization for the elderly be initiated and achieved at a reasonable cost.

Utilization Review

The need for utilization review arises from the occurrence of unforeseeable problems. The number of prescription drugs to be covered is estimable if the program is properly utilized. The problems of waste and proven abuse are not ascertainable but will depend upon the degree of control exercised by the administrator. Controlling the prescription pattern will require the cooperation of the physician, the pharmacist and the consumer. Effective utilization review will be required as recommended by the Task Force.

Economic Features

The Task Force has made many recommendations which cannot be resolved by a short review and may require further particular, concentrated studies. True research is a very important factor in the manufacturing of drugs and any firm or agency performing such function should be encouraged. However, the word "research" has been used loosely and the Task Force has set forth its analysis of this subject. The generalization concerning duplicative and combination products is not a fair statement of the facts. There are so-called duplicative and combination drugs that are genuine improvements and have a purpose and an advantage. Each such drug must be judged on its own merits.

Pharmacological Issues

Compulsory purchasing and prescribing of prescription drugs under generic name, because of the price differential between the lower-cost drugs sold under the generic name and those under brand-name, where feasible, has probably become the one stumbling block to the enactment of a Medicare Program for out-of-hospital drugs.

The costly propaganda program of the brand-name companies does not substitute for the lack of scientific evidence documenting clinical inequivalency. The Task Force correctly found that "lack of clinical equivalency among chemical equivalents meeting all official standards has been grossly exaggerated as a major hazard to the public health."

The absence of scientific evidence on non-equivalency is made more conspicuous when you consider the extremes to which the brand-name companies have gone and the excessive amount of money spent on their campaign to convince the physician, the academician, the consumer and the government of this unproven theory.

Confusion and uncertainty does not prove clinical efficacy or determine clinical inequivalency. The most that can be said is that there is wide disagreement with respect to the contention in the scientific community. A thrust in the wrong direction may cause irreparable harm to the entire industry and the consumer.

As to quality control, the FDA has been making intensive inspections of pharmaceutical plants throughout the country and, as a whole, the manufacturers, both large and small, have been complying with current Good Manufacturing Practices and are using acceptable quality control methods. It can be firmly stated that the pharmaceutical industry is composed of reputable manufacturers.

Licensing

With respect to licensing manufacturers, it is submitted that the FD&C Act provides the government with adequate authority to strictly enforce its regulations and to exercise strict control over the industry. In fact, the most controlled industry in this country is the pharmaceutical industry. The FDA already has the power of inspection, seizure, injunction, and criminal prosecution. These powers are supplemented by the role of the Justice Department,

Bureau of Narcotics and Dangerous Drugs, and the Federal Trade Commission. There does not appear to be any necessity for further controls by licensing of the pharmaceutical manufacturer.

Flow of Information to Physicians

Further studies should be required for the publication of a compendium through the USP or NF. This would serve as a very useful source of information to the practicing physician. My experience, however, indicates that the publication of a compendium raises many complicated issues and further discussion is impossible within the limited space of this report.

CHARITY HOSPITAL OF LOUISIANA
AT NEW ORLEANS

LOUIS BURROUGHS M D
DIRECTOR

April 22, 1969

Dr. John T. Dunlop
Harvard University
1737 Cambridge Street
Room G-4
Cambridge, Massachusetts 02138

Dear Dr. Dunlop:

I regret very much indeed that I will be unable to attend the meeting of the Secretary's Review Committee of the Task Force on Prescription Drugs on Tuesday, May 6th. A commitment to participate in a postgraduate program at Minnesota over a year ago precludes my being available at that time. I am, however, submitting to you my views concerning the report, as well as the feelings I have concerning prescription drugs. Many of the views that I hold are from the experience of thirty years association at the Charity Hospital of Louisiana at New Orleans, which is entirely tax supported, and five years experience at Bellevue Hospital, which at the time I was there, was a similar type institution.

1. I concur with the findings of the Task Force that the requirements for prescription drug therapy by the elderly are far greater than those of other age groups and that many elderly men and women are not able to meet the needs because of limited sources of funds. The State of Louisiana, for example, does not supply drugs on an out-of-the-hospital basis. We have a large out-patient service. Nearly 2,000 patients are seen daily. The funds from Social Service are inadequate for those who are not eligible for payment by the Welfare Department. The Welfare Department of the State of Louisiana is now in dire need of funds and have drastically reduced the allotment of drugs for patients. In spite of this, the cost for drugs at the present time is over $1,000,000 per month. Many patients are unable to buy drugs prescribed. It would appear to me, therefore, that in order to improve this situation the elderly must have access for out-of-hospital drugs.

2. I am inclined to agree with the findings of the Task Force that the contributions of industry to research, at least over the past decade, have been minor. The type of unbiased research which is worthwhile has been financed by N.I.H. or grants from foundations. The industry does finance drug testing, but drug testing and bona fide drug research are two entirely

different things. Perhaps one of the strongest criticisms that one can make about the package insert is that the data contained therein has been accumulated from reports of investigators of the pharmaceutical firm's choice, many of whom can be classed in the category of "testimonial writers." Many qualified researchers are not interested in drug testing.

3. I can see no objection to the recommendation that the drug industry, pharmacy, clinical medicine and consumer groups consider the matter of cost of prescription drugs and that a study be made, if indeed there is a substantial difference in the prices at which drugs are offered to community pharmacies, hospitals, government agencies and American and foreign purchasers.

4. I have strong feelings about physician-owned pharmacies and physician-owned repackaging companies. No physician should engage in any of these activities. The medical societies could, if they chose to do so, do their own policing in this regard. The Carrione Laboratories in Louisiana affair, to me, was a disgrace. They were owned by both physicians and some of the politicians in the Legislature. The Legislature members were quite upset when the physicians in the Louisiana State Hospital system refused to purchase the items offered by this company for use in the State hospitals.

5. The American Medical Association has undertaken the task of preparing a drug compendium. A "crash committee," of which I am chairman, of members of the Council on Drugs and the Department of Drugs has been appointed by the Board of Trustees of the American Medical Association to expedite the completion of this volume. I would suggest that the Secretary of Health, Education, and Welfare negotiate with the American Medical Association for the distribution of this volume to physicians, pharmacies, hospitals and other appropriate individuals as recommended by the Task Force. More details concerning this particular volume can be had from me if you so desire.

6. For many years, formularies were common in hospitals of all sizes. With the advent of the multiplicity of drugs and the combinations dispensed under proprietary names, it has been difficult to control drug utilization due to the multiplicity of compounds available. The solution to this chaotic state would be legislation requiring that a drug be sold under its given, or generic, name. If a pharmaceutical firm chooses to have a brand name, this could appear on the labelling in very fine print. For example, meprobamate would be MEPROBAMATE in large letters. The term Miltown or Equanil could appear in parenthesis, with the manufacturer's name in about one-eighth or one-tenth the size print of the given name. Mixtures would designate the ingredients. For example, Coricidin would be called CHLORPHENETON, ASPIRIN, PHENACETIN MIXTURE on the labelling. Again, a parenthesis with Coricidin and the name of the manufacturer could appear on the label in fine print. A physician would then have the privilege of designating the manufacturer of his choice. Deletion of the multitude of names would make a formulary practical and simplify the dispensing of drugs. We have a formulary at Charity Hospital. A formulary will have to be a "must" if an out-of-hospital prescription program for the elderly or other groups is to be economically feasible and workable.

7. A code of good manufacturing practices and other criteria with a licensing system and registration for all pharmaceutical firms is essential. While much has been said about the fact that some drugs are chemically equivalent but not biologically equivalent, this is not an impossible problem to resolve. All groups, both voluntary, such as the USP, NF, AMA, and the FDA, HEW, etc., could work in coordination to standardize and have products be generically equivalent. I concur with the recommendation that a drug code adopted by the government governing industry be utilized in a national drug code directory.

8. The Hospital Pharmacy Committee, required by the Joint Commission on Accreditation of Hospitals, should be strengthened and its scope broadened to include the reporting of adverse drug reactions and drug utilization and drug education, as well as policing of the members of the staff. The philosophy that the staff governs itself can be workable. Tissue committees are quite effective. Utilization review methods applicable to patient stay and hospitalization could be extended to drug utilization.

After watching the struggle of the Welfare Department for providing drugs, I feel at a loss in coming to any conclusion at this time as to what features a program for out-of-hospital prescription drugs should embody. I would favor payment under Part A, utilization control and the use of a formulary. Those with long-term illnesses certainly should be given priority consideration and perhaps a program initiated along these lines at first. A restritive formulary allowing payment of essential drugs, well known and established, would be a must.

9. The impact of the proposed program on various groups of the community will depend a good bit on the locality. The medical profession will oppose any program which in any way limits the physician's right to prescribe the drug he deems best. This objection will be voiced as long as trademark names are used for drugs. The goal, therefore, should be uniformity of nomenclature. Thus, not only will a physician know the generic anme, but also the patient, the pharmacist, the nurse, the relatives and everyone concerned with the use and prescribing and dispensing of drugs. Labelling of all prescriptions dispensed to a patient, unless for some medical reason the physician feels labelling would not be advisable, will be helpful in reducing the price of drugs.

10. The flow of information to practicing physicians concerning newly released drugs is biased information supplied by the pharmaceutical industry. Most physicians are surprisingly well informed about drugs which are well established and which they use frequently. I base my opinion from observations made when I have lectured in clinical pharmacology to small groups, in small communities in programs of continuing education, sponsored by the Louisiana State University School of Medicine. Unfortunately, this program has been curtailed this year due to deficiency of funds.

11. This, my last statement, may sound naive and I may appear to be idealistic, but HEW should take into its confidence various scientific bodies, and the AMA, and attempt to work jointly. Any legislation which is restrictive and appears to encroach upon the physician's prerogative to make a

choice and to practice medicine as he sees fit will be construed as being punitive, will create resistance and the main goal, namely, providing better health care, will not be achieved. Such a situation will create a feeling of frustration among members of the medical profession and those who are administering health insurance programs.

If you wish me to elaborate on any of these points, I shall be happy to do so.

I might add that the opinions that I have expressed are mine, as a practicing physician. I have been advised by Dr. Thomas Hayes, who is the Director of the Department of Drugs and a paid employee of the American Medical Association, that he will present the American Medical Associations's point of view; therefore, even though I am Chairman of the Council on Drugs, I am not expressing the views of the American Medical Association. They may be identical but I would be inclined to think not. I would suspect, though, that you would find many of the members of the Council on Drugs would share many of my views.

Sincerely yours,

John Adriani, M. D.
Chairman, Council on Drugs
American Medical Association and
Associate Director
Charity Hospital

JA:dl

WILLIAM S. APPLE, Ph.D.

April 28, 1969

TO: Dr. John T. Dunlop
Chairman of Review Committee

FROM: Dr. William S. Apple

SUBJECT: REVIEW OF RECOMMENDATIONS BY THE
HEW TASK FORCE ON PRESCRIPTION DRUGS

Below, you will find my brief summary views on the "Major Issues" as delineated in your memorandum of April 7, 1969. I have provided my comments in the same order as the issues were presented in your memorandum.

I trust that these views will prove to be useful in the further discussions of the Review Committee.

* * * * * * *

I. Insurance Plan

1. On the basis of the Task Force report, the Secretary should recommend the inclusion of a program that would provide pharmaceutical services to non-institutionalized Medicare beneficiaries. The present system which requires institutionalization of the patient to secure the drug benefit is irrational and wasteful. The savings that would result from making ambulatory care more effective and reducing or eliminating a portion of institutionalized care would, in my opinion, contribute significantly to reducing the total cost of a complete medical care program. It is inconceivable that the nation which has contributed the most to the development of drug therapy in this century should continue to ignore its essential and mandatory role in medical treatment of ambulatory patients.

2. Features to be considered in a drug benefit program:

   a. Co-insurance and deductibles--both of these mechanisms represent approaches to fiscal and utilization control. Because of the nature of pharmaceutical services, administrative costs for processing claims become a critical factor. I favor a co-pay mechanism relating to each individual prescription order, because it would be more readily understood by the beneficiaries and less complex to administer.

In this regard, a flat co-pay contribution for each prescription would appear to be more logical than a fixed percent of the total prescription charge. Obviously, there will be some beneficiaries that lack the financial resource to make any contribution, and provisions to insure their participation is essential.

b. A program limited to drugs for chronic diseases would be difficult to administer and to explain to elderly beneficiaries. Further, this approach ignores the frequently substantial expenditures that the elderly have for acute conditions. Additionally, inclusion of a drug for payment because it is used in treatment of a chronic disease might distort medication regimens. The prescribing practitioners should have the right to utilize the appropriate drug therapy (not to be confused with a particular manufacturer's drug product) for the condition diagnosed.

c. Perhaps the most misunderstood and resisted concept in pharmaceutical service is the formulary. The tendency is to equate the formulary system with a drug list or a drug price list. Others confuse the formulary system with The National Formulary--an officially recognized compendium of drug standards. The formulary system is a method by which physicians and pharmacists evaluate and select specific medications for use in treating patients. The basic purpose of the formulary system is to foster more rational drug treatment. In 1963, the American Medical Association, the American Hospital Association, the American Pharmaceutical Association and the American Society of Hospital Pharmacists approved a set of guiding principles for the operation of the formulary system in hospitals. While the system was designed to meet the needs of pharmaceutical service in hospitals, the principle of the formulary system is equally applicable to improving pharmaceutical service to ambulatory patients and should be included in any proposed program.

d. Both the method and level of reimbursement to the pharmacist should be programmed to insure the cooperation of the profession. One of the unique characteristics of the pharmaceutical service system in the United States is its immediate geographic availability to more than 90 percent of the population. Any system developed should assure beneficiaries free choice of pharmacist. If the pharmacist (vendor) is to be reimbursed by a third party, the administrative system for claim processing must provide for prompter payment and more simplified paper work than pharmacists have experienced under most Title XIX programs. With regard to the level of reimbursement, the most advantageous method from the viewpoint of any vendor (physician, hospital or pharmacist) is "usual and customary charge". It is also the least desirable method of insuring the fiscal soundness of any health care benefit program.

The dispensing of a prescription order involves providing a professional service and a physical product. The value of the former is totally unrelated to the cost of the latter. Obviously, the final charge must include both components. Most of the government-financed and prepaid private plans are utilizing a reimbursement method based on the cost of the drug product to the pharmacist and a professional fee which includes the cost of providing the service and a profit component. There is nothing inflexible about this method. It can be adjusted to marketing area factors and levels of service provided. It can be tailored to provide efficiency in claims processing, payment and auditing.

e. Utilization of Part A or Part B poses a question of social as well as fiscal philosophy. There is no reason why the drug benefit program can not be established as a separate part, but this does not eliminate deciding on a basic financing mechanism. While there appears to be some tendency to favor the Part A approach for its administrative advantage, at this particular time from a political viewpoint the Part B approach might be more saleable.

f. Except for the drug "equivalency" issue, it appears that 18-24 months is an adequate lead time in program development. I do not believe that the "equivalency" issue should be permitted to further deter implementation of the essential and urgently needed drug benefit.

g. The drug benefit should become available to beneficiary at the same time other health care benefits become available. It is discriminatory and illogical to make medical and hospital services available at age 65 and pharmaceutical services at age 70 or 72.

h. Utilization control all too often is looked at as a cost control mechanism. In my opinion, the Task Force properly emphasized that utilization review is a dynamic process with the primary objective of fostering rational prescribing. I support the Task Force recommendation that there is an urgent need for further research in this area.

3. The impact of the proposed program on various groups within the community will relate directly to the specifics of the program finally established. A government program of this magnitude will leave its imprint on the private pre-pay and self-pay markets. Conditions of participation could stimulate the advancement of pharmacy as a health profession or relegate the pharmacist to a nonprofessional distributive functionary. Many of the Task Force observations are directed toward the positive, but recent experiences with Title XIX have resulted in anxiety and suspicion among pharmacists.

For example, the original conditions of participation eliminated the dispensing physician as a competitor to the pharmacist. The regulations were subsequently modified to benefit the dispensing physician.

If the program is designed to take advantage of the pharmacist's professional input in developing rational drug therapy and cost controls, both the public and profession will benefit. Pharmacy is unique among all the health professions in that it has the trained manpower immediately available.

II. Economic Features of Drug Manufacturing and Drug Distribution

1. The Task Force found that much of the drug industry's research and development activities would appear to provide only minor contributions to medical progress.

We do not believe that minor modifications or combination products are per se a waste of the drug industry's research and development activities. The crux of the issue with regard to this subject is the purpose of the activity. If the sole purpose of the minor modification is to achieve or extend a monopoly position, the public does not benefit. When a minor modification or combination product results in a more effective or safer therapeutic product, such research and development serves the public interest.

The Task Force has recommended that the Secretary call one or more conferences to consider provision of incentives to the drug industry to invest more research effort in products representing significant improvements to therapy and less in duplicative, noncontributing drug products and combinations.

We believe that such conferences would serve a useful purpose if both incentives and deterents were considered. For example, should the marketing of any new drug entity or combination drug product be permitted unless there is evidence demonstrating significant improvements in effectiveness and/or safety over comparable existing entities or products. There is the argument that on occasion, after wide use, clinical experience reveals some previously unrecognized benefit in the case of what was considered to be a drug with essentially comparable therapeutic proprieties. To permit such drugs to be marketed on the remote chance of obtaining a significant benefit for society is as illogical as prohibiting the marketing of a new drug entity or combination product with demonstrated advantages on the basis that wide use will reveal unexpected untoward properties.

2. My views on the structure of drug prices have been presented to Congress on several occasions during the past three years, and I believe are generally well-known to all the members of the committee.

The Task Force addressed itself to the problems generated by the discriminatory pricing practices of the pharmaceutical industry, but failed to recommend any positive actions in this regard. I believe the recommendations of the Task Force will only serve to delay resolution of this serious problem.

III. Pharmacological Issues

1. We believe that the Task Force made a significant contribution by discriminating and defining "equivalency" in more precise terms than previously used. We believe that the definitions developed by the Task Force are generally valid and provide useful classifications for describing the various kinds of equivalency.

Based on our review and analysis of documented scientific reports and our experience in the field of establishing drug standards, we conclude that the Task Force assessment of clinical equivalency among chemical equivalents meeting all official standards is valid.

There is adequate scientific evidence to demonstrate that formulation factors can influence biological availability and, therefore, may affect equivalency among drug products. However, there is very little scientific evidence documenting clinical inequivalency. The reasons for this are that the possibility of such inequivalency has only recently been recognized and that methodology for determining equivalency or nonequivalency is still subject to wide disagreement within the scientific community.

In the Fourth Interim Report, the Task Force discussed the concept of a reference product. The pharmaceutical industry, pharmaceutical science, the Food and Drug Administration and the official compendia have had a long and favorable experience with reference standards for comparative testing of drug entities. It would seem that a logical extension of this approach would be the development of specific measurable criteria for a standard reference product. I believe that the Secretary should take prompt action to insure further investigation of this concept.

2. I support the Task Force recommendation that a registration or licensing system be developed under which every drug product would be produced under quality control standards set by the Secretary. No drug product should be allowed to enter the distribution system which was produced in a facility that did not meet such quality control standards. Under the present system, it is possible for a manufacturer to produce a drug product and put it into the distribution channels before the government makes its initial inspection of its facilities and methods. There is no justification for not requiring prior inspection.

Licenses are not issued to either pharmacies or pharmacists until they meet prescribed standards and qualifications. We should accept no less for the source of our drug supply.

IV. Information and Identification

1. The Task Force made several recommendations which are of direct concern only to the medical profession. The specific recommendation (Item 10 under The Drug Prescribers) is of concern to the pharmacy profession. It is essential that information on drug therapy be readily available to pharmacists who also have a role in drug selection and functions as a pivotal source of drug information to the entire health community.

2. In 1960, I brought to the attention of HEW the need for a complete compilation of therapeutic information on a drug by drug basis. This recommendation was made because of our apprehension at that time that the then proposed package insert information system would prove to be unsatisfactory. The need for such a compilation has become more apparent and unless the health professions and pharmaceutical industry privately meet this need, the only alternative is implementation of the Task Force recommendation.

3. Steps have already been initiated to develop a classification and coding system through the combined efforts of the professions, industry and government.

V. General Observations

From a hindsight posture, it is not difficult to criticize several of the findings and recommendations of the Task Force. In some instances, there is a lack of correlation. It can also be said that too many peripheral issues were interjected but not adequately covered. But, considering the magnitude of the mission undertaken and the time in which it was accomplished,

the effort represents a positive contribution. It has touched off debate and controversy which will stimulate further research.

From my personal viewpoint as a pharmacist, I was disappointed by the lack of emphasis on the professional and scientific factors involved in drug discovery, manufacture, distribution and dispensing.

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LEIGHTON E. CLUFF, M.D.

April 21, 1969

To: John T. Dunlop, Chairman

From: Leighton E. Cluff, M.D.

COMMENTS

I. Insurance Plan

1. The Secretary of DHEW should recommend a program for out-of-hospital prescription drugs in the Medicare program.

2. Secretary Cohen, in his letter to the President dated January 13, 1969, suggested a payment scheme for out-of-hospital drugs only for those medications important in treatment of certain specific serious chronic conditions of the aged, including a cost sharing program. This recommendation, I believe, needs further study and evaluation. Some States with existing programs to provide out-of-hospital prescription drugs indicate that such a recommendation might foster falsification of diagnosis, prescribing of expensive and less suitable drugs and excessive drug prescribing. Evaluation of existing programs, such as in Florida and Maryland, could be useful in arriving at more satisfactory methods of payment and coverage. I question the desirability of restricting coverage for drugs to treat only certain diseases.

3. I believe a program for providing out-of-hospital drugs, to be dispensed through present channels, would be acceptable to most practicing physicians, as long as it did not entail excessive additional work for the physicians. The latter is critical - in view of the physician shortage increased allocation of his time to administrative functions, such as filling out forms, correspondingly reduces the time for direct patient care.

II. Economic features of drug manufacturing and drug distribution.

1. Recommendation No. 25 in the Task Force Report and as presented by Dr. Ley is essential - particularly regarding the requirement that a new drug be marketed only if shown to represent an improvement over existing products. This could encourage manufacturers

to invest in "truly" new drugs rather than in "duplicative drugs."

2. Surveillance of drug costs, prices and use indicated in Recommendation No. 22 is desirable, but utilization can be evaluated in many different ways, e.g. bulk utilization, individual drug use and use per patient. The Social Security Administration can evaluate bulk and individual drug use but may have difficulty if data other than cost is desired. The study proposed in Recommendation No. 20 should be done before it is decided to have all utilization surveillance done by the Social Security Administration. The Food and Drug Administration and other agencies may be equipped to contribute to this objective.

III. Pharmacological Issues

1. In Recommendations No. 14, 15 and 16, it should be indicated that evidence of biological equivalency for a product must be obtained by the manufacturer and not be a responsibility of the FDA. The FDA has a responsibility as indicated in Recommendation 14, however, to evaluate such data and to investigate methods for determining biological equivalency. Recommendation 15 indicates that the FDA should develop educational and investigational operations. The involvement of FDA in education requires clarification.

2. If the FDA is to assure equivalency of the same drug produced by different manufacturers, recommendation 2b is critically important.

IV. Information and Identification

Recommendations 7, 8, 9, 10, 11 and 12 have far reaching implications for Schools of Pharmacy, Dentistry, Public Health and Medicine. Increased support of these schools to improve and develop new education programs in pharmacy, pharmacology and medicine is required, but the specific recommendations about pharmacy aides, drug information specialists, clinical pharmacology and continuing education require further study. Someone needs to develop a compendium but this should not be a document with regulatory function or unnecessary legal restrictions. For this reason it should be developed by

knowledgeable persons, preferably out of government, even though the cost of the compendium is largely carried by government.

I believe those recommendations dealing with education and research should be evaluated by the Drug Research Board of the NRC-NAS. This could provide an objective and acceptable means for approving or revising the recommendations in these areas.

MARIAN WRIGHT EDELMAN

WASHINGTON RESEARCH PROJECT
1823 JEFFERSON PLACE, N. W.
WASHINGTON, D. C. 20036
(202) 659-4240

MARIAN WRIGHT EDELMAN
HARRY HUGE
RUBY G. MARTIN

THE SOUTHERN CENTER FOR STUDIES IN PUBLIC POLICY
CLARK COLLEGE
240 CHESTNUT STREET, S. W.
ATLANTA, GEORGIA 30314
524-0446
GEORGE BOOKER

M E M O R A N D U M

To: Dr. John T. Dunlop

From: Marian Wright Edelman

Re: Findings and Recommendations of the U. S. Dept. of Health, Education, and Welfare's Task Force on Prescription Drugs

I. On the basis of the Task Force Report, should the Secretary recommend for or against the inclusion of a program for out-of-hospital prescription drugs in the Medicare program?

I strongly favor implementation of a program for out-of-hospital prescription drugs under Medicare. The crying need for such a program is amply documented in the Task Force Report and background paper (The Drug Users) as well as in my own experience as an attorney for the NAACP Legal Defense and Education Fund, Inc., in the rural South over a five-year period. The single, most chronic complaint, other than food, from rural impoverished blacks of all ages was the need for and inability to purchase needed medicines for themselves and their families. The aged and children were the greatest sufferers from nonexistent and/or inadequate medical care, including drugs. It is long past time when this country should develop and implement a comprehensive

health insurance plan, in- and out-of-hospital care, with drugs, for all its needy citizens including the elderly. Protection for the aged in out-of-hospital prescription drugs would be a vital step in this direction.

2. If so, what should be the features of such a program? Which features of such a program require further study?

The chief consideration in developing an out-of-hospital drug prescription plan under Medicare should be the health of the recipient. I oppose any financial or administrative deterrents on recipient access to needed drugs. For the elderly poor, any cost-sharing requirement will be a deterrent to the purchase of prescribed drugs; for the poorly educated elderly (6% no education; 11% less than five years, and 33% elementary), any requirement placing on them the burden of seeking reimbursement will prevent needed purchases. The responsibility for prescribing drugs rests with the physician. The sole criterion should be need of the patient.

That cost-sharing has no established effect on utilization control is shown by the Task Force's Report. Moreover, greater costs in the long run may result from denial of needed care because of financial or other disability. I do not believe that the United States cannot afford to bear the relatively small cost burden of providing adequate drugs for the elderly, and I urge strongly that the Secretary recommend that it do so.

Should some form of cost-sharing be considered necessary, the recipient should pay a specific, minimal amount per prescription with a maximum ceiling on such payments. Co-insurance poses a more unacceptable financial burden on recipients and renders them susceptible to increasing drug costs. Deductibles are the least desirable form of cost-sharing in that they place a large administrative, as well as financial, burden on the recipient and impose a much greater administrative burden on the government which would have to handle millions and millions of recipient claims.

I support the Task Force finding 38 that "Reimbursement for product cost should be based on the cost of the least expensive chemical equivalent of acceptable quality generally available on the market," (pp. xv-66).

The Task Force recommends that "particular consideration should be given to providing coverage at the outset mainly for those prescription drugs which are most likely to be essential in the treatment of serious, long-term illness (p. 57). Secretary Cohen supports this position. I disagree. The most comprehensive coverage possible is desirable and needy recipients, regardless of the nature of illness, should be helped. Prevention of chronic or acute illness should be as important as cure of serious illness. Moreover, a large group of people would be excluded from help under a restricted program who are included under the general Medicare provisions. It is difficult to justify a dual standard. Moreover, doctors

may be restricted from lending full and adequate care for all their patients and pressured to conform diagnosis to the categories of illness covered.

I reiterate the relatively minor cost burden involved here with the important service to be rendered by the program. If cost reductions are essential, they should not be borne by the patient but by those more able to afford it, the manufacturers and the distributors.

Formularies?

Findings 18, 19 and 20 of the TaskForce support establishment of formularies, which I support. They are an effective means of cost control and if widely established, will be a deterrent, through selectivity, pushing to/more duplicative products on the market and will hopefully force more original drug research.

Vendor reimbursement? Fee?

I recommend vendor reimbursement with a fixed fee approach which eliminates the incentive/to distributors to push high cost drugs. Patient reimbursement places heavy administrative and financial burdens on the beneficiary and increases the administrative cost to the government. The most frugal suggestion seems to be direct purchase by the government of drugs in an out-of-hospital prescription plan. I recommend further study of this, as suggested in Task Force recommendation 39 (pp. 66,67). This method, if adopted, would also lead in some measure, to/more effective cost control mechanisms.

Method of payment, Part A or B?

Part A would provide broader coverage, be easier to administer and more readily assure treatment by needy recipients. It would pose the least financial burden on the elderly when they can least afford to bear it--when they are unable to work.

Lead time in program development?

The Task Force estimates a two-year lead time, which if so, calls for prompt action by the Secretary to institute such a program immediately. Medicare, however, was implemented in half as much time, and has provided experience in administering such a program. More rapid implementation of an out-of-hospital prescription drug program, therefore, should be possible. I favor its earliest feasible establishment.

Age limitation?

I oppose any age limitation and think beneficiaries should be the same as under Part A of Medicare. Such an approach eliminates the unfairness of one segment of the elderly subsidizing another.

Utilization control?

The patient should be provided with the medicine he needs. They have no incentive to purchase medicines they do not need and are limited to those prescribed. Any controls should be placed on the physician through better education in pharmacological areas and through medical review boards lending guidance in this area. The use of formularies will be another means of utilization control.

3. The elderly poor will clearly be helped by this program. Civil Rights groups who have long pushed for broader social insurance protections for the poor will be supportive and view this as a promising step toward broader health care for all citizens. I can speak specifically in behalf of a number of poor community groups in the rural South and the Southern Christian Leadership Conference with whom I work closely who have expressed great interest in health needs for the poor generally. Physicians should favor such a program as an aid to their ability to provide better service to their patients. Moreover, drug manufacturers and pharmacists should welcome the increase in their market from additional drug purchasers who have been excluded from the market because of financial disability.

II. Economic Features of Drug Manufacturing and Drug Distribution

How do you appraise the findings and recommendations related to research by drug manufacturers? Product differentiation, new entities, "duplicative drugs," etc.?

The Task Force's findings that (1) "important new chemical entities represent only a fraction--perhaps 10-25%--of all new products introduced each year" and that (2) to the extent that the drug industry produces duplicative noncontributory products, it produces more confusion among physicians and burdens on the taxpayer are supported by the evidence it cites, as well as by various Senate hearings over the last several years. This is clearly undesirable. Hopefully the use of formularies will deter

the trend toward more duplicative "me too" drug products and more carefully established research standards by the drug industry will be adopted to promote original research in the drug field.

2. How do you appraise the findings and recommendations related to the structure of drug prices by retail vendors?

Careful and thoughtful review should be given to increasing drug costs. The high rate of profit by the drug industry is well established. (The Drug Makers - Competitive Problems in the Drug Industry, Senate Subcommittee on Monopoly - January, 1968) and the special risk factor alleged by the industry not established. The impact and importance of the industry on the public's health, the irrational disparity in drug costs to various purchasers, public and private, hospital and non-hospital, domestic and foreign, clearly raises serious questions. It would be hoped that the industry would be more self-regulating in its price structure. They, like the government, should bear in mind the primary needs of the consumer.

Several approaches may be taken to review the high prices of drugs: (1) wider use of formularies; review of state substitution laws; review of Robinson-Patman and its effects on cost; direct purchase of drugs by the government; and exploration of greater use of low-cost chemical equivalents and generic named products. Basically, drug manufacturers charge what the traffic will bear (see the testimony of Mr. Squibb

before Senate Subcommittee hearings on Competitive Problems in the Drug Industry, part 5, January 1968), and they must be encouraged to take more public responsibility in keeping their product within the reach of all the consuming public.

Adoption of a fixed dispensing fee for pharmacists will be an additional step towards lowering costs of drugs to the consumer. I also support recommendations 4, 5, 6 and 7, pp. xvii-xviii of the Task Force Report.

III. Pharmacological Issues

How do youappraise the conclusions of the Task Force relating to chemical, biological and chemical equivalency?

The Task Force finds that the problems of clinical equivalency is not so difficult of solution as had been earlier thought, and that the use of chemical equivalents can yield important savings in such areas. They recommend that "the use of such products should be encouraged whenever this is consistent with higher quality health care," (p. 37). I agree. That low-cost chemical equivalents are already being used without substantial detriment supports this recommendation.

How do you appraise the conclusions and recommendations of the Task Force related to licensing and registrations?

The need and desirability for tighter quality control standards for products in interstate commerce seems evident. I support recommendation 2(b), p. xvii. The goal must always be maximum protection for the consuming public.

IV. Information and Identification

How do you appraise the conclusions and recommendationsof the Task Force with respect to the flow of information regarding drugs to practicing physicians?

Physicians should have balanced and independent information concerning drugs. This is essential to consumer protection. I support the Task Force's recommendations 9-11. I question whether already overburdened physicians are going to make adequate use of a massive compendium. However, this along with other feasible methods for improving informational techniques to doctors should be explored.

JOSEPH F. FOLLMANN

SECRETARY'S REVIEW COMMITTEE
OF THE TASK FORCE ON PRESCRIPTION DRUGS

The Committee has been appointed to review the Findings and Recommendations of the Department of HEW's Task Force on Prescription Drugs. It has not been asked to develop, initiate, or recommend a program of its own.

The Report of the Task Force is not a simple matter to address oneself to. The body of the Report is a mixture of fact findings, which may or may not be correct; several unsubstantiated speculations; and a body of material of questionable relevance to the subject or purposes of the Report. At the same time, it leaves undiscussed and unanswered some matters of direct pertinence and importance to the subject. The Report then documents its Findings. These are not a statement of factual findings by the Task Force, but include surmise, material of questionable relevance, and conclusions which appear to be much more in the nature of recommendations arrived at after trying to compromise such difficult matters as benefits, costs, sources of financing, and administration. Yet, when one examines the Recommendations, and despite the Findings, no program whatever is recommended with respect to adding a prescription drug benefit to the Medicare program; and consequently there are no Recommendations with respect to what such an addition would constitute in the way of benefits, costs, financing, and administration. Instead, the Recommendations are concerned with matters which appear for the most part irrelevant, particularly since no program is recommended.

Since neither the Report nor the Findings make a clear case for adding such a benefit to the Medicare program, despite the fact that Finding No. 2 says there is a "need", it seems sufficient to express concurrence with the fact that no program is recommended. This would seem particularly advisable at this time since the cost of the Medicare program is at present unsettled and should be resolved before any additions are made to the program.

There are members of the Committee, however, who will not concur in this conclusion. Therefore, some discussion of certain details of the Report is necessary, based upon the outlined agreed upon at the April 4, 1969 meeting of the Committee.

I. AN INSURED PLAN

1. Should the Secretary Recommend an Insured Plan?

No. The Task Force Report has not made a case for, nor has it recommended, the addition of an out-of-hospital prescription drug program to the Medicare program. The facts stated in the Findings show that 51% of the aged have supplemental private health insurance benefits. While it is stated that only 9% have private health insurance

coverage for drugs, this can be misleading, since any type of supplemental benefit relieves individual funds which can then be used for the purchase of drugs. The Report recognizes that an additional role can be played by Medicaid, but does not attempt to show what role Medicaid actually plays or could play in the payment of drugs for Medicare beneficiaries. The Report recognizes that such matters as tax relief, other public assistance programs, and OEO clinics all can play a role with respect to payment for drugs, but does not delineate this role. Beyond this, it appears that some 12 to 15% of the aged incur prescribed drug bills in excess of $100, and about 9% receive drugs with no cost to the patient. Such facts are only glimmers of the situation as respects older people. What is needed is data which relate the ability of older people who are heavy users of drugs to pay for such drugs, as well as the number of the aged who have financial problems with respect to the cost of drugs, after taking full cognizance of the role of Medicaid and other means of assistance available to the aged since it would indicate the type of program, if any, which would be needed. This is necessary before any decision could be made with respect to the inclusion of drugs in Medicare.

Incidentally, the discussion of drugs in Government programs in other nations dismisses without much notice the difficulties which these programs have occasioned. Finding No. 10, for example, says that these programs are shown to be "economically feasible". This statement seems to be subject to considerable doubt. There is evidence that these programs have run into considerable problems and this should be examined more carefully before a decision would be made. The Report, for example, does not go on to say that in the United Kingdom charges for drugs had to be reinstituted by the Labour Government.

2. If so, What Features Should be Included in Such a Program?

The Report expresses a preference in Finding No. 31 for covering the costs for the treatment of certain chronic conditions only. This would be unwise, since the specified diseases would be a constant subject of bargaining and change. In addition, the beneficiaries would never clearly understand the benefit and the result would be public dissatisfaction. The Report also expresses a need for some form of beneficiary copayment. This is a wise conclusion if costs, including administration, are to be kept within any reasonable bounds. A more feasible approach, if one is found necessary, would be to cover all prescribed drugs, subject to a $100 yearly deductible, and with benefits paid to the beneficiary, not to the pharmacy. Present Part B administrators have developed a workable approach directly with the beneficiaries.

The costs for such a program are, of course, of basic importance. These might not be inconsiderable. Obviously, they would depend upon both the benefit structure and the nature of administration. The matter of cost is not, nor could it be, resolved in the Task Force Report. A parallel matter of importance is the question of how the costs should be borne. The Report expresses a preference for including the program in Part A of Medicare because the costs would be borne by the Part A employer-employee tax. Here a contradiction occurs in the Report, however. On page 4 of the Report this statement occurs: "the provision of free drugs through welfare agencies -- under Medicaid or other Federal, State or local programs -- may solve the problem as it directly affects some of the elderly. The basic economic problem is not solved, however, but merely shifted from the elderly to the taxpayer". While correct, this is an odd observation for a Report which expresses a preference for including drugs in Part A of Medicare. Such an inclusion in Part A would clearly shift the cost "from the elderly to the taxpayer." Of significance is a statement by Walter Reuther, President of the UAW, in appearing before the House Committee on Ways and Means in 1967: "we do not believe that it is a sound matter for public policy to constantly put that (the costs of Social Security) increased burden upon the wage earner." Particularly, he expressed a concern for the younger worker rearing a family. He also stated that the share required to be borne by the employer became a significant factor at the bargaining table in restricting union demands. This is a matter of considerable importance as expressed by Mr. Reuther. The Task Force Report expresses a concern that if a program were provided under Part B of Medicare the added cost would cause some to drop out of Part B. However, Commissioner Ball has reported that the Part B enrollment has increased from 90 to 95% of all the aged. Perhaps more important is the fact that all persons age 65 and over are eligible for Part B of the Medicare program, whereas this is not so as respects Part A. What has been said gives cause to question the Task Force preference for inclusion of a drug program in Part A. Further consideration should be given to the inclusion of such a program in Part B, provided there is evidence of need for some type of prescription drug coverage in Medicare.

A further matter of basic importance is that of the administration of any drug program. While the Report contains a section on administration and discusses certain aspects of the subject, it does not make clear just how the administration would work. Finding No. 54 places considerable responsibility upon the pharmacist, and the pharmacists should be heard on this subject because such a procedure can be costly to them. Beyond that, the Report, on page 61, rests the administrative responsibility with the Secretary

of HEW and SSA, saying in addition, it is "desirable to enlist the assistance of non-governmental organizations." The present Medicare program is administered by private insurance agencies. There are differences between the Part A and Part B approaches both in the Medicare legislation and in practice. Before any program could be recommended, this matter demands clarification. In any instance, such a program should be administered by the Part B carriers who have developed experience in dealing with the beneficiaries of the program and, therefore, serve the beneficiary rather than the provider of services.

II. IMPACT OF THE PROGRAM

A drug program in Medicare could affect the providers: the manufacturers and dispensers of drugs. The reactions of these persons would be important to any appraisal of a proposed program. Finding No. 54 places an administrative burden upon the pharmacist. Finding No. 57 appears to leave the matter of reimbursement open. However, some type and degree of regulation of prices appears to be inherent in the discussion on pages 63-64 of the Report. These are matters which should be given serious consideration.

The impact upon the consumer would, of course, depend upon the type of program which might be proposed.

The impact upon insurers as respects the supplemental coverages which they now provide for the Medicare program might be to result in a duplication or overlap of present coverages. The degree to which this would be so would depend upon the degree to which insurers have contractually protected themselves against such an occurrence.

III. ECONOMIC ASPECT OF THE DRUG INDUSTRY

Comment here should come from those with expertise in this area. However, a considerable amount of the Report in this respect is concerned with matters which appear to be irrelevant to the purpose of the Report and the considerations by Congress for the inclusion of prescribed drugs in the Medicare program. It could be a valuable contribution if the Committee were to identify in its report these irrelevant sections, including the Recommendations.

IV. EQUIVALENTS

Comment here should rest with those who are competent to address themselves to this subject. A question is raised, however, as to just how much saving would result from intrusion of a Government program into this area and, conversely, how much the administrative costs

would be increased by such intrusion. With respect to formularies, it should be noted that Findings 18, 19, and 20 appear to be contradicted by a statement on page 39 of the Report that "no agreement on the need for formularies is evident from private insurers."

V. INFORMATION

Comment here should rest with those who have professional competency.

J. F. Follmann, Jr.

VICTOR R. FUCHS, Ph.D.

June 30, 1969

In discharging my responsibilities as a member of this committee, the existing organization and financing of medical care have been taken as given. I have responded to the questions concerning prescription drugs under the assumption that nothing else could or would be changed.

It is my considered judgment, however, that the problem of prescription drugs should be viewed as an integral part of the larger problem of the organization and financing of medical care. Truly satisfactory solutions to the drug problem, as well as to hospital costs and the like, it seems to me, require far-reaching changes in medical education, medical practice and medical financing mechanisms. My views on these matters are set forth in numerous speeches and articles, copies of which are available upon request.

Victor R. Fuchs

April 21, 1969

Comments of Victor R. Fuchs on the Findings and Recommendations of the Task Force on Prescription Drugs, Final Report, February 7, 1969

Findings

1. I am in general agreement with the finding that the need for prescription drugs is particularly great among the elderly and that their financial ability to purchase drugs is often weak. The statements concerning needless sickness, costly hospitalization, and the like are not adequately documented.

2. Agree.

3. This finding is not supported. One would need to know the distribution of funds for different types of research. One would also have to know how predictable are the "contributions to medical progress." How often do expenditures for "minor modification" result in major advances?

4. Many companies in many industries engage in duplicative and wasteful research. In the context of the free enterprise system decisions concerning research expenditures are not fundamentally different from decisions concerning capital investment, purchases of raw material and other expenditures. Attention should be focused on the question

why the drug companies find it profitable to engage in "wasteful expenditures," and what changes in laws, institutions, medical education and the like are feasible that would result in the companies making "better" decisions in their pursuit of profit.

5. Agree.

6. No comment.

7. through 10. Agree

11. No comment.

12. Agree.

13. No comment.

14. Agree

15. & 16. No comment.

17. through 22. Agree.

23. through 25. No comment.

26. Agree

27. & 28. No comment

29 through 32. Agree.

33. No comment.

34. through 36. Agree

37. No comment.

38. I am in general agreement but would like to see some elaboration. If "cost" varies with quantity, location, or other factors which cost provides the base?

39. No comment.

40. I agree. There is little economic justification for a fixed percentage markup on all drugs.

41. & 42. Agree.

43. through 48. No comment.

Recommendations

1. No comment.

2. I am in favor of people talking to one another but am skeptical about the value of conferences in the absence of more details concerning format and content.

(a) I assume that the primary incentive of the drug industry is the same as other industries, namely profit. See my comment on finding #4.

(b) Might be useful

(c) Sounds OK

(d) See no need for conference.

3. & 4. Agree.

5. Seems like a good idea. However, I would like to know why it is not being done at present.

6. through 8. Agree.

9. Medical school curricula are already overloaded. What will this course replace? An alternative to physicians knowing more about drugs is that they should realize how much they don't know and make more use of pharmacologists and pharmacists.

10. I especially agree with the recommendation of HEW support for such a publication. The AAMC might be a good organization to supervise the publication. It should not be given official sanction.

11. Something more is needed if this is to have much effect. Perhaps a requirement for relicensure is the only answer. Unless meaningful incentives are provided, the money might be wasted.

12. A government sponsored compendium might not be as attractive as a government supported one. There is definitely a need for such a publication; perhaps, the AAMC should be subsidized to develop it.

13. No comment.

14. through 16. Agree.

17. through 19. No comment.

20. Agree.

21. No comment.

22. I wonder if the Bureau of Labor Statistics and the National Center for Health Statistics might not be the more appropirate agencies for this task.

23. Agree.

24. One alternative might be to place the work in NIH.

25. Agree.

THOMAS H. HAYES, M.D., Ph.D

I. Insurance Plan

1. On the basis of the Task Force Report should the Secretary recommend for or against the inclusion of program for out-of-hospital prescription drugs in the Medicare program?

The Medicare program has been operative now for almost three years. This has been a period of trial and adjustment with many administrative problems arising and with many remaining yet to be resolved to make the program function smoothly.

Administrative problems were not the only ones to arise, however. It early became evident that actual costs were exceeding predicted costs. It became necessary to adjust the Part A deductibles payable by the patient, by 10%. It also became necessary on April 1, 1968, within two years' operation, to increase the Part premium by 33-1/3%.

The Task Force Report recommends the addition of drugs, on an outpatient basis, as a new benefit under Medicare. The former Secretary has proposed a somewhat limited program, restricting it to drugs "important in the treatment of heart conditions, high blood pressure, diseases of the circulatory system, diabetes, respiratory conditions, and kidney conditions." While the Task Force saw the feasibility of providing such a program under Part A or Part B the former Secretary's proposal would place the new benefits under Part A, and the beneficiary would pay $1.00 toward each prescription for covered drugs.

We believe that the program should not be expanded at this time to include this additional benefit. The Secretary's letter indicates the annual cost in the first years would be approximately $600 million. This would be exclusive of administration costs.

We are in sympathy with the concern in the Task Force Report for the drug costs of the elderly. This stated concern pervades a substantial portion of the Committee's report. Our

similar concern for the elderly's drug costs, however, leads us to a conclusion different from that of the Task Force. We believe that greater benefit can be supplied the nation's elderly through Title 19, by virtue of the fact that greater concentration of the available funds will be restricted for the use of those who most need the economic assistance.

We must object to the proposal on still another ground. The American Medical Association has repeatedly affirmed the position that the physician must be free to select the drug which he believes to be the best therapeutic agent for his patient. The Task Force has made clear its recommendation that the Secretary shall create a list of drugs covered for the included chronic conditions. In so doing the suggested guidelines would permit him to determine which drugs within a particular class would be covered and which would not. Such a concept removes from a physician's total armamentarium those drugs not approved by the Secretary for inclusion in the list. It is stated that one of the conditions for inclusion would be that the drug not be "unduly expensive" in relation to its therapeutic efficacy. We do not believe that such considerations should comprise primary criteria in the determination of selected therapeutic agents.

For these reasons, and because we believe that greater experience is required before the Medicare program is opened up on such a magnitude as providing drug benefits, we recommend that the drug program outlined by the Secretary in his letter of January 13, 1969, and based on the Task Force Report, not be adopted at this time. We believe that further study and experience are necessary before embarking on such a major expansion of the program.

2. If so, what should be the features of such a program? Which features of such a program require further study? (Refer to the program proposed in Secretary Cohen's letter of January 13, 1969)

Co-insurance?
Deductibles?
Limited to Long-Term Illness?
Formularies?
Vender Reimbursement? Fee?
Method of Payment, Part A or B?
Lead Time in Program Development?
Age Limitation?
Utilization Control?

While the foregoing under No. 1 recommends against including drugs under Medicare, we shall nevertheless comment on parts of question No. 2, relating to the hypothetical inclusion of a drug program under Medicare. Certain parts are not commented on inasmuch as we feel we do not have sufficient information on which to base a recommendation.

Co-insurance or Deductible?: If a drug program is to be included under Medicare, it would be important that appropriate safeguards be built in to reduce the potential for fiscal abuse of the program. Whether the means should be by a deductible or a co-insurance payment, or both, is a question requiring further analysis. It would appear that an appropriate co-insurance feature would provide more ease in administration, and at the same time provide a control factor without any undue hardship on the patient.

Limited to Long-term Illness: We recognize that this proposed limitation has economic and administration advantages in initiating a new benefit under Medicare. We believe, however, that this recommendation requires additional study and consideration, for any such limitations carry inherent problems relating to identification of diseases, the drugs involved, and the basic question relating to the equity of payment for drugs for one patient and not another, when really the purpose of the program should be to alleviate the burden of drug costs for those unable to pay.

Formularies: We have stated earlier that under any drug benefit program, the physician should be free to prescribe the drug which he deems to be the best therapeutic agent for his patient. Accordingly, we cannot approve the creation of limited formularies whereunder the physician may be inhibited, either directly or indirectly, from selecting (from all drugs available to patients generally) only those drugs for Medicare patients for which reimbursement would be made under the program. The physician must be free to provide for the Medicare beneficiary, as other patients, the highest quality health care available.

Vendor Reimbursement? Fee? : While it would appear that administration of the program would be simplified if the vendor were reimbursed, we do not feel we have sufficient information on which to base a firm recommendation concerning the method of payment.

Method of Payment, Part A or B: The Secretary's proposal recommends the drug benefit as a Part A benefit.

We believe that this innovation would change the basic concept of the Medicare program. Part A was designed to provide in-patient benefits, and drugs furnished in the hospital or extended care facility are already covered. Out-patient benefits, on the other hand, were intended to be covered under Part B. Even the last amendments to Medicare consolidated the out-patient hospital benefits under Part B.

Two principal arguments are advanced for favoring Part A: identification of beneficiaries and financing. The argument in the Task Force Report concerning ease of identification of eligible persons under Part A, in contrast with Part B, is in our opinion without substantial merit. This is to imply that currently the Part B beneficiaries are not sufficiently

identifiable for present benefits. We are not aware of any such difficulties. The reference in the report to difficulty in identification of Title 19 patients for purposes of drug benefits is not applicable since the elements of eligibility for Title 19 benefits or Part B benefits are so different. Nor do we believe that the composition of the Part B group, which includes 95% of eligible individuals, has been one fluctuating to any substantial degree.

Concerning financing, the cost figures presented under a Part B consideration were based on comprehensive drug coverage. This should not be used to compare costs under Part A for a limited coverage program. If, as the Secretary states, a Part A limited program would have an outlay of $600 million, this figure should be used to estimate the premium under Part B. Using a round number of 20 million beneficiaries, for purpose of approximation, this premium would be $30.00 annually to be paid one-half by the beneficiary, or $1.25 monthly. The monthly amount would be less if further deductibles or co-payments are required of the beneficiary.

We believe that additional realistic appraisal and study are warranted before any sound conclusion is made as to whether a drug program be included under Part A or Part B.

Lead Time in Development?: The amount of lead time would have to be based on a realistic appraisal of the time necessary to establish efficiently operating administration procedures, in order to avoid confusion. Under Part B, necessary time would have to be allowed for an adjustment in premium.

Age Limitation: We have no specific recommendation, but question the advisability and equity of a classification based on an age over 65.

3. How do you appraise the impact of the proposed program on various groups within the community?

The precise reaction a program would have on various groups within the community is difficult to assess, particularly when the details of the program are not stated. It seems apparent, however, that any drug program would have direct impact on at least the following: beneficiaries, physicians, pharmacists, and the taxpayers in general.

Generally, it can be expected that present Medicare beneficiaries, who will not have contributed toward a drug program under Part A would favorably receive the program. A program however, providing benefits for a limited classification of drugs would be, to say the least, confusing for the elderly. For some it may foster disappointment. For instance, a patient in the course of treatment of an ailment may have one drug paid for and another one not, or one patient being treated for an acute condition may have a "listed" drug paid for while another patient with an acute condition would not.

A patient who is required to pay a portion of each prescription may wonder why he has to pay $1.00 towards a $5.00 prescription and also pay $1.00 towards a $2.00 prescription. Or he may question why the program does not cover (per prescription) a drug for an acute condition, when it is more costly than another drug (per prescription) which is covered for a chronic condition. It can also be anticipated that the demand will soon arise for a more comprehensive drug coverage.

We have already indicated the objection of physicians on any limitations, directly or indirectly, on their ability to prescribe a drug of choice in the treatment of their patients.

The reaction of the taxpayer must also be considered, for the burden of paying for the program will fall upon him. His disenchantment may stem from the anticipation of only limited future benefits, in contrast to the increased social security tax which would have to be imposed.

II. Economic Features of Drug Manufacturing and Drug Distribution

1. How do you appraise the findings and recommendations related to research by drug manufacturers? product differentiation, new entities, "duplicative" drugs, etc.?

When one considers the pharmaceutical industry in relation to all others, its purposes - and products - are directed towards an abnormal condition of society: that of disease. As such it is difficult for society to eliminate emotionalism from any examination of this industry since people instinctively find it disagreeable to pay to get rid of something they didn't want in the first place. Notwithstanding the fact that the industry's reason for being is unique, when one views its corporate structure and its corporate relationship to society, it is not afforded any special treatment. On the other hand, the industry is regulated to some extent by government; in fact, its productive existence, in a sense, is at the pleasure of the government.

It is from this viewpoint that the recommendations of the Task Force relative to research, product duplication, new entities, etc., are considered.

1) Research Activities: The Task Force Background Paper, "The Drug Makers and the Drug Distributors" examines the profit structure of the drug industry at considerable length. On the basis of this information, it appears that the drug industry enjoys an "exceptionally high rate of profit". From this alone, it would seem that the industry should not be afforded any special incentives, as is suggested, to confine its its research efforts to the development of new and unique drug products. In the

main, this appears to be the primary goal of industrial research, although specific goals are dictated by the available resources and reasonable expectations for a marketable drug product. In other words, this leads to the development of "me too" products, for it is unlikely that a manufacturer would expend a major portion of its research effort seeking a cure for the common cold, or for cancer.

2) Duplicative Drug Products: Recognizing that the successful commercialization of a unique drug product stimulates other manufacturers to develop and introduce similar, competitive drug products does - upon superficial examination - appear wasteful. Upon closer scrutiny, however, there may be certain economic advantages to this type of product competition. For example, the wholesale cost of one of the first oral contraceptives at the time of its introduction was approximately $2.10 for a month's supply. Now, in the presence of a number of competing products, the cost of the drug is approximately $1.20.

Another advantage occurring from drug product competition is that research teams of various manufacturers acquire new knowledge and develop new techniques of medicinal chemistry, which may well lead to the discovery of new drugs.

2. How do you appraise the findings and recommendations related to the structure of drug prices, by manufacturers and by retail vendors?

Manufacturers' prices: The report states that current drug prices at the manufacturer's level reflect, a) research costs substantially higher than other industries which include a

substantial amount of "non-innovative" effort devoted to the manufacture of duplicative and combination drug products, b) intensive promotional efforts, and c) a high degree of competition based on quality and innovation, but not price.

How and to what degree these characteristics contribute to the manufacturer's price is not readily apparent from reading the Final Report and the background papers. It is possible that further examination of the report and its supporting papers by an independent group of knowledgeable economists might allow them to pass judgement on the validity of the recommendation to "conduct a continuing survey of drug costs, average prescription prices, and drug use" and whether or not this proposed additional study would be appropriate, as well as productive.

The Task Force was concerned that present patent and trademark policies have the effect of restricting price competition in the drug industry. (Paradoxically, it raps the drug industry for commercializing too many drugs, a practice which tends to further price competition.) In this connection it recommended that revision of patent and trademark laws on prescription drugs be studied jointly by the Department of Health, Education, and Welfare and other federal agencies. On the other hand, the requirement that manufacturers demonstrate safety and efficacy for all "new" new drug products results in long and expensive laboratory and clinical trials that are easily afforded by only the largest and richest manufacturers. In a sense, this tends to a form of monopoly and the possibility of further restriction in price competition. Obviously, the entire matter, including the FDA procedures for new drug approval, needs additional study.

Vendors' prices: The Background Papers treat in considerable detail the percentage markup and flat dispensing fee systems for pricing prescriptions. The Task Force preferred the latter, although the reasons therefore are not immediately apparent. It finds, in addition that there is a need for medical associations, pharmacy associations, and consumer groups,

working together at the local level to develop mechanisms whereby patients may obtain information on local prescription prices, especially for long-term maintenance drugs. This finding is worth further consideration since several prescription pricing surveys have shown wide differences in the pricing structures among community pharmacies located in the same city.

III. Pharmacological Issues

1. How do you appraise the conclusions of the Task Force relating to chemical, biological and clinical equivalency?

The Task Force found that, on the basis of available evidence, lack of clinical equivalency among chemical equivalents meeting all official standards has been grossly exaggerated as a major hazard to the public health. However, these standards are being questioned as to their relevancy in predicting biological equivalency of chemically equivalent drugs. Moreover, it is not so much a question as to whether the lack of clinical equivalency constitutes a hazard to the public health but whether like drugs reaching the market will consistently produce predictable clinical effects. Results of current studies sponsored by the FDA cast doubt that this is so. It seems evident that the present physical-chemical tests for drug product quality cannot be relied upon to predict biological equivalency. Much more extensive laboratory and clinical research is needed to develop appropriate models for testing drug product quality. Until uniform, meaningful standards for assessing drug product quality have been developed and are assiduously applied to all drugs reaching the market, the practicing physician must rely upon his own experience.

We agree with the Task Force recommendation that the present clinical trials to determine the biological equivalency of important chemical equivalents should be continued by the Department of Health, Education, and Welfare on a high priority basis. But it is difficult to understand published reports, if correct, that the FDA has withdrawn financial support from certain of these studies which it had originally sponsored.

2. How do you appraise the conclusions and recommendations of the Task Force related to licensing and registration?

The Final Report of the Task Force recommends that the Secretary of Health, Education, and Welfare should call one or more conferences with representatives of the drug industry, pharmacy, clinical medicine, and consumer groups to consider the development of a registration and licensing system under which no drug product would be permitted in interstate commerce unless produced under quality control standards set by the Secretary of Health, Education, and Welfare. Since the details of such a system are not spelled out, it is difficult from an inspection of the Report and supporting information to determine what it is this procedure is intended to accomplish. The Food and Drug Administration already has the statutory authority and responsibility to insure that, with few exceptions, all commercialized drugs are safe and effective. In light of this, it seems irrelevant that another system should be imposed upon the existing one. What needs to be done is a study of the standards applied to determine safety and efficacy in order to determine if, in themselves, these standards are meaningful.

The Task Force also considered licensing in connection with the matter of the patent system as applied to drugs. If our objectives are a viable pharmaceutical industry capable

of maintaining a research organization designed to produce more specific and more effective medicinal chemicals, it would seem that before placing any restriction on the present system we should consider not only the interests of the persons directly affected, but also the long term interests of the American people as a whole. We are able to do this only if we make an effort to trace the consequences of the restrictions and then see how well they serve our objectives.

IV. Information and Identification

How do you appraise the conclusions and recommendations of the Task Force with respect to the flow of information regarding drugs to practicing physicians?

The final Task Force Report makes four recommendations which purport to better provide for the drug information needs of the practicing physician:

1) The Department of Health, Education, and Welfare should provide expanded support to medical schools enabling them to include a course in clinical pharmacology as an integral part of the medical curriculum.
2) The Department of Health, Education, and Welfare should establish or support a publication providing objective, up-to-date information and guidelines on drug therapy, based upon the expert advice of the medical community.
3) The Department of Health, Education, and Welfare should support the efforts of county medical societies, pharmacy and therapeutics committees, medical foundations, and medical schools in taking the responsibility for providing continuing education to physicians on rational prescribing.

4) The Secretary of Health, Education, and Welfare should be authorized to publish and distribute to all physicians, pharmacies, hospitals, and other appropriate individuals and institutions a drug compendium listing all lawfully available prescription drugs, including such information as available dosage forms, clinical effects, indications and contraindications for use, and methods of administration, together with price information on each listed product in readily accessible and comprehensive form.

Complaints about the inadequacy of training in therapeutics are not new. If this were a simple, easily soluble problem, satisfactory solutions would have been reached long ago. Whether the introduction of a required course in therapeutics or clinical pharmacology will be such a satisfactory solution is difficult to judge. Clinical pharmacology, per se, is not yet a recognized academic discipline. Most pharmacologists are not clinicians and vice versa. Recognizing the necessity for more effective training in therapeutics, it would seem that this would require combining continuing exposure to the subject with a system of self-evaluation rather than a single, formal course. Further study of this recommendation is necessary.

There is a great deal of information on drugs and drug therapy. The problem, however, is that it is not readily available in a form that will meet the immediate needs of the practicing physician. It is possible that this line of thought may have led to the second recommendation. To be objective and up-to-date, guidelines on drug therapy must contain statements of comparative efficacy on drugs. Since the Food, Drug, and Cosmetic Act precludes the FDA from making statements of comparative efficacy, it is a moot point whether the Department of HEW could establish or support a publication that would contain such statements.

In consideration of the third recommendation, the general encouragement that continuing education to physicians on rational prescribing should be conducted at the local level is sound. What the Task Force had in mind regarding "support" is unclear. Generally speaking, the educational process is more effective and relevant when it remains the responsibility of the local community, and this is particularly true in the case of continuing education for physicians.

The publication of a federal drug compendium has been the subject of much opinionated discussion. The format and content of such a book have not been clearly delineated by its proponents, so it is hard to develop logical arguments whether the idea is good or bad. Since the Task Force recommendation calls for a listing of all lawful, available prescription drugs - together with all pertinent usage information - the mere size of such a publication would tend to defeat the concept of "readily available drug information".

Much of the difficulty in focusing on the problem of drug information is because the question, "How does the physician develop his prescribing habits?" has yet to be answered. What drugs he uses, why he uses them. and how he uses them can only be determined when effective drug usage surveillance programs become an established fact. Until it is, recommendations such as these seem premature.

Comment

As a society when confronted with a problem, we tend to say "There are two sides to every question" and then in this conceptuality develop argumentative positions. In this light, we are often poorly prepared to deal with a many-sided question, as is the matter of drugs and drug therapy. The Task Force Report appears to reflect this difficulty and, in fact, has been criticized in the public press for lack of scholarship and objectivity.

After reviewing the findings and recommendations of the Task Force concerning the use of drugs by physicians, together with the supporting background information, one gets the feeling that here the Task Force considered but one side of the question. "The Drug Prescribers" projects the viewpoint that the physician is a poorly trained, poorly informed, naive therapist and that the remedy for this situation lies in the several projected Department of HEW supported, or directed, programs. Documentation in support of these contentions consists largely of opinions rather than facts. And, if indeed the Task Force did weigh all opinions - pro and con - before drawing its conclusions, it is not evident. Considering the evidence, the apparent indictment of the physician in terms of his prescribing habits and practices is not justified. A member of the AMA Council on Drugs in summing up this aspect of the Task Force Report wrote: "It is quite easy to criticize on a theoretical or philosophical basis. The opinions of panels of medical experts are, of course, interesting and often instructive. Nevertheless, I am unable to agree that the usage of drugs by physicians in active practice is uniformly, or even mostly irrational. No doubt some physicians do a better job than others as in any type of work where a variable competence may be expected. The general level of performance, until proven otherwise, must be considered to be adequate; certainly it has not been proven otherwise by the Task Force.

Their point on rational prescribing is good and I believe that most physicians engage in a rational and careful consideration in the administration of drugs. The obvious fact that some do not may constitute a serious problem but the entire profession should not be condemned on that basis alone."

WILLIAM HUTTON

April 21, 1969

A brief overview of the Findings and Recommendations of the U.S Department of Health, Education, and Welfare's TASK FORCE ON PRESCRIPTION DRUGS.

by William R. Hutton, Executive Director
National Council of Senior Citizens
1627 K Street, N.W., Washington, D.C. 20006

I. INSURANCE PLAN

1.) Should the Secretary Recommend?

The need for an out-of-hospital prescription drug insurance program under the Medicare program is clearly established in the Task Force reports and in the relevant and authoritative government data reproduced in the background study, "The Drug Users", published in December, 1968.

The Task Force, over a period of 20 months, carried out comprehensive, investigative studies involving the advice and guidance of highly qualified experts, both governmental and non-governmental. These studies covered an extremely broad range of factors interrelated to the problem. The final report is unequivocal with regard to the need and to the economic and medical feasibility of providing a drug insurance program under Medicare.

In addition to the clear recommendation of the Task Force, the Secretary of H.E.W. will be aware of the rising expectations of the nation's elderly for government action in this area. Considerable testimony on the need for an out-of-hospital drug program was heard in the Congressional hearings which preceded enactment of the Medicare law.

In the three years since Medicare became operational, its effects on national health patterns have heightened public interest--and there is greater public awareness concerning the program's lack of out-of-hospital drug benefits.

The evidence of need by the elderly for out-of-hospital drugs has been highlighted in hearings of the U.S. Senate Special Committee on Aging for the past six years. Meanwhile, revelations from the U.S. Senate's hearings on monopolistic practices in the drug industry over the past two years have increased public concern about the high cost of drugs.

2.) What Should Be the Features of the Program?

a.) Coinsurance and deductibles?

The studies we have been able to make through the cooperation of the leadership of NCSC's 2,500 older people's clubs and their two and a half million combined membership, lead us to conclude that the coinsurance and deductible features of the Medicare program are tragic barriers between the elderly poor and their access to adequate health care.

There can be no medical justification for the use of such provisions--only financial justification, to enable costs to remain within desired limits for whomever is paying the premium.

Blue Cross and private insurance companies who are serving as carrier-intermediaries for the Medicare program have also been highly critical of coinsurance and deductible features because of the high administrative costs of these provisions.

In a deductible drug insurance program, with many small bills to be checked--the record-keeping necessary by beneficiaries would provide an intolerable burden for older people.

Deductibles and coinsurance will never deter the few elderly who are wealthy--but will impose excessive burdens on the average elderly and on the poor.

b.) Should Drugs Be Limited to Long-Term Illness?

While there is wide agreement that a drug insurance program should cover only prescribed medicines, the issue is less clear on the question of comprehensive drug coverage.

Many current drug insurance programs exclude certain classes of drugs--i.e., anti-obesity drugs, etc.

High program costs would indicate that something less than comprehensive coverage is inevitable.

But it would be difficult indeed to justify coverage of those drugs important for the treatment of serious chronic illnesses (maintenance) while omitting other drugs which might be prescribed for conditions due to acute illness.

Coverage of those drugs important for treatment of chronic illness will concentrate the protection in most cases where it is most clearly needed.

But if we are to continue to encourage treatment of the sick at home, when high cost hospitalization is unnecessary, we must provide for acute illness drugs.

A study by physician teams in Rochester, New York, hospitals concluded that from 14% to 18% of hospital beds on any one day were occupied by patients who did not require hospital level care.

Another study revealed an under-use in the ratio of 3 to 1 in the community's use of patient's homes as a place of care. We would help to reverse this trend if we avoid limiting the new drug insurance program to chronic illness drugs.

c.) Establishment of Formularies?

While recognizing the necessity of the fewest possible restrictions on the traditional right of physician to prescribe, it would be virtually impossible to provide a drug insurance program without a formulary.

Use of formularies by hospitals in recent years have been found acceptable and practical by physicians. It should be possible to provide for emergency situations when a physician can prescribe an unlisted drug he considers necessary for the wellbeing of a particular patient.

Unquestionably, a formulary can provide an effective means of cost control and be a useful guide to rational prescribing.

d.) Vendor Reimbursement

A direct purchase program utilizing regular pharmacies as distributors and pharmacists receiving a service fee for filling the prescriptions would be the most efficient and economical way of handling the program.

The pharmacist can submit composite claims forms and get periodic reimbursement for multiple claims.

The primary goal of the drug insurance plan must be to help those persons with large drug expenses--and a copayment factor for a service fee should be kept as low as possible--say $1.00 per prescription or less.

e.) Method of Payment

The drug benefits program should be provided under Part "A" of Medicare to insure that the elderly will not have to pay for drugs out of their limited retirement incomes. Entitle-

ment would thus be established on entrance to the program and continued until the beneficiary's death.

If the program were established under Part B of Medicare, the administrative expenses would be vastly increased--because it would then be necessary to check each applicant for benefits with regard to the applicant's status on payment of Pt. B premiums or other terminations from the program.

The deductible under Part B is already presenting sufficient administrative difficulties without the further complications of a drug program.

f.) What Lead Time for Program Development?

As complicated as our drug industry is, it is doubtful whether, in the public mind, it is any more complicated than Medicare itself.

It would be hard for the public to understand why setting up a drug insurance program under Medicare should take any longer than the setting up of Medicare itself--namely, one year.

g.) Age Limitation

Of all the approaches to limiting the costs of the program, reducing the age limitation is the least satisfactory method.

65 is the eligibility age for Medicare--it should also be the age for eligibility for the drug insurance program.

h.) Utilization Control

As useful as this technique is for keeping costs down, utilization control can only be instituted after development of procedures by physicians to protect the medical welfare of the patient. State and local medical societies should be encouraged to improve patterns of prescribing, and the American Medical Association should be encouraged to support efforts to develop appropriate utilization review methods for out-of-hospital prescribing.

3.) Appraising the Impact

Before the enactment of Medicare, usually reliable polls showed a very large majority of all the American people supported the concept of providing health care for the aged under Social Security.

There would be similar results if polls were taken today on the question of adding a drug insurance program to Medicare.

Many young workers are still called on to provide cash to help their elderly parents with needed medications--and in so doing they deprive their immediate families.

For all the elderly, a drug insurance program would be a blessing. For the elderly poor it will be a godsend. It will mean that many old people do not have to make the cruel choice between spending their limited income on life-sustaining food or on pain-killing drugs.

II. ECONOMIC FEATURES OF DRUG MANUFACTURING AND DRUG DISTRIBUTION

1.) Findings and Recommendations Related to Research

We agree with the Task Force that joint efforts by industry and the Federal Government are needed to avoid costly proliferation of drug products.

In recent years there has been increasing publicity concerning the exceptionally high rate of profit which marks the drug industry, and there is increasing public understanding that there are no unusual risks in the industry.

The Task Force's report that new chemical entities represent only a small fraction of all new products each year would indicate that the industry's current research and development activities are not contributing as much to medical progress as they are contributing to increased profits through minor modifications of drugs or combination products.

2.) Structure of Drug Prices

We believe with the Task Force that there is an obvious need for patients to be able to determine readily the prices charged by the various pharmacies in their community.

Congress should require that the containers of prescription drugs be labelled with the identity, strength and quantity of the product.

Encouragement should be given to the wider use of pre-package dispensing in drug stores and the National Center for Health Services Research and Development should seek ways to improve the efficiency of community and hospital pharmacy operations.

The conflict of interests which can arise with physician-owned pharmacies should make them unacceptable for reimbursement in any medical program.

The use of low-cost chemical equivalents should be encouraged whenever consistent with high-quality health care.

III. PHARMACOLOGICAL ISSUES

1.) Chemical, Biological and Clinical Equivalency

The substantial savings which could be made by generic prescribing are becoming apparent to all consumers--as a consequence of well-publicized testimony at Congressional hearings and a broad range of new books on the subject.

On the basis of available evidence, lack of clinical equivalency among chemical equivalents meeting all official standards, has been grossly exaggerated as a major hazard to public health.

The public believes that the generic drugs prescribed for a President, Senator, or Congressman, in Walter Reed or Bethesda Naval Hospitals are also good enough for the public.

However, it is important that the present clinical trials to determine biological equivalency of important chemical equivalents be continued by H.E.W.

There should be uniform standards of quality and efficiency in any Federal drug program--and it would be utterly inappropriate to provide for differential cost ranges for products sold under brand or generic names.

The FDA should be authorized and financed to inspect and maintain quality control methods in all drug manufacturing and packaging establishments.

2.) Licensing and Registration

We support the Task Force recommendation that the Secretary of H.E.W.--after consultation with industry, medical and consumer groups--should appoint a Study Group to reappraise the efficiency of methods now used by DBS and FDA to evaluate the safety and effectiveness of drugs.

Clearly, it would be an important consumer protection to ask this group to develop a registration and licensing system which would assure that all drugs marketed in interstate commerce are produced under adequate quality control standards.

IV. INFORMATION AND IDENTIFICATION

- A permanent mechanism is needed at the Federal level to collect, analyze and exchange information on all federal drug programs.

- A drug program which will involve several hundred prescriptions annually must adopt a universal coding, classification and identification system.

- The Department of H.E.W. should establish a publication providing objective, up-to-date, guidelines on drug therapy based on the expert advice of the medical community.

- Bureau of Health Medicine should develop curricula for pharmacy and medical schools for training pharmacists to serve as drug information specialists.

- H.E.W should provide expanded support to medical schools to include a course in clinical pharmacology as an integral part of the medical curriculum.

- Most American physicians do not have adequate access to complete and objective information on prescription drugs.

  Consequently, H.E.W. should publish and distribute to all physicians, pharmacies, hospitals and other appropriate individuals and institutions a DRUG COMPENDIUM, including available dosage forms, clinical effects, indications and contraindications for use, price information, generic equivalents, etc.

V. D. MATTIA, M.D.

HOFFMANN-LA ROCHE INC.

NUTLEY • NEW JERSEY • 0711

May 2, 1969

Dr. John T. Dunlop
Chairman
Secretary's Review Committee
Harvard University
Room G-4
1737 Cambridge Street
Cambridge, Massachusetts

Dear Dr. Dunlop:

I am sorry that I have not been able to forward my response to your letter of April 7th by April 25th. A major reason for the delay was to permit me time for further study of the Background Paper entitled "Approaches to Drug Insurance Design". As you know, the original purpose of the Task Force was to study whether drugs should be put under Medicare for out-patients. Until we received this advance, confidential Background Paper, nothing had been published by the Task Force in the past months on this basic issue.

While I do not claim to have fully studied all the ramifications contained in this important document, I did want more time to study it.

What follows are my present views on the various issues which you have raised. In some cases they represent my preliminary thinking and are subject to further refinement. In others, I am satisfied that enough factual material is available to give definitive comment.

I. Insurance Plan

I believe that out-of-hospital prescription drugs should be made available under the provisions of the Medicare program. The absence of such a provision in the current Program represents one of the serious gaps in providing comprehensive medical care for this important segment of our population. I do not claim to have all of the financial,

insurance and actuarial expertise to fully evaluate all of the facets of such a proposal which were explored by the Task Force in its Background Paper on "Approaches to Drug Insurance Design". However, I would make the following comments on some of the features on which you requested our views:

1. Co-Insurance

It is my feeling that a co-insurance factor in any drug program is exceedingly important to reduce costs and to discourage unnecessary usage. For the reasons advanced in the Background Paper, it would appear to me that a co-payment feature would be the desirable way of implementing this concept. Based on the figures generated in the report, it would seem that a co-payment of approximately $1.00 might prove to be a reasonable sum

without being a deterrent to the obtaining of necessary prescription medication. The exact sum should be established by experts in this field. In those instances where the sum established might be a financial hardship, I believe that assumption of the co-payment might be made by the appropriate state welfare agency. It is my judgment that such a co-payment feature represents a much more easily administered approach than a deductible one.

2. Deductibles

As detailed in the Background Paper, the administration of any program containing the deductible feature presents numerous administrative and financial problems. In addition, the use of a high deductible, although it conceivably would materially reduce the number of claims, could also

prevent the elderly from obtaining needed medication.

I agree with the argument that the details of a deductible reimbursement feature would be difficult to understand by many of the elderly. Furthermore, it seems to be well documented that the development of mechanisms that would insure that deductible requirements have been met would be administratively complicated and much more costly than would be a co-payment approach. For these reasons, I would not support the establishment of a deductible feature initially. After experience is gained with the program, it may become necessary, however, to reconsider this alternative.

3. Limited to Long-Term Illness?

As a physician, I strongly feel that there should be no limits imposed under the

program. We either accept the concept that the elderly are entitled to prescription drug coverage under Medicare for whatever ailments they may have as dictated by sound medical practice or we don't. To attempt to draw the line either with regard to long-term or other types of illnesses is to impose an arbitrary hardship upon such people and to deprive them, perhaps, of adequate medical care. Furthermore, the imposition of any such limits might encourage manipulation of the Program and might interfere with the development of data which could result in more effective prescribing and dispensing under a drug program.

4. Formulary

It is questionable whether the benefits to be derived from a formulary would outweigh the disadvantages involved in its establishment

and administration. In addition, it seems to me that since basically this program would be an "insurance" program, we should accept the concept that the patient-recipients of the benefits should be entitled to receive the drugs which their physicians feel are appropriate and proper for the treatment of their specific conditions.

One of the primary arguments and perhaps the only real argument for the establishment of a formulary is its purported ability to reduce costs by encouraging the prescription of lower priced drugs. Certainly where equivalency has been shown to exist, it is possible that the establishment of certain price limitations would, for certain drugs, accomplish the cost savings in a more economical fashion than would the establishment and administration of a formulary. Since, in my judgment, the concern

on prices and costs is really the heart of the argument which prompts the proposal for a formulary, it seems to me that we should address ourselves to the cost problem directly. To do so would in the long run best serve the interest of all parties.

5. Vendor Reimbursement? Fee?

It would seem that the Background Paper of the Task Force presents persuasive arguments that reimbursement should be made to vendors rather than beneficiaries so as to simplify the already formidable administrative task of handling a multitude of small claims. Vendor reimbursement presumably is more adaptable to automatic data processing techniques, and efficiencies and economies should result. It also should be simpler for the beneficiary. A basic problem to vendor reimbursement is how to determine

the cost to be reimbursed. Reimbursement involves both the cost to the pharmacy or dispensing agency as well as whatever income the pharmacist or dispensing agent should be entitled to for the dispensing.

The Task Force Background Paper speaks in terms of "acquisition costs" and points out the difficulty in determining what these might be as attributed to a specific prescription. However this cost is defined, it could be in a manner which would encourage the vendor to purchase drugs economically both with regard to choosing between manufacturers and suppliers and in terms of purchasing in the most economical quantities and sizes.

I feel that much more thought must be given to this important question and that final definition of reimbursement mechanisms must

be worked out between all affected parties. This would also apply to the establishment of the basis for which the vendor receives remuneration for his function.

6. Method of Payment - Part A or B

It seems to me that the Task Force Background Paper makes a persuasive case that a comprehensive drug program best could be financed under the "Part A" mechanism of Medicare and be of the service type rather than a reimbursement program; I have no strong feeling on this question at this time. This is a question for the financial and actuarial experts and their views should be given greater consideration.

I would add a comment to those of the Task Force with regard to their cost estimates of such a program. It seems to me that the institution of such a program may result in

savings under other Federal or State financed programs which should be considered in the cost estimates of the basic program. For example, under existing or planned Title XIX programs, a considerable amount of funds expended by the States for drugs are for the aged. If a comprehensive out-of-hospital program covering drugs is provided under Medicare, it seems reasonable to assume either that States would no longer have to assume these costs or that they might be reduced materially.

Since funds are provided on a matching basis, the Federal Government's commitment also should be lower. It is also possible that a slight increase in income tax revenue might be achieved from those who no longer would claim deductions for drug expenditures. Finally, there might be off-setting savings in such other programs as hospital care.

7. Lead Time in Program Development

It is very difficult for me to assess just how much lead time will be necessary to institute a program. Certainly, the Task Force target date of 1971 is the soonest that it will be reasonable to expect the program to be instituted and, I suspect, may be a little optimistic. Much will depend upon how simple the program can be made and whether or not time and decision making is going to be involved in formularies, in limiting drug coverage and other questionable matters which will involve considerable debate and evaluation. It seems doubtful whether HEW can by 1971 complete all drug equivalency studies if that is to be an issue or a factor, which I don't think it need be if all approved drugs were to be covered.

In short, I believe that the program should be instituted as soon as reasonably possible, but it should be recognized that a program

having as many ramifications and involving as much paper work as this one will require some considerable lead time to implement.

8. Age Limitation

As I have indicated previously, I do not believe that any artificial limitation should be established other than those generally applicable under the Medicare Program.

9. Utilization Control

I believe that the more accurate term would be utilization review. This is a necessary part of a program as broad as the one envisioned. There are at least two forms which a utilization review could take.

First of all, it could involve the review of claims including the quantities and the relationship to the dosage regimen, as well

as the frequency of prescribing. In addition, validation of claims would be a necessary part of the review so as to insure that the Government would be paying only for claims which are valid.

The second and much broader utilization review mechanism would involve an educational factor. Tremendous quantities of data on physician prescribing habits could be accumulated and disseminated to the practicing physician. The review of such a program could be far reaching and undoubtedly would benefit the recipients.

With regard to substantive questions of utilization, however, I believe it is important to keep in mind that utilization review best should be conducted by physicians

reflecting both academic and practicing medicine so as to command the respect of the entire medical community. Utilization review should rely on persuasion rather than on coercion. Its goal of a proper and efficient use of drugs at reasonable costs is shared by all the disciplines involved.

Assuming the implementation of such a program, you have asked the group to appraise the impacts which it might have on the various groups within the community. To attempt to appraise the impact of the proposed program on such groups naturally depends on its final nature. Based on the comments which I have made, it would seem that the following might occur:

- The aged would receive better treatment.
- The rate of hospital or nursing home admissions might be reduced.

- The pharmacist would experience an increased demand for his services, but one which could be met.
- A lesser burden would be imposed on the relatives of those covered by the program.
- With proper communications better patient treatment could result.
- Total cost may be reduced or at least kept within acceptable limitations without impairing medical care or the freedom of physicians to prescribe a drug which they deem most suitable for their patients.
- Existing hospitalization and medical care insurance rates for the remainder of the population might decline somewhat, or the increase slowed down, because of the exclusion of the aged from these programs as a result of their coverage under Medicare.

II. Economic Features of Drug Manufacturing and Drug Distributio

1. Drug Research

I feel that the Task Force erred in finding that the majority of drug industry research is non-productive. The suggestion that such research is wasteful and that centralized government control of all research would be more desirable or more productive is not substantiated by compelling evidence.

Those who advance this view usually rely upon the phrase "molecular manipulation" to derogate drug industry research. This is unfair and unsound, since some of the world's most important discoveries have come from slight changes in molecular structure. If we say that all drug research must be devoted to "major molecular" change, we may be ruling out potentially great discoveries and adopting an arbitrary, unscientific test.

Today's drug market is so competitive and current approval standards of the FDA for new drugs so strict that I seriously doubt that any major research company is consciously devoting significant time or research effort which knowingly would merely duplicate or slightly modify existing products unless they envision that useful new products will result. Cost of research is so great, and possibilities of success so restricted, that it would be poor business judgment to pursue research which was not thought to lead to meaningful new products.

2. Prices

Generally speaking, I believe that drug prices are reasonable; however, for certain segments of our population they may be an undue burden.

Certainly prescription drugs should be made available to the aged, to the indigent, to the handicapped, to the chronic patient and

to all those who may experience financial hardship in the purchase of drugs. Providing drugs to the aged is a major step forward.

I would support a study to consider price differentials of drugs offered to pharmacies, hospitals, Government agencies as well as foreign drug sales. My Company supported such study proposals in testimony before Congressman Dingell's Subcommittee on Activities of Regulatory Agencies' Relation to Small Business of the Select Committee on Small Business. I would support eliminating the Robinson-Patman Act exemption for sales to Government and eleemosynary institutions.

III. Pharmacological Issues

1. Equivalency

I have consistently supported constructive programs designed to enhance the capability of the various regulatory agencies of the

Government to upgrade the quality of prescription drugs. The difficulties in stating whether chemically equivalent drugs can be assumed to be therapeutically equivalent has been demonstrated.

On the basis of present knowledge, I believe it would be a serious mistake to assume that chemical content, dissolution, absorbtion and blood level studies are certain indicators of equivalency for all drugs. However, it is equally true that there is not a need for human therapeutic trials to prove equivalency in most cases. For certain drugs, blood level studies may be sufficient to demonstrate clinical effectiveness. For other drugs, human therapeutic trials or some other type of test may be required.

For these reasons, I would urge that the present efforts to determine selected biological equivalencies be continued by HEW on a high priority basis.

I would also recommend that additional financial aid be provided to improve the scientific capabilities of the FDA and for increased inspection operations designed to improve quality in manufacturing.

2. Licensing and Registration

I endorse the concept that no drugs should be permitted in interstate commerce unless produced under quality control standards which represent the best obtainable under current good manufacturing practice. Much has been accomplished under the "Good Manufacturing Practice" regulations of the FDA and under the registration, plant inspection and new drug approval provisions of the Food and Drug law. However, I feel that consideration should be given to tightening the registration provisions. At the present time, no affirmative action is required by the FDA on a registration other than the immediate

issuance of a registration number. Perhaps, the effectiveness of a registration should be delayed for a period of time (such as 60 days) to give the FDA an opportunity to inspect the facility and determine the adequacy of quality control if it feels such inspection is warranted.

It is clear, moreover, that the FDA needs additional funds and manpower to adequately implement the current quality control provisions in the law. Therefore, I strongly support its efforts to obtain them.

IV. Information and Identification

1. Drug Information

Much has been said about the publication of a national drug compendium listing all lawfully available prescription drugs.

Roche communicated its position to Senator Gaylord Nelson in 1967 indicating that we support the general idea of a compendium because we believe it could be a useful addition to the existing means of making available information on drug products.

However, I am convinced that an official compendium must not limit or impair the physician's prerogative or ability to prescribe those drug products which he believes are in the best interests of his patients.

Again, due to the complexity involved in such a publication, including the question of quality or therapeutic value and equivalency, we urge that a "Compendium Task Force" be convoked, with the participation of all interested groups to recommend methods of implementation.

I hope that these brief comments will prove helpful to you and to the committee. I look forward to being with you and the other members of the committee on May 6th.

Sincerely,

V. D. Mattia

V. D. Mattia, M.D.
President

VDM:Aip

MARGARET M. McCARRON, M.D.

April 24, 1969

Statement by Margaret M. McCarron, M.D.
Regarding Findings of the Task Force on Prescription Drugs

I. Insurance Plan

1. I am strongly in favor of having the Secretary recommend that a program of out-of-hospital prescription drugs be included in the Medicare program.

2. I believe the features of such a program should include:

   A) Cost sharing by the beneficiary of $1.00 per prescription as recommended by Secretary Cohen.

   B) A formulary system with reimbursement by the government for formulary items only.

   C) The formulary should be complete with drugs in each category represented, a pragmatic way to begin this program would be to include only drugs used for the treatment of long-term illness. I would have no objection to this as the first step.

   D) I feel strongly that this program should be covered under Part A of the Medicare legislation.

   E) I think the age limitation should be set at 65 years. Patients who live beyond 70 years are generally in need of less medical assistance than those who are chronically ill at age 65 and live until age 70. I think there is a greater need to cover this group and would begin coverage at age 65.

   F) I think it is imperative to have a workable system of drug utilization review. I think it would be folly to start such a program without it.

3. If this program is to be successful in accomplishing it's stated aim - to relieve elderly people of the burden of high drug cost, I believe the drugs should be carefully selected, eliminating all questionably useful products, all fads, all obsolete medications, all drugs contraindicated in elderly patients, and most set combinations. The government should assure the therapeutic effectiveness of the drugs available under the program and should carry out drug utilization review to determine whether the patient actually obtained the drug, whether he received the proper amount, and whether or not he took it or just accumulated it on his shelf at home. Another important aspect of this program is physician educatior I assess the impact as follows:

1. ON THE PATIENT:

Advantages: Decrease in the cost of drugs.

Disadvantages: May meet resistance from personal physician who does not want to participate in the program and doesn't care how the patient pays for his medication.

Patient may find he is covered for an inexpensive drug and not covered for an expensive one.

Abuse Potential: Patient may try to obtain drugs for friends. May be inclined to get prescriptions filled and not use medication.

2. ON THE PHYSICIAN:

Advantages: Helps the patient to obtain his medication at decreased cost. If therapeutic effectiveness of low cost items is a fact, can prescribe these for other patients.

Disadvantages: A concerned physician will have difficulty working from a formulary which is not applicable to all his patients and which does not include all of the drugs needed for the care of his medicare patients.

Abuse potential: May prescribe excessive amounts to cover family members who also need the same medication but are not eligible for medicare.

3. ON THE PHARMACIST:

Advantages: Increase in amount of business. Inventory control of approved items will simplify stocking.

Disadvantages: May feel he has to treat all patients equally - with green stamps, etc. and not be reimbursed by government on medicare patients.

Abuse potential: May be inclined to fill more prescriptions than needed in order to increase income, or filling prescriptions for lesser amounts or may tend to increase prices to regular customers to compensate for decreased profit level under the Medicare program.

II. Economic Features of Drug Manufacturing and Drug Distribution

1. I agree completely with the findings of the Task Force related to research by drug manufacturers. I think that the physician is prescribing with an unnecessarily complex array of drugs that have enough slight differences that the products are unequivalent. I think that much time and effort is spent in drug research aimed at profit making rather than research aimed to improve patient care. I think that competition in the drug industry should be aimed toward better and more economical drugs for the patient rather than higher profits for the manufacturer.

2. I think drug prices are unnecessarily inflated by the cost of advertising and promotion. Much of the promotion I personally find to be distasteful. I see no reason for drug companies to spend money entertaining interns and residents to expensive dinners, to giving out gifts and to subsidizing medical meetings. I would also be in favor of stopping the practice of providing free medicines to physicians, "drug samples" to be used on patients. I personally feel it would be a good thing that physicians would have to pay for drugs for their own use so that they would appreciate the problem that patients have in paying for the drugs that are prescribed for them. I think that the practice of a percentage mark-up by the retail vendor should also be stopped. Some method should be found so that the pharmacists doesn't have to tie up large amounts of capital in keeping his pharmacy stocked. I think the pharmacist should be reimbursed for his professional services on the basis of a fee per prescription and recovery of drug costs and a national formulary would help the pharmacist in decreasing his inventory and decreasing the variety of the products that need to be purchased.

III. Pharmacological Issues

1. At the present time I think that there is no assurance that drugs are chemically, biochemically or clinically equivalent. I think this assurance is mandatory. The system of dissolution tests now being applied to antibiotics should be applied to other drug categories or similar useful tests should be found. I think the reputation of the drug manufacturer does not guarantee that his products are any better than any other manufacturer. Drug manufacturers emphasize their quality control. I feel every drug manufacturer should be required to exercise appropriate quality control. I think a standard should be set nationally not only for the active ingredients in a product but also for all of the materials used in the manufacture of the tablet or capsule, etc.

2. I am in favor of licensing and a registration system under which only drugs which are produced under quality control standards set by the Secretary of Health, Education and Welfare are available in interstate commerce. I also feel companies involved in intrastate commerce should also be regulated.

IV. Information and Identification

1. I am strongly in favor of expanding government support to departments of clinical pharmacology and medical schools. I think these departments should then be required to take on part of the responsibility of postgraduate education of physicians practicing in the community.

2. I question the conclusion of the Task Force in providing governmental assistance in supplying a publication, providing up to date information and guidelines on drug therapy to physicians. I think that this is an unnecessary expense to the taxpayer. I think physicians should be educated to be interested in this kind of material and the material should be available to them. I think they have the responsibility to purchase materials themselves and not spend tax money in providing this information to the physician. I feel that a physician that has a license to practice medicine also has the responsibility to keep himself informed on the latest information regarding the practice of medicine.

3. I think it is appropriate for the Federal government to expand the efforts of the county medical societies, pharmacy and therapeutic committees, medical foundations, and medical schools in taking the responsibility for providing continuing education to physicians on rational prescriptions. I do not feel that any portion of this program should be supported by drug companies. I think practicing physicians should also assume some of the cost of their postgraduate education in this field.

4. I strongly favor the publication and distribution of a drug compendium. I think that this should consist essentially of the information materials obtained in the product brochure of each product. I do not think this drug compendium should be used as a guide to therapy but should be simply a source book listing all of the approved products on the market and the information contained in the product inserts. I feel that the Food and Drug Administration should make an effort to see that the information on the product insert is accurate. In my opinion this drug compendium should be published each year by the Federal government and distributed free of charge to all physicians licensed to practice medicine in the United States. I also feel that the Federal government has a responsibility to support another type of publication related to drug therapy written by qualified physicians and pharmacologists. For example, I think Federal support should be given to the A.M.A. council on drugs and their efforts to produce a book on rational prescribing. I think this book should be sold to physicians throughout the country and I see this as a very important function of the American Medical Association.

Comments of
Bert Seidman, Director,
Department of Social Security, AFL-CIO
On the Findings and Recommendations of the Task Force on
Prescription Drugs

BERT SEIDMAN

I. Insurance Plan

1. On the basis of the Task Force Report should the Secretary recommend for or against the inclusion of a program for out-of-hospital prescription drugs in the Medicare program?

I strongly urge that the Secretary should recommend inclusion of a program for out-of-hospital prescription drugs in the Medicare program. The limited incomes of the elderly combined with their requirements for prescription drugs greater than that of any other group in the population strongly dictate the urgent need to relieve inordinate financial burden the elderly now bear for the prescription drugs they require not only for health but indeed, in many cases, for life itself. This can only be done by incorporating in Medicare a comprehensive drug insurance program financed on social insurance principles. This is my strong personal recommendation. It has also been the policy recommendation of the AFL-CIO ever since the inception of the Medicare program. We have regarded the lack of this essential feature as perhaps the most important gap in the program.

2. If so, what should be the features of such a program? Which features of such a program require further study?

I strongly favor a comprehensive program financed on social insurance principles without financial deterrents to necessary utilization and without administrative burdens on the elderly beneficiaries. All physicians should prescribe for their patients on a rational basis the drugs they need to maintain their health or cure their illness. This is a responsibility which can fall only on the physician. Once the physician prescribes a drug it must be assumed that the health of the patient will suffer unless he can obtain it. The patient should not

be forced by lack of adequate financial resources to forego purchase of the drugs his physician prescribes. The patient has no incentive to purchase drugs he does not need and he has no way of purchasing any prescription drugs unless they are prescribed by his physician. Therefore, there can be no justification whatsoever for financial deterrents as a means of controlling utilization. Such controls should rest exclusively with the physician. If the drug insurance program is to be effective, every physician and every patient should be assured that there will be no financial or other deterrents to the ability of every patient to obtain the drugs his physician prescribes.

The Background Paper of the Task Force ("Approaches to Drug Insurance Design") states:

> "Implicit in the control function philosophy is an assumption that cost-sharing discourages 'unnecessary' utilization without impeding 'necessary' utilization. There is no available empirical or theoretical evidence to support such a contention. Moreover, if necessary treatment is postponed because of financial constraints, health care will be inadequate and eventual claims upon the drug program or a related health insurance program may be larger than if care had been received when originally indicated."

What this means is that if cost-sharing is used it cannot be justified on the grounds of controlling unnecessary utilization. To the contrary, its only possible justification is if it is considered that patients, regardless of their limited financial resources, must pay for some part of the cost of the program. I do not believe that is necessary. But if cost-sharing in any form is introduced, it must be recognized that <u>its result will be to discourage necessary utilization</u>.

Co-insurance?

Deductibles?

If there is to be any cost-sharing, I strongly oppose deductibles and favor co-pay over co-insurance. Deductibles are the worst form of cost-sharing because:

1. They are most likely to deter necessary utilization. This is because the patient would have to meet the total cost of prescription expenses up to the deductible amount before the program would provide any financial assistance for his drug purchases.
2. They put the administrative burden of keeping track of many relatively small bills on the elderly patient.
3. They involve a high administrative cost.

If a choice must be made between co-insurance and co-pay, I favor the latter. Under co-pay the patient would be required to pay some specific amount (e.g. $0.50) of the cost of each prescription, but if this is done there should also be a maximum limit on such payments. This is preferable to co-insurance because it places less of a financial burden on those patients whose medical condition requires them to use high-cost drugs.

Whether or not there is any cost-sharing, effective controls should be placed on both doctors and pharmacists as the Task Force recommends so that reimbursement is "based on the cost of the least expensive chemical equivalent of acceptable quality generally available on the market," (Finding 38, p. xv).

Limited to long-term illness?

I favor a comprehensive program rather than, as Secretary Cohen recommended, a program restricted to a limited number of specified chronic conditions. The basic Medicare program itself is comprehensive and thereby relieves the elderly of a large part of the financial burden of illness, both chronic and acute. The

same principle should apply to drug coverage under Medicare. Otherwise, many of the elderly will be barred by their financial limitations from necessary drug therapy

Moreover, a limited program confined to long-term illness is impractical because:

1. If the coverage is limited to specified diseases, doctors would be under great pressure in order to assure proper treatment for their patients to conform their diagnoses to the restrictions of the program.
2. If the coverage is limited to certain drugs, it must be recognized that there are no, or virtually no, drugs used exclusively for long-term illness.

If it is considered that the costs of the program must be reduced, the only effective avenue is by the imposition of specific cost controls and not by placing a financial burden on the patient barring him from necessary drug therapy and thus defeating the fundamental purpose of the program.

Formularies?

One way of controlling costs is to restrict the program to a national formulary covering drugs in all therapeutic categories needed to provide adequate treatment. All such drugs should be covered by the program. I agree with the following finding (No. 20) of the Task Force:

> "Although use of a formulary is not a guarantee of high quality, medical care, rational prescribing, effective utilization review, and control of costs, the achievement of these objectives in a drug program is difficult if not impossible without it," (p. xiii).

Vendor reimbursement? Fee?

The Task Force Background Paper makes a strong case for a direct purchase program which ought not to be ignored. This would apparently be the best way

of achieving both maximum coverage and maximum economies. This approach should certainly be explored before any decision is made to restrict the program and/or introduce burdensome cost-sharing features.

If the choice, however, is between vendor and patient reimbursement, I strongly favor the former. Patient reimbursement has two major defects:

1. It places an administrative as well as a concealed financial burden on the patient. The financial burden results from his inability to handle the administrative requirements and thus to obtain the full reimbursement to which he is entitled.
2. Because there are many more patients than vendors, patient reimbursement would involve a much larger administrative cost. Moreover, as the Task Force Background Paper states, with patient reimbursement the program administrator would not deal directly with vendors or drug producers and therefore cost controls could not be effectively applied, (p. 38).

Whether or not the program is set up on a direct purchase basis, I assume distribution would be through regular vendors. They should be reimbursed on the basis of a flat professional fee per prescription. This is the fairest system to both the pharmacists and the program. It is also most susceptible to effective cost controls since, as the Task Force Report states, there would be no "inducement to a pharmacist to dispense the more expensive brand of a prescribed drug," (p. 16).

Method of payment, Part A or B?

The program should be set up under Part A because:

1. It would have broader and more assured coverage than a voluntary program under Part B.
2. More fundamentally, it conforms to the basic principle of social insurance that, as the Background Paper states, "an individual would pay for this protection during his working years, rather than at a time of life when he may well have low income, limited assets, and

Lead time in program development?

The program should be established as soon as technically possible.

Age limitation?

Anybody covered by Part A of Medicare should be covered by this program.

Utilization control?

I favor appropriate types of utilization controls which place responsibility on the physician but not the patient. Thus, as I have already indicated, the physician's prescriptions should be confined to drugs included in the formulary. In addition, I agree with the Task Force Report that every effort should be made to develop peer utilization review techniques "as an appropriate means of discouraging unnecessary use of medical services and of encouraging improved patient care," (p. 61). This is being done increasingly in the hospitalization and extended care features of Part A and similar procedures should be developed under the drug insurance program.

Appropriate utilization controls directly involving physicians should be developed to the maximum extent possible. But there should be no so-called "controls" which place deterrents on patients from purchasing the drugs their doctors prescribe or deterrents on doctors from prescribing drugs their patients need. Controls should place no constraints on effective treatment.

3. How do you appraise the impact of the proposed program on various groups within the community?

The major groups concerned with this program are the elderly, Social Security contributors (at the present time, workers and employers and government to a very limited extent), physicians and pharmacists. Without going into details, the program I have recommended would meet a very urgent need of the elderly without adding significantly to the financial burden of Social Security contributors. It would provide a fair return to pharmacists. Physicians could be assured of the best possible opportunity to provide necessary and effective drug therapy for their elderly patients.

II. Economic Features of Drug Manufacturing and Drug Distribution

1. How do you appraise the findings and recommendations related to research by drug manufacturers? product differentiation, new entities, "duplicative" drugs, etc.?

I regard the findings of the Task Force on these question both persuasive and conclusive. It would appear that much of what the industry calls research really involves wasteful activity aimed at differentiating one company's product from a similar product which a competing company is already selling. This duplicative type of research is aimed at maintaining the competitive strength of the company rather than genuine improvements in the drugs that are sold.

The Task Force recommends that the Secretary of Health, Education and Welfare should call one or more conferences to consider provision of incentives to the drug industry, to put more effort into products representing significant improvements to therapy and less in duplicative drug products and combinations, (p. xvii). While I agree with this objective I do not know what incentives the Task Force has in mind. I would want to have that information before subscribing to this specific recommendation.

2. How do you appraise the findings and recommendations related to the structure of drug prices, by manufacturers and by retail vendors?

Again it appears to me that the Task Force findings are correct. In dealing with the question of high drug prices and profits, the Task Force appropriately, in my judgment, places its emphasis on production rather than distribution. As far as the distributors are concerned, their prices tend to be a percentage mark-up on the producer's price so that the latter is the basic determinant of what the consumer pays. While, as I have indicated, I favor the dispensing fee approach to compensation of the pharmacist, under that system, as well, the manufacturer's price would still be larger determinant.

There is no question that this industry enjoys an unusually high rate of profit. The Task Force has found that "the exceptionally high rate of profit which generally marks the drug industry is not accompanied by any peculiar degree of risk, or by any economic difficulties in obtaining growth capital," (p. 14). Pricing in this industry is not related principally to cost but instead the "worth to the buyer." Since the purchaser needs the drug to maintain or restore his health or even to continue living, there is almost no limit to this "worth." Thus, the pricing policy is clearly monopolistic. As Professor Henry Steele, of the University of Houston, has stated before the Senate Subcommittee on Monopoly, drug prices are "too high relative to production cost, since that is the standard of efficient pricing in a competitive market." He added that drug manufacturers follow "the monopolistic practice of charging what the traffic will bear."

All of this is made possible by the exploitation of brand-name prescription in which the physicians, by and large, have cooperated. The patient, unfortunately, as the consumer has no control over this situation at all since he can purchase only the drugs his physician prescribes. I favor the Task Force recommendations for conferences and studies (recommendations 1, 2 and 3 -- p. xvii). But more reasonable than this will be needed to bring about a price and profit structure in this industry. One beginning step would be to introduce generic prescribing wherever possible in all programs sponsored by government, labor and management.

III. Pharmacological Issues

1. How do you appraise the conclusions of the Task Force relating to chemical, biological and clinical equivalency?

The Task Force has found that "lack of clinical equivalency among chemical equivalents meeting all official standards has been grossly exaggerated as a major hazard to the public health," (p. xii), and that the use of low-cost chemical equivalents can yield important savings, (p. xiii). I claim no technical competence on this matter. However, as a layman, I find it very persuasive that

the use of low-cost chemical equivalents in foreign drug programs, leading American hospitals, State welfare programs, VA and PHS hospitals, and American military operations has seldom produced clinical non-equivalency and even less often had significant/therapeutic consequences, (Task Force Report, pp. 31-32). They are used in these programs because they are cheaper and because in almost all cases give predictably equivalent clinical effects.

I find it very difficult to accept the drug industry's assertion that in any appreciable number of cases when two products have an identical generic name, the generic equivalency is not the same as therapeutic equivalency. I find it hard to understand how all of these institutional users could be subjecting their patients to the alleged lack of safety and therapeutic equivalence of the generic drugs. This is an anomaly the drug industry would find it very hard to explain.

2. How do you appraise the conclusions and recommendations of the Task Force related to licensing and registration?

The Task Force has recommended development of a registration and licensing system under which no drug product would be permitted in interstate commerce unless produced under quality control standards set by the Secretary of Health, Education and Welfare, (p. xvii). As a representative of consumers, I regard this as a very desirable recommendation. It was provided in the original Kefauver bill in 1962 but unfortunately this provision was dropped before final enactment. It is urgently needed and ought to be made effective as rapidly as possible.

IV. Information and Identification

How do you appraise the conclusions and recommendations of the Task Force with respect to the flow of information regarding drugs to practicing physicians?

Again, as a consumer representative, I find it very disturbing that most physicians obtain their information on drugs from advertising and drug detail men.

It is particularly regrettable that, as the Task Force Report states, "many and perhaps most American physicians do not have adequate access to complete and objective information on prescription drugs," (p. 23). I therefore strongly support recommendations 9 through 12 (p. xviii). The compendium would be a particularly worthwhile innovation.

THE NATIONAL ASSOCIATION OF RETAIL DRUGGISTS

Washington Representative • 440 NATIONAL PRESS BLDG. • 529 14th STREET N. W. • WASHINGTON, D. C. 20004
TELEPHONE 347-7495

April 25,1969

TO: John T. Dunlop, Chairman, Secretary's Review Committee of The Task Force on Prescription Drugs

FROM: Willard B. Simmons, Executive Secretary, The National Association of Retail Druggists

In accordance with agreements at the April 4 meeting of the Committee, I am submitting my views and appraisal of the findings and recommendations of the Task Force under the headings suggested by Chairman Dunlop. At the April 4 meeting, Secretary Finch also requested comments on certain aspects of the Task Force activity which I am including at the outset of my statement.

In general, I would like first to state that NARD agrees with the Task Force recommendation that drugs should be made available for the Medicare home-patient. In a complimentary sense, the Task Force brought together in an organized fashion much material that will be most useful to government and non-government groups concerned with drugs. From the standpoint of constructive criticism, I would have to admit that the Task Force devoted too much time in areas unrelated to their assignment and that many of the conclusions and dissertations on how pharmacy should be practiced are highly impractical and apparently written by staff

members with no particular competence in the areas of drug distribution at the retail level. Such espousals by government pharmacists who are hospital oriented and who dream of the eradication of all drug stores and of all pharmacists becoming mini-physicians, are neither new nor practical. Frankly, the public has a higher regard for the traditional American drug store and its important drug distribution role in the community than do some of these theorists. Admittedly there will be a constant change in all aspects of the delivery of health care including the distribution of drugs but a practical program for providing drugs to the medicare home patients must be realistic in terms of existing conditions in the 1970's and not based on what the theoreticians hope or think the pharmacists role may be in 20, 50, or 100 years. Obviously, the report reflects too much desire to engage in "empire building" - government studies to revamp state pharmacy laws, establish new pharmacist roles, finance restructuring of pharmacy education, engineer greater efficiency in the practice of retail and hospital pharmacy, perpetual government studies of drug economics that duplicate existing non-government services, etc. It is interesting to note that many of the proposals for never ending government studies that are totally unrelated to the Task Force's commission are urged by non-pharmacist staffers and contemplated to be conducted by non-pharmacists unfamiliar with the practice of pharmacy in a free-enterprise environment.

The members of the National Association of Retail Druggists operate some 40,000 drug stores where more than 75% of the nations prescriptions are filled daily. We submit that a program for medicare home drugs through the nation's retail pharmacies be implemented as expeditiously as possible and that the manner in which these drugs are provided to the medicare

patients should be as much like the procedure followed by private patients as possible - this will assure maximum cooperation from the nation's retail drug stores. Radical departure from customary practices known to patient and pharmacist will guarantee chaos and defeat the paramount purpose of a medicare home drug program.

We strongly urge that the program should be inaugurated on the basis that all pharmacists and medicare patients are honest. This will keep administrative costs at a minimum. With experience, there will naturally be a need for audits and controls which can be added, but I would strongly urge that it is totally unnecessary to begin the program with a multiplicity of unnecessary controls.

I. Information requested by Secretary Finch (The Secretary's "Charge to the Committee").

1. The procedures used by the Task Force left much to be desired. The workshops provided only superficial discussions rather than active consultations. The effort reflected primarily the preconceived opinions of HEW staff members and their acquaintances of similar persuasions. Insofar as the pharmacists' staff was concerned, it is obvious there was not enough practical understanding of how prescription drugs are distributed and what is necessary for a retail pharmacy to succeed or survive in a free enterprise environment.

2. We feel there was too much attention given to many matters outside the competency of the staff and outside the relevancy of the purpose of the Task Force. We would have to admit that our confidence in the Task Force staff to deal with many issues regarding the profession of pharmacy is most guarded. It is felt that in other areas the recommendations reflect

only the views of some government pharmacists who appear to live in hopes of being administrators of a government pharmacy program operated outside the purview of the free enterprise system. Such a drug distribution system could only bring about a deterioration in quality pharmaceutical services and inflict great inconvenience on the Medicare recipients.

3. Our assesment of the impact of the Task Force recommendations is naturally related more to the pharmacy profession and the consumer. We feel that drugs for the Medicare home-patient can be provided under the existing drug distribution system in a way that would be acceptable to the retail pharmacists of this country. The Task Force was vague in its recommendations on reimbursement and coverage. Some of the possibilities discussed would be unacceptable and other possibilities would provide no problem. Many of the recommendations would have an effect on other health providors and various segments of the industry and we feel sure that their representatives on the Committee will make appropriate comments.

II. Information requested by Chairman Dunlop in his memo of April 7, 1969, to members of the Review Committee.

INSURANCE PLAN

1. The Secretary should recommend the inclusion of a program for out-of-hospital prescription drugs in the Medicare program. This is an important omission of the Medicare program and if drugs are provided in time they will prevent more costly health expenditures in the areas of physician services and expenditures for hospital and E.C.F. services.

2. The features of such a program may include a variety of combinations, and while some features may require additional study, it would appear that enough study has been undertaken on most issues and that positive action is now needed to develop a program that will provide

quality drugs to the Medicare home patients in a manner that will necessitate the least departure from the existing drug distribution in this country. Of the features listed in Chairman Dunlop's memo of April 7, it is possible that several combinations would provide an adequate drug program. To facilitate an understanding of our reaction to the features mentioned, they are listed below in the order presented in the April 7 memo.

Co-insurance:

The patients are accustomed to the co-insurance approach incorporated in the existing Title 18-B program and consequently the co-insurance approach could be used effectively. A co-pay approach might be preferable because the patient would know exactly how much he should pay on each prescription, whereas the Medicare patients would be confused and uncertain in many instances in determining how much their part of the co-insurance payment would be.

Deductibles:

Annual deductibles will unnecessarily bring about a heavy administrative cost and could create tremendous problems for retail pharmacists if a mandatory assignment requirement is incorporated in such a program. In no event should annual deductibles be used if there is a mandatory assigment feature. If there is no mandatory assignment feature, the patient would still have much difficulty in maintaining and validating his drug expenditures in the process of meeting the annual deductible.

Limited to Long-Term Illness:

It seems unfair to limit the program to long-term illness. A better approach would seem to be a program that provides drugs for all Medicare patients and to reduce the total cost of the program by increasing

the co-pay factor of each prescription. Such an approach would have the same end result as co-insurance and annual deductible features, but would involve much less administrative cost and would be more intelligible and acceptable to Medicare patients.

Formularies:

From the standpoint of the retail pharmacist, he would be opposed to a formulary which forced him to dispense drugs in which he did not have confidence or which exercised price controls over what he might dispense to the extent that he again would be compelled to dispense drugs in which he did not have confidence. Pharmacists believe that quality drugs and economical drugs should be made available to the American public whether they are private patients or patients receiving drugs that are paid for by the Government or any third party. In this context, the pharmacists feel that a physician should be allowed to prescribe drugs that are in the patient's best interest. Restrictive formularies which interfere unnecessarily with the professional responsibilities of the physician or pharmacist are not in the public interest. However, formularies of the type used in the Pennsylvania Welfare Department are not restrictive and encourage the cooperation of the physician and pharmacist towards the use of quality drugs in an economical manner.

Vendor Reimbursement:

The recommendation of the Task Force on the method of reimbursement is vague, unclear, and offers a variety of possibilities. It would seem the best approach for vendor reimbursement at the beginning of such a program would be to allow the pharmacist his "usual and customary charge." Much has been written about the fee to be fixed by the federal or state governments and an attempt will not be made here to rehearse the

many facets of the argument. It should be clearly stated, however, that the overwhelming majority of pharmacists in this country do not think there is anything "unamerican" or "unprofessional" about the mark-up system. It is doubtful that much more than 10% of the retail pharmacists use a dispensing fee. The NARD certainly has no objection to the fee approach in a pharmacy where the pharmacy owner can adjust the fee any day to reflect his operational cost and to remain competitive. The fixed fee approach which is now being recommended by many government and other third party spokesmen is a distortion of the original fee approach contemplated and proposed 10 or 15 years ago. At that time it was stated that the fee would reflect the operational cost of doing business in each individual store and did not contemplate the same fee being fixed by a third party for use in all stores. It might also be noted that the recommendation that a store be allowed only actual acquisition costs does not enable a pharmacy owner to collect many of the expenses incurred in the acquisition, dispensing and distribution of his pharmaceuticals. Actual acquisition costs, in fact, would penalize many retail pharmacists who are seeking to reduce the cost of drugs for their customers. Wholesale or some type of standardized cost would be fair, enable more stores to participate, and would reduce program costs.

Method of Payment, Part A or B:

Either approach could be satisfactory depending on the other features of the program. We would suggest that not enough consideration may have been given to a Part C or Title XX program for drugs. Certainly there is an advantage in having a universal drug program so that there are no eligibility questions but does it make sense to put such a program under Part A which is for hospital insurance.

Lead Time in Program Development:

It is doubtful that the lead time of one or two years originally contemplated for this drug program is necessary because there has been so much material published and distributed about a drug program for Medicare home patients. The quicker the program is started, the quicker necessary and life-saving drugs will become available to many of our elderly citizens. The program should begin within six months of passage of the necessary legislation. Don't study the program to death. At least start the program on a modified basis and get experience on issues that may not be nearly as difficult as the Task Force thinks.

Age Limitation:

Drugs should not be limited because of age in this program except to comply with the age 65 requirement of all Medicare recipients. It would be most unfair to make drugs available to Medicare patients over 70 or 75 only. The Medicare program is for all persons over 65 and they should all be entitled to the benefits of a drug program. The cost of the program should be controlled by co-payment requirements and not by age requirements or disease categories.

Utilization Control:

There is no reason that appropriate utilization controls cannot be developed and would not be accepted by the pharmacists of this country. Certainly they would object to unreasonable controls but it would appear that many controls reflecting experiences with other third party drug programs and state welfare drug programs would be useful. With respect to utilization controls, it is doubtful that such measures should prohibit physicians from prescribing any quantities they believe to be professionally desirable. If physicians are restricted to prescribing supplies for 30 days, or some other arbitrarily decided-upon length of time, the total

Medicare program cost could be unnecessarily accelerated. In other words, is it necessary to restrict physicians to a prescription for a 30-day quantity in order to make the "fixed fee" approach economically feasible for the pharmacist? Such a utilization control would be a fictitious necessity and would increase physician costs and pharmacy fee charges. It would be preferable to allow both the physician and the pharmacist "usual and customary charges" so that there would be no interference with the physicians' prescribing or other professional practices. It should be stressed that utilization controls for pharmacists need not be as elaborate as those for staff physicians in hospitals.

Economic Features of Drug Manufacturing and Drug Distribution:

We were disappointed that the Task Force did not come to grips with the price discrimination policies of some drug manufacturers who charge the retail pharmacist much more than they charge hospital pharmacies and the government. Such policies unnessarily militate against our present drug distribution system because private patients and third parties are paying more than their share due to the low prices hospitals and the government are paying for drugs.

It is unfair to say that a fixed fee is necessary to get the retail pharmacist to dispense lower cost quality drugs. Such a charge does great injustice to retail pharmacy and cannot be substantiated.

III. Observations on other subjects mentioned in Final Report.

1. Pharmacy Aides - The Task Force did a great disservice to the pharmacy profession and demonstrated a great unawareness of the important contributions of retail pharmacists to high quality health care by recommending pharmacy aides. The recommendation can only lead to lower

standards and a deterioration in pharmaceutical services. It is understandable, although we suspect pharmacy standards will suffer, that hospitals want to use sub-professionals. If hospitals want to use aides, technicians, or sub-professionals, we feel that this can be done by merely calling them hospital aides, or hospital technicians. Use of the terms pharmacy technicians or pharmacy aides will create more problems than they will solve. The major difference in retail pharmacy and hospital pharmacy is that retail pharmacists are patient-oriented and in daily contact with patients, whereas hospital pharmacists are not.

2. Dispensing Physicians are not necessary in the modern practice of medicine. Their activities are not accompanied with health safeguards for patients and they restrain the patients' freedom to get his drugs from a community pharmacy of his choice. The Final Report of the Task Force was less than effective in its recommendations on this issue and the recommendations will, in fact, create a public health hazard.

3. Government Pharmacies. The Task Force recommendation was vague and ambiguous and may encourage the use of government dispensaries such as OEO proposes. An effective drug distribution system is impossible unless it contemplates use of retail pharmacies and the free enterprise systems but the Task Force seems to have some hidden reason for not championing the good in America's free enterprise system. The report did not recommend government dispensaries "at this time."

4. Price Information. The Task Force Report seems to be blind to the fact that price information is now available to any patient and any physician from any drug store. The Task Force seemed to be equally blind to the chaos that can be caused by the advertising or "week-end specials" of prescription drugs.

5. Pre-labeled and Pre-packaged Containers. This recommendation raises a question as to whether the Task Force was genuinely interested in economical drug programs. Even an amateur economist knows this would increase the costs of a drug program fantastically. It would intefere with the physicians prerogative to prescribe quantities needed and would also encourage other physicians to set up dispensing rooms.

Outline of "Major Issues" Involved in Report of HEW Task Force on Prescription Drugs

MAJOR ISSUES

I. Insurance Plan

(a) Should the Secretary recommend for or against a program for out-of-hospital prescription drugs in the Medicare program?

Although it is doubtful whether administrative costs can be kept at a level which will not appear excessive in a program involving many millions of small claims, I believe the answer to this question is yes. The United States is one of the few remaining developed countries without a social insurance program for out-of-hospital drugs. Having already provided drug coverage under the Social Security system for hospitalized beneficiaries, the program is now somewhat distorted in omitting prescription drugs for non-institutionalized patients.

I believe it should be stated, however, that the case for this expanded coverage has not been documented by the Task Force.

(b) What features should be included in the plan? Which features require further study?

1. Co-insurance. The Task Force prefers a flat contribution by the patient which it designates as "co-payment", which would not vary with the price of the prescription. This suggestion was endorsed by Secretary Cohen in his letter of January 13, 1969, in which he proposed that the co-payment be set at $1 for the products to be covered, i.e., those most used for certain chronic conditions of the aged.

I am in agreement with the Task Force as to the general principle of beneficiary contribution, at least during the first year of the program and until it is possible to estimate the costs more precisely. Whether a flat co-payment is to be preferred to a percentage co-payment is a subject which deserves further consideration.

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2. Deductibles. The Task Force considered, as one means of limiting costs, the imposition of a deductible charge which the beneficiary would have to pay before becoming eligible for Medicare coverage. This method was rejected, evidently in favor of the alternative of limiting coverage to certain designated drugs.

I am not suggesting that a deductible is particulary desirable. Obviously, it limits the benefits to be received by the elderly and it adds somewhat to administrative costs. But its drawbacks on both counts are no worse than the two alternatives proposed by the Task Force, i.e., limitation of coverage to maintenance drugs and limitation of reimbursement to the price of the least expensive chemical equivalent. It would be difficult to explain to an elderly person on an inadequate pension why his drug needs for an acute infection, or for some uncovered chronic condition such as arthritis, should not be covered while some other patient, who might be in easier financial circumstances, is covered for his drug requirements for a chronic condition which happened to be eligible.

In any event, the use of a deductible deserves more discussion or study.

3. Limitation to Long-term Illness. As noted in my comment under the previous item, I believe that this proposal must be considered as an alternative to the use of a deductible. It is a less equitable method of conserving funds on the basis of relative need. It would cause a problem for pharmacists due to the fact that most drug products used for chronic conditions are also prescribed for acute conditions. It would be time-consuming for the pharmacist, when confronted with a doubtful case, to have to check with the physician to see if the prescription was for a chronic condition covered by Medicare.

There is an additional danger which should be considered. Elderly patients in particular are likely to receive more than one prescription at a time from their

doctors. If one is for a drug covered by Medicare and another for an uncovered drug, it is likely that a substantial number of beneficiaries may not have the prescription, requiring full payment from their own funds , filled even though this may be the drug most essential for their treatment. Studies of the rate of unfilled prescriptions suggest that this can be a significant danger.

4. Formulary. The Final Report recommends, on page 66, that reimbursement should be limited to the cost of "the least expensive chemical equivalent of acceptable quality generally available on the market". To the lay reviewer, unfamiliar with the drug industry or with the experience of other countries in operating drug insurance programs, this may seem reasonable. The reader who does not look beyond the "Findings" and "Recommendations" of the Report, might even be impressed by the promise that this restriction would allegedly result in a modest 5 percent saving in program costs.

But the reader who looks behind the summaries and explores the background studies discovers that the experience of state welfare programs with limited formularies as an approach to cost control is, as the authors admit, "inconclusive". He will search in vain, in the study of foreign programs, for a country which has ventured to apply the approach in the fashion proposed by the Task Force. The Task Force is quite mistaken in its discussion of the French health insurance program in saying that "reimbursement is limited to the least expensive equivalent product."

If he studies the background paper on Current American and Foreign Programs he may be struck by the fact that there is one characteristic common to all Federal programs: Department of Defense, Public Health Service, Veterans Administration, and OEO. They use formularies as a guide to the procurement and stocking of drugs in their own hospitals and clinics but with quality criteria and controls much stricter than that of the FDA. None of them, however, attempt to apply the type of formulary proposed by the Task Force to programs operating through community pharmacies.

In commenting on this formulary issue, the Department of Defense has strongly opposed the proposition on the grounds that it would subject civilian dependents and retirees of the armed services to second class medicine, since the DOD had no way of assuring, for products sold in community pharmacies, the same quality control standards as existed in Defense Department procurement for its own hospitals.

If the reader examines the data on this issue even more carefully, and analyzes the items in Appendix N of the Drug Users, he will detect important errors in arithmetic in the study of "Generic Prescribing and Theoretical Cost Savings". It should be recalled that the Task Force warns, on page 66 of the Final Report, that "this hypothetical saving is based on the assumption that the lowest priced generic drugs were all of acceptable quality and were available on a nationwide basis." It may be in recognition of the unrealistic nature of these assumptions that the Task Force cautiously reduced its claim for an overall saving -- on the entire comprehensive list of 409 products -- from 6.1 percent to 5 percent, as the possible gross gain to be had from applying the least expensive chemical equivalent rule.

But there are other reasons for deflating the estimate of hypothetical savings. I mentioned that there were important errors in Appendix N. After eliminating these various errors, we have calculated that the hypothetical savings at the retail level from the use of the "least expensive chemical equivalent" mechanism would not be $41.5 million but only $32.7 million. (A separate statement discussing these errors in detail is available from PMA on request.)

It should be remembered, finally, that these are gross savings. The Task Force itself makes it clear that its estimates make no allowance for the additional administrative costs needed to apply this principle. And these additional costs would be

considerable. They would make up a large part of the expenditure of $111.6 million, for the first year alone, which Secretary Gardner, in his letter of August 24, 1967, to the Senate Finance Committee, estimated as the administrative costs of implementing a bill of this type in the 90th Congress.

In summary, with respect to the formulary proposal:

(a) The Task Force has confused the concept of a hospital formulary, or an executive agency formulary -- which can be a rational instrument for economizing on drug procurement and inventory in an institutional setting where there is also provision for the doctor to order outside the formulary without penalty -- with the idea of a national formulary, whithout such escape clause provision, to be applied through community pharmacies.

(b) It has failed to recognize that as "generic products" achieve nationwide distribution, their prices will rise -- a tendency already evident in the fact that the average prescription charge written generically has been rising at over twice the rate as the average of all prescriptions.

(c) Since the costs of administering this restrictive approach will greatly exceed the gross savings, and since it will certainly arouse resentment on the part of doctors and beneficiaries, the only possible explanation for the proposal seems to be that its advocates consider it to be in the public interest to enlist the full force of the Government's purchasing power, applied directly or indirectly, to divert sales from those firms which now devote an average of 11 percent of their sales receipts to research and development for the benefit of other firms which do not engage in research.

5. Vendor Reimbursement. The Task Force recommends that reimbursement be made to vendors rather than to beneficiaries, arguing that it would simplify the already formidable

administrative cost of handling a multitude of small claims, since vendor reimbursement is more adapted to automatic data processing techniques. Presumably, it would also be simpler for the beneficiary.

This is a matter of primary concern to pharmacists and their organizations and to those representing the elderly. As an Association, the PMA has no position on the issue.

6. Professional Fee. Whether the fee is to be preferred to the markup, or to the "usual and customary" charge, which is generally a combination of the two systems, is a matter of concern primarily to pharmacists.

7. Method of Payment -- Part A or Part B. The Task Force concludes that if placed under Part B, the additional premium required to finance an out-of-hospital drug program "might prove sufficiently burdensome for the elderly who have to pay the present monthly premium so that more of them might decide to reject coverage under Part B", whereas, if placed under Part A., "an individual would pay for this protection during his working years, rather than at a time of life when he may well have low income, limited assets, and high health costs."

Whether Part A coverage is desirable or not is an issue on which individuals may differ and the PMA has taken no position. One senses that a major consideration for the Task Force was a desire for administrative simplicity, and they have made a persuasive case that Part A would involve fewer administrative problems.

Certainly the Social Security Administration experts are best qualified to advise on the feasibility of the two forms of financing.

8. Lead Time in Program Development. I agree that a generous period for "tooling up" will be required, but I do not believe that the current drug equivalency studies, whose target date has been set as 1971, provide an excuse for a two-year delay. I do not believe that HEW can by 1971, or by 1981, provide any assurance that all versions

of multiple source drug products on the market are either biologically or therapeutically equivalent, and I do not believe that implementation of a drug insurance program should be made conditional on the completion of this unattainable objective.

9. Age Limitation. The Task Force considered and rejected the possibility of limiting program expenditures by setting the eligibility age for the drug program at 70 or 72. I agree that it would be better to make eligibility coincide with the age fixed for hospital and medical benefits, particularly since prescription drugs are complementary to these other sectors of health care.

10. Utilization Control. This is a subject of primary concern to the medical profession and to the program administrators rather than to the industry. I believe, however, that the Task Force has made a good case for utilization review, which has proved in a number of state and foreign drug programs to be an effective method of improving the standards of drug therapy and of restraining any tendency to excessive prescribing. To be effective, utilization review should be conducted by physicians, whose judgments will be respected by their colleagues, and who have had experience in community practice.

Utilization review should rely on persuasion rather than coercion. Ideally, it should not be merely disciplinary but should facilitate the exchange of clinical experience and the accumulation of additional data on indications and contraindications of drugs. The total effect, moreover, should be to increase the physician's knowledge of available drugs and his cost consciousness so that he will not prescribe an expensive drug unless clearly indicated.

(c) What would be the effect of the plan on various groups in the Community:

Other members of the review committee are in a better position to comment on the effects of the proposed program on the medical profession, the profession of pharmacy, and the welfare

of our elderly population. I can more appropriately comment on its effect on the pharmaceutical industry. Before doing so I should like to make one observation on the possible effect of the proposal on the overall health care of the elderly.

As indicated in my comment on the first question, prescription drug therapy is complementar to and interconnected with total health care. A major goal of pharmaceutical industry research and development has been to discover new ways -- either through new drugs or new dosage forms -- which will save in the costs of other sectors: length of hospitalization, demands on the time of physicians and nurses, etc. Thus, the preparation of an injectable drug in disposable syringes relieves the burden on professional personnel, and by improving their productivity tends to reduce total health care costs. The introduction of an oral form of a drug formerly requiring an injection is also a contribution to lower total costs. Tranquilizers and the antituberculars, just to mention two classes of drugs, have saved enormous amounts in the costs of hospitalization.

Because of this continuing process, one might reasonably have expected that the share of prescription drugs in total health care costs would be increasing. Instead, it has been declining, and this is because other cost factors have more than offset this substitution aspect.

If an out-of-hospital drug program is to be introduced, I believe it is essential that its costs and benefits not be considered in isolation but in the larger context of total health care. We may reasonably expect that the authorization of payment for this one remaining uncovered segment, and the only segment whose prices have been relatively stable, should serve to restrain increases in other health care costs. We may well find, as was found by the Walsh Committee of the New Zealand House of Representatives in 1968, that:

> "...there is a great deal of evidence that the more potent drugs which have become available in more recent years and which are still becoming available although generally more expensive than those they replace, reduce the total health bill by cutting down the time spent in hospital and doctors' time."

Turning now to the specific effects of the proposal on the drug industry, its overall impact will depend a great deal on how it is implemented. In the first place, it is reasonable to expect

that it would lead to some increase in national drug consumption. I do not believe, however, that the increase will be quite as substantial as the Task Force indicates, because a considerable portion of the elderly are already covered by other forms of third party payment.

Secondly, the proposed program is likely to have some influence on the distribution of sales between those drug firms which engage in research and development, which maintain systems of nationwide distribution, returned goods policies and a round-the-clock medical information service for doctors, and those firms which produce copies of compounds discovered and developed by others and which compete primarily on a price basis and often in restricted local markets. I prefer this way of describing the difference between the two types of manufacturers rather than employing the misleading designation of "brand name" or "generic" because companies in both groups sell products under both brand and generic names.

Just what the effect of the program will be on the two categories of firms within the industry will depend on the emphasis to be placed on the words "of acceptable quality" in the key recommendation of the Task Force on page 66 of the Final Report:

> "Accordingly, we find that reimbursement for product cost should be based on the cost of the least expensive chemical equivalent of acceptable quality generally available on the market."

On page 34, the Task Force recommends that when a product's patent expires, other manufacturers wishing to produce the same drug for inclusion in a list of drugs acceptable for use in any Federally-supported drug program should be required to match the reference product, not merely in regard to compendial (chemical) standards but:

> "when required by the Secretary, presentation of appropriate test data to demonstrate essentially equivalent biological availability, or to present acceptable evidence of safety and efficacy through the New Drug Application procedure."

If the Department of HEW decides that this additional evidence is required in only rare cases, then the application of the proposal for a national formulary based on the least expensive chemical equivalent will result in providing a significant stimulus to the non-researching firms

at the expense of the researching innovators. To the extent that such firms offer or are able to develop nationwide distribution, to qualify as being "generally available", their prices will rise and the differential between the price of the copy and that of the reference product will narrow -- particularly at the retail level after payment of a standard professional fee.

If, on the other hand, the Secretary were to use this discretionary authority in order to require the imitator to produce the same evidence of clinical effectiveness as that submitted for the reference product, then the price of the second product would rise substantially. Some such manufacturers might even disappear from the industry.

In short, the effect on the industry will depend entirely on how the program is designed and administered.

II. Economic Features of Drug Manufacturing and Distribution

(a) Appraisal of Task Force Findings and Recommendations regarding:

1. Research and Development of Manufacturers. While this section of the Report, commencing on page 7, begins with a tribute to the intensity and productivity of the industry's research effort, the average reader is more likely to notice the conclusion, which in bold print finds that "much of the industry's research and development activities would appear to provide only minor contributions to medical progress." This conclusion appears to be based on the relatively high proportion of new products which the Task Force describes as "duplicates" or "combinations."

This harsh judgment stems, we believe, from a failure to recognize:

--that research is by its nature a hazardous pursuit.

--that the development of a new dosage form, of a duplicate or a combination requires nothing like the research effort involved in the development of a new chemical entity, so that the ratio of such new entities to the total number of new products introduced each year is no indication of the share of research

and development expenditure required for each of the categories. Indeed, a great proportion of the duplicates and combinations are introduced by manufacturers which do not have any research expenditures.

--that the so-called "duplicate" may quite conceivably offer a real therapeutic advantage over the older product. Thus, a micronized version of the same compound may permit more rapid assimilation, lower dosage and diminished side effects for some patients. And even if the duplicate provides no therapeutic advantage, it may at least provide the consumer the advantage of increased competition and the likelihood of price reductions.

--that the combination product is apt to have been introduced in response to an expressed need on the part of prescribers. Even if it proves to be more expensive than either of its constituents, it is almost certain to be cheaper, at retail, than the constituent products sold separately. The active ingredients are combined in the proportions found most suitable for the largest group of patients; for those whose conditions require a different proportion, the doctor still has the option of prescribing separate drugs.

2. Product Differentiation. This is a characteristic of American industry generally, although it seems to be criticized chiefly when encountered in the drug industry. It is ironic that Soviet economic reformers are seeking to upgrade the quality of their own pharmaceutical industry by introducing the characteristic of product differentiation.

Whether the product is sold under a brand name, or under a generic name with the manufacturer's name added, the quality-conscious manufacturer seeks to identify his name to the doctor as a symbol of quality. This is a two-edged sword, for if the doctor is disappointed, he may extend his disapproval to other products of the same manufacturer.

The anonymous product is difficult to trace in the case of an error in manufacturing. In addition, when identification is missing, there is not the same incentive for the manufacturer to maintain high quality control standards.

(b) Findings on the Structure of Drug Prices. I find the Task Force treatment of this subject highly misleading. Disconcerted by the evidence from the price indices (wholesale and consumers') of the Bureau of Labor Statistics that prescription drug prices have been declining, they have apparently sought to discredit the BLS approach by:

--suggesting that if the sample were larger and more representative, prices would be shown to be rising. Yet the BLS Wholesale Price Index sample of over 50 products, and the privately-funded Firestone price index sample of almost 400 products both show the same declining tendency.

--seeking to equate with (or substitute for) the price index a measure of average unit expenditure, which includes factors other than price. If the average prescription charge is to be used instead of the price index, then there is no reason why the same change in statistical method should not be applied to other sectors. The result would be that the component for television receivers, for instance, would no longer be shown as having declined, as we are told by the Consumers Price Index, but to have risen, because the average unit expenditure has risen as more consumers choose color TV sets. What would be the effect on the all-items CPI if every instance where the consumer "trades up" were interpreted as a price increase?

--by failing to note the fact that even if this double standard were applied, the increase in the average prescription charge -- 1.9% in 1967 and again in 1968 -- has been significantly lower than the rise in the overall cost of living.

III. Pharmacological Issues

(a) Chemical, Biological and Clinical Equivalency

The subjects discussed in this area deserve the most careful study, because they are crucial to the interests of the program beneficiaries, and to the prescribers, dispensers and manufacturers as well. The central assumption on which the Task Force program rests may be stated along these lines: equivalency questions are minor and will soon be resolved; control over drug quality is virtually within the grasp of the FDA, and will be in hand within 20 months; therefore, it will be proper in 1971 to pay only for the least expensive chemical equivalent available on the market.

We can follow the course of the above progression, but we see no reason to ask the American people to believe it will come to pass. Indeed, the Task Force itself has recognized in its papers that the status of drug quality in the U.S. is not what it ought to be (and it has ignored the quality problem posed by the millions of doses of drugs imported each year without being inspected

In its recommendations, the Task Force has asked that the clinical trials now underway, involving some of the drugs in doubt, be continued on a priority basis. And, that FDA be given added financial support in order to improve its capability to enforce drug standards. Further, that FDA move to provide support to state and other agencies concerned with drug quality on an intra-state level.

In principle, we agree with these recommendations. The PMA has for more than a decade supported, in Congressional testimony and letters to the Congress, FDA budget requests.

But while the Task Force has recognized the existence of an equivalency problem, it has labeled the matter as "grossly exaggerated as a major hazard to the public health." It seems to us that such flamboyant language is not particularly helpful. The words seem to be chosen more to attack those who raise the question than to provide a significant answer.

In fact, it attempts to change the whole agenda of the dialogue so as to make the issue irrelevant. The question is hardly whether the critics of the generic equivalency doctrine have exaggerated, but whether this doctrine is a valid basis for public policy.

In our view, it is more useful to weigh the question in terms of the kind of medical care program that best suits the patient and his physician. It is particularly important to avoid a substitution of the Government's assumptions for the reasoned judgment of the patient's doctor and pharmacist.

Government experts may be qualified to judge which product is most effective for most patients suffering from a given condition. But that drug may be ineffective or highly toxic for a particular patient, and his own doctor is in the best position to make the choice. It would obviously be unwise if the doctor's desire to use a particular product, one of established, predictable quality, is frustrated by the government's determination to supply only the lowest cost chemical equivalent. It may well be argued that the doctor will be permitted to prescribe products in which he has confidence, but it is obvious that the result, very often, will be an economic burden on the elderly patient, one that the patient assumes the Government has shouldered.

It should not be difficult to see also that the contemplated approach implies a lack of confidence by the Task Force in the capacity of the nation's pharmacists to make responsible judgments about the products they dispense in filling generic prescriptions. The pharmacist, too, will have to choose between stocking the product the Government says is priced right, or risking his patron's annoyance by stocking products he has confidence in.

Our view is that the judgments of the prescriber and dispenser should not be ignored by the new program, nor should they or the beneficiaries be penalized economically for exercising sound judgments. On the contrary, their competence should be respected.

Perhaps it is worthwhile, in this context, to take note of the fact that the hospital-oriented Medicare program takes advantage of the staff of the hospital and its ability to make intelligent decisions about the sources of products dispensed there. We believe that certain members of this very committee can testify to the value of the practice, even though the cheapest prices are not always obtained under it. Many hospitals insist on just one company's thyroid preparation, for

example, even though that product costs several times as much as the cheapest. Similar illustrations can be repeated in hundreds of instances, in thousands of hospitals, Federal, state and municipal, involving scores of drugs.

It will be indefensible, in our opinion, to continue letting doctors and pharmacists in hospitals use their experience to decide not only which drug the patient needs but which firm can be relied upon to supply it -- but to hamper or deny that privilege to the same doctor and the same pharmacist serving the same patient, outside the hospital. If the current Medicare drug procedures are rational (and we think, in general, they are) then it seems to us that the Secretary should insist that any extension be compatible with them.

One further note should be made with respect to program compatibility: The committee should bear in mind that the Task Force recommendation is at variance with every established Federal program. In the outpatient drug programs of the Veterans Administration, the patient is not penalized by the doctor's insistance on drug quality; nor is the beneficiary of the drug programs of the Public Health Service; or of the Office of Economic Opportunity; or of CHAMPUS, the military program.

In every other Federal program, while various kinds of controls are applied, no attempt is made to encourage or compel the physician to change his prescribing decision in the interest of conforming to what the program administrators desire. Rather, the benefit derived by the patient is determined by the actual cost of the prescription, not the cost of a supposed "equivalent."

Without compelling evidence showing that the nation's doctors and pharmacists cannot be relied upon to choose quality products, and a showing that the government is actually ready to fully shoulder that responsibility (and liability) the professions should be left unhampered in going about their work.

At the beginning of our notes on this question, we acknowledged our lack of faith in the Government's 1971 date for assuring the quality of the nation's drug supply. We should comment further on this point, because of its importance. The Task Force, while claiming that lack of

equivalency is "grossly exaggerated," notes that there is some doubt about at least 27 separate drugs. In its background paper covering the subject, the Task Force goes on to give a status report on tests run on five products. It reports that non-equivalency problems were serious enough in the case of two of the five to justify removing the questionable ones from the market.

A too-rapid look at the list of 27 drugs which the Task Force reports may be subject to lack of equivalency, may lead one to assume that the problem is small -- only 27 drugs out of the hundreds in common use for treating the elderly. But, the Task Force's own study shows that those 27 drugs accounted for 24.4 million prescriptions for the elderly in 1966.

To complicate this matter, it has just been announced that the FDA is discontinuing the Georgetown equivalency studies for budgetary reasons at the end of this current fiscal year. Clearly, at this rate the Department will not be in a position by 1971 or any other year, to assure the public that all products on the market, or all variants of the products on the Master Drug List, are therapeutically equivalent.

Part of the rationale that might support a government claim assuring the quality of the nation's drug supply would be a marked decline in the number of drug recalls on quality grounds. With increasing FDA surveillance, a declining recall rate would suggest a rise in drug quality. Yet the recall rate is stable, and it is high. At least one firm had more than fifty recalls in 1968, twice the number it had the year before.

Another rationale might be an increase in the number of drug plants inspected by the FDA. That number fell by about 340 between 1964 and 1966, the last year for which FDA reported the number of firms inspected. Without question, FDA is performing as best it can with the available resources and personnel -- and it is conducting more thorough and more complex inspections, which require additional time. Nevertheless, the number of drug companies inspected each year is not growing. It is declining. Similarly, FDA's intensified drug plant inspection program, originally predicted to cover 900 of the nation's 1,200 drug firms (FDA figures) by 1971, is

behind schedule and is now targeted to cover but 700 firms. Even though the task, in our view, is impossible of achievement, we believe it is desirable for the FDA to continue making the effort. Important as it is, FDA has never claimed and cannot be expected to guarantee every batch of every drug made by every firm selling drugs in America. The nation's doctors and pharmacists, among others, must continue to use their own intelligence and experience. Hospital staffs reserve to themselves the right to choose their drug sources, the efforts of FDA notwithstanding, and they must continue to enjoy that privilege.

(b) Licensing and Registration

This question asks our views on the licensing and registration recommendation of the Task Force. The recommendation is that interested organizations should be asked to confer with the Government about the "development of a registration and licensing system under which no drug product would be permitted in interstate commerce unless produced under quality control standards set by the Secretary (of HEW)."

We do not understand how the envisioned system would differ greatly from the present one. It is illegal under current law and regulation for any prescription drug product offered in interstate commerce to fail to meet the quality control (i.e. Good Manufacturing Practices) regulations established by the FDA. Similarly, it is a requirement of existing law that firms engaged in drug manufacture register with the FDA.

Still, the PMA would be most pleased to cooperate in explorations of further steps designed to improve drug quality. One suggestion which seems to us to merit serious study is the proposal that no firm be permitted to begin drug production until an FDA inspection has been made and the agency is satisfied as to the manufacturer's capabilities and that the firm's products are suitable for patient use. Stronger product approval standards, more inspection powers, and self-certification programs for drug manufacturers are among other approaches which merit sutdy. PMA endorses such efforts.

IV. Flow of Information to Physicians

Although I believe that utilization review, as recommended by the Task Force, may beneficially increase the interchange of expert opinion and hence assist the doctor in his difficult task of diagnosis and prescribing, I should think that doctors might be justifiably irritated by the somewhat patronizing tone in much of the Task Force Report on the subject of the information resources now available to the medical profession. There is the implicit assumption that medical journals must be editorially corrupted by drug advertisers and that the most widely used compendium, the Physicians Desk Reference, must be considered a tainted source because the manufacturers pay for the insertions of the monographs on their products. The Task Force fails to point out that these monographs must correspond with the FDA-approved package insert and thus provide detailed information on contraindications and warnings.

We continue to believe that whether a new Government-sponsored compendium should be added -- in addition to the PDR and to the new publication now being prepared by the AMA -- is a matter which should be determined by the expressed desires of doctors. To the extent that their views can be judged by a recent survey conducted by the Opinion Research Corporation, and by the testimony on this subject before the Nelson Committee from representatives of the AMA and several associations of medical specialists, it seems that the answer is clear: physicians do not see the need for nor do they want such a government compendium.

The Task Force would also like to see a publication similar to the Prescribers Journal in Great Britain or similar to the Medical Letter but of official origin, which would provide comparative evaluations of different drug products indicated for each disease condition. The authors do not seem to recognize that there is already an abundance of such evaluation source material, not merely in standard texts but in current journal articles.

However, physicians and their associations are best qualified to comment on this proposal.

SUPPLEMENTARY COMMENTS

In addition to the subjects on which comments have been requested, there are three additional items in the Task Force Report on which, I believe, comment is needed.

(1) Elimination of Combination Drugs. I have already commented on the estimate of the Task Force that 5 percent of program costs might be saved by limiting reimbursement to "the least expensive chemical equivalent of acceptable quality generally available on the market". But we should also consider the basis for the Task Force statement that a further 10 percent might be saved by "the exclusion of certain combination products, duplicative drugs, and noncritical products from Federal reimbursement..." (page 43).

If this means that the list should exclude important categories of disease and the drugs required for them -- as for instance arthritis, which is the most widespread disease of all among the elderly -- then it is quite possible that the costs, as well as the benefits, could be reduced by 10 percent or more. But if it means that the saving would come largely from the exclusion of "duplicates" (which now provide a greater range of choice and greater competition) and of combinations, then I cannot agree that it would save anything like 10 percent. In fact, I question whether there would be any savings at all.

Certainly this is a subject which deserves further study. They should be asked to explain just what they mean by this statement and the basis for their estimate.

(2) Responsibility of HEW for Price Surveillance. I have not commented on the various proposals in the last chapter (No. 17) on the Organization of HEW Pharmaceutical Activities, since most of these proposals deal with internal questions of administrative structure. Although I am sure that there are many views within the industry on these issues I do not believe that there is any concerted industry position except that we wish to have FDA receive the resources in funds and manpower needed to carry out its mandate and we would certainly concur in the recommendations, at the end of this chapter, that there should be a reappraisal of present methods of drug evaluation, particularly with a

I would like to comment, however, on the recommendation on page 76 that HEW assume and continue responsibility for the "surveillance of drug costs, average prescription prices, and drug use."

All of these matters are appropriate fields for government research and surveillance. My only reservation has to do with the possibility that HEW might seek to duplicate, or displace, the work already being done by the Bureau of Labor Statistics in this important component of the Consumers Price Index. In addition there are already several good measures of the average prescription charge collected by private research groups.

What we do object to strongly is any attempt to confuse a measure of average expenditure with a pure measure of prices, particularly if it involves subjecting prescription drugs to an entirely different measure than that applied to other components of living costs or wholesale prices. We are not reassured by the data in the Drug Users that HEW statisticians, at least those engaged in the Task Force exercise, appreciate the important distinction between price and expenditure.

(3) Marketing Expenditure. The Task Force Report contains a great deal of misleading comment on the role, the composition, and the extent of the industry's expenditures on marketing. Without going into detail on this subject at this time, I would merely point out that any "industry agreement", which the Task Force proposes in order to reduce expenditures for advertising, detailing and sampling might raise questions under the anti-trust laws.

WARREN E. WEAVER, Ph.D

TASK FORCE COMMENTARY

Major Issues as Outlined in Doctor Dunlop's April 7 Memorandum

I Insurance Plan

1. The Task Force Report has made a case showing that many elderly persons have costly drug bills, and that the drug bill for the elderly may be generally higher than the usual citizen. While it can be subjectively argued that this is and has been detrimental to this group of citizens, there does not seem to be any evidence offered that objectively leads to the conclusion that "needless sickness and disability" have indeed resulted. If this is indeed the case, it is a serious indictment of our present system of providing health care for our citizens. It should be borne in mind that this indictment relates to out-of-hospital prescription drugs. It could be very helpful if the Task Force, or a similar group, could develop data indicating any relationship between availability of drugs and drug use with iatrogenic disease related to drugs.

Nevertheless, we obviously do need a system that provides drugs to those persons who need them to prolong life and prevent needless sickness and disability, but who are otherwise prevented from obtaining them due to cost. A system that would protect the citizen against unusual or major costs, or "unusually high" costs would seem to be in order. Since the Medicare program does provide a mechanism for taking care of one group of our citizens, consideration of providing for these unusual drug costs might well be included in the Medicare program.

2. My own inclination would be to favor Part B of the Medicare program as being preferable to Part A. A system with a major deductible would seem to be preferable, but hopefully either a sliding scale could be incorporated or some

provision could be made to permit governmental agencies to pay premiums for certain categories of beneficiary. If prescriptions were included, each prescription should be subject to some co-insurance factor, or deductible, as far as the beneficiary is concerned.

It is not clear in my mind that a good case has been made for the establishment of a formulary to improve the quality of medical care, or of the drug products prescribed. Existing formularies and pharmacopeias would seem to be an ample base to protect drug quality. It is quite possible that some of our principal formularies, such as the NF and USP, could be improved and supplements issued that would serve as unbiased sources of information for drug prescribers and distributors.

Any system of reimbursing vendors on some kind of uniform fee is certain to work hardships on some vendors and redound to the economic benefit of others. The fairest to vendors would appear to be usual and customary charges, but the Task Force has summarized in great detail the various aspects related to controls necessary to determine that public funds are being wisely expended. In my own view, a flat professional fee on each prescription transaction represents the fairest charge to the consumer, but even this fee can vary from vendor to vendor depending on the quality of service provided by that vendor. This might suggest minimum standards of service as a criterion for reimbursement. In fairness to vendors, some kind of peer review with consumer representation would be fairest to vendor and consumer alike.

3. If an out-of-hospital prescription program adopts unrealistic fees and controls, consumers who are not Medicare beneficiaries could be penalized by being forced to bear additional costs for their own drugs. Any unrealistic system could be potentially disastrous to manufacturers and practicing pharmacists, especially if the emphasis on cost of the product leads to unrealistic mechanisms for drug pricing. There is always a danger that a fixed charge for service will lead to a standard of mediocrity when, in fact, health care is a service that needs a standard of excellence. The major problem confronting American medicine and pharmacy, as far as health care is concerned, is elevating quality. There is no evidence that driving costs down improves quality, and in fact always bears with it a greater risk of destroying quality.

II. Economic Features of Drug Manufacturing and Drug Distribution

1. The findings of the Task Force with respect to the manufacturers appear to me to be partly correct, and the situation is not one that is all positive or negative in the various issues discussed. Some combinations are perfectly rational, and in fact are preferred to individual chemical entities so that a physiological effect can be assured. Unfortunately, the great bulk of combinations and other duplicative drugs do not contribute to drug therapy to any great extent. It is true, however, that one cannot always predict in advance because of our present state of knowledge whether a drug positively is "duplicative". In some instances it's perfectly clear, but in other instances it is not. We also would find it unfortunate if elements of serendipity were no longer operative in drug therapy. It would seem well, though, to remember that introduction of multiple

In fact, the Task Force should be complimented on bringing out many facets of this particular issue and analyzing them so well.

2. The recommendations of the Task Force relative to licensing and registration appear to be in order.

IV Information and Identification

1. The observations of the Task Force regarding the current flow of information to physicians, in my view, is essentially correct. I also concur with the observations made in regard to clinical pharmacology in medical schools. It is my belief that the average practicing physician generally needs much more information on drugs than he now has conveniently available to him.

It is questionable, in my view, whether a new compendium as proposed would solve the information problem for the physician. Programs of continuing education, seminars and conferences that emphasize drug efficacy and side effects as part of physician re-education programs, should be promoted. In my own view, since we have officially recognized compendia of drug standards (the USP and the NF) it would be far more profitable to the profession of medicine and to pharmacy and to the public if needed information were provided as supplements to these well known references. Price and quality are not necessarily equatable and it would be regrettable to see a new compendium introduced for the sole purpose of trying to equate price and quality. A question should be asked, "Is this an attempt to hammer down drug prices or to improve drug quality and drug therapy?". If drug prices are "high" some other mechanism

might be used rather than the use of a compendium having the force of a required formulary. The Task Force has noted that quality standards are expected to be adequate by 1971, and hopefully these standards would be incorporated as part of the USP and NF standards.

2. In my view, the best short-term and long-term solution to the problem of correct and adequate drug information for the prescriber is through the utilization of pharmacists as drug information specialists. Many pharmacists are currently serving in this role, both in institutions and in the community. The pharmacist is the only health team member having such a wide range of information on drugs. As a mechanism for providing impartial drug information to the physician, an especially good case can be made for the pharmacist having this role. In this role, the pharmacist would not serve as a prescriber but could select, impartially, the product of highest quality on the physicians order. With the range of drug information required today, it is probably hopeless to expect any one physician to have the complete range of knowledge that the well educated pharmacist presently has and utilizes. Consequently, the Task Force recommendations with respect to medical and pharmacy curricula should be given serious consideration. The recommendations with respect to a broad study of present and future requirements in pharmacy and the adequacy of current pharmacy education, and educational changes, should be pursued. The recommendations of the Task Force with respect to pharmacist aides should await better definitions of the role of the pharmacist on the health care team and the study of pharmacy education. In addition, our present structure in law is in need of much revision to accommodate the expanding and changing role of the pharmacist and the delivery of pharmaceutical services. The

broad study of education which was recommended by the Task Force could lead to:

a. A revision of laws.

b. A redefinition of the role of the pharmacist and pharmacy aides.

c. Development of appropriate educational programs to better prepare pharmacists to evaluate and select drugs for the prescriber and fill the role as a drug information specialist, as pointed out by the Task Force.

Warren E. Weaver