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STATEMENT OF
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BEFORE THE
MONOPOLY SUBCOMMITTEE
SELECT COMMITTEE ON SMALL BUSINESS
UNITED STATES SENATE

on

DIRECT AND INDIRECT EXPENDITURES
BY FEDERAL AGENCIES FOR PRESCRIPTION DRUGS

We are pleased to be here today to discuss our work related to procurement of and reimbursement for prescription drugs by the Federal Government and related matters.

Among the matters we will comment on are:

--The conclusions and recommendations contained in our recently issued report to the Congress entitled "How to Improve the Procurement and Supply of Drugs in the Federal Government" (B-164031(2), dated December 6, 1973).

--Status of Federal efforts to promote the use of formularies and encourage the use, where appropriate, of lower priced drugs, including generics.

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--Status of actions taken by Federal agencies to assure that only effective drugs are procured with Federal funds.

It is estimated that direct Federal expenditures and reimbursements for prescription drugs amounted to about $1.6 billion in fiscal year 1973--an increase of more than $44 million over the expenditures in fiscal year 1972. This amount includes about $252 million in direct drug purchases by Federal agencies and reimbursements of over $1.3 billion under federally-sponsored health programs, such as Medicare and Medicaid.

Direct Procurements

The estimated $252 million in direct drug procurements represents a slight decrease from those in fiscal year 1972. Most of the direct procurements were made by the Defense Supply Agency (DSA) and the Veterans Administration (VA).

DSA's expenditures for its depot stocks amounted to about $91.4 million while VA spent about $38.1 million for its depot stocks. VA also administers Federal Supply Schedule contracts for drugs under which Federal agencies spent over $84 million. Purchases made by such agencies as the Public Health Service and the Agency for International Development and local purchases made by individual Federal

installations account for the remaining fiscal year 1973 expenditures for direct drug procurements.

Federal Expenditures for Drugs under Federally-Supported Health Programs

Available statistical data and agency estimates indicate that about 84 percent of the total Federal expenditures for prescription drugs during fiscal year 1973 were indirect in that they consisted principally of the Federal share of drug costs provided to beneficiaries of health programs supported by the Government. The Medicare and Medicaid programs administered by the Department of Health, Education, and Welfare (HEW) represent the major federally-supported health programs. The Federal Employees Health Benefits Program (FEP) and the Civilian Health and Medical Program for the Uniformed Services (CHAMPUS) are other large programs under which Federal expenditures for drugs are significant.

Federal expenditures for drugs under the Medicare program during fiscal year 1973 were estimated to be about $674 million--an increase of about $57 million over the program expenditures during fiscal year 1972. The Federal share of the cost of drugs provided during fiscal year

1973 to beneficiaries of the Medicaid program amounted to about $605 million--an increase of about $39 million over fiscal year 1972 Federal Medicaid drug costs. Federal expenditures for drugs under the CHAMPUS program were estimated to have exceeded $31 million in fiscal year 1973--an increase of over $5 million above fiscal year 1972 costs. Estimates of Federal expenditures for drugs under the FEP program for fiscal year 1973 were not available; however, expenditures for drugs under the program exceeded $40 million in fiscal year 1972.

Pending legislation pertaining to Federal participation in health care activities suggest that Federal expenditures for drugs may increase in the future--in some cases very substantially. For example, during the first session of the 93d Congress, numerous bills were introduced which dealt, in part, with drug purchases under the Medicare program. Most of these bills included provisions to extend Medicare to cover the costs of certain drugs to be dispensed to eligible recipients on an outpatient basis, and used to treat specified chronic illnesses. The Social Security Administration (SSA) estimates that such an extension of Medicare coverage would cost about $1.1 billion a year.

As you know, several legislative proposals concerning a national health insurance plan are currently under consideration by the Congress. The passage of a national health insurance plan would have a significant impact on Federal outlays for drugs.

WAYS TO IMPROVE THE PROCUREMENT AND SUPPLY OF DRUGS IN THE FEDERAL GOVERNMENT

In our December 1973 report to the Congress, we discussed the effectiveness of Federal agencies' administration of programs and activities relating to the direct procurement and supply of drugs. This matter has been a subject of interest since at least 1963 when Federal agencies began studying the possibility of a single agency having Government-wide responsibility for managing pharmaceuticals, thereby eliminating unnecessary duplication between military and civil agencies. For example, in February 1971, the General Services Administration (GSA) and Department of Defense (DOD) agreed to assign medical material to DSA for integrated management, but the assignment was deferred pending the outcome of a comprehensive study proposed by the Office of Management and Budget (OMB) in June 1971. This study which was made by representatives of OMB, VA, DSA, GSA, and HEW was started in January 1972.

As of December 1973, no final agreement had been reached as to whether a single manager for drugs would be established. Our report supports the need for coordinated action in procuring and supplying drugs. I will briefly summarize our conclusions and recommendations and suggest that the report be included in the hearing record.

In summary, we concluded that:

--Significant savings and other advantages could result from greater cooperation and coordination between agencies in procuring drugs, such as consolidating requirements, making joint procurements, and reducing small-quantity local purchases by authorizing use by any Federal agency of any centralized Government supply source.

--Increased use of specifications for many drug products to encourage greater competition and central management of drugs should reduce costs.

--Better reporting of drugs bought locally and better use of related reports would improve selection of items for central management.

--Responsibility for all quality assurance activities relative to Federal purchases of drugs should be assigned to a single agency--the FDA.

To improve the direct procurement and supply of drugs by Federal agencies, we recommended that:

--The OMB lead in developing--with representatives of GSA, DOD, VA, and HEW--policies and procedures, including consolidating requirements, to increase agency cooperation in buying drugs and achieve substantial savings through large-volume buys. Field installations should be authorized to obtain their drug requirements from any centralized Government supply source.

--The VA should develop specifications for (1) all new drugs which VA decides to manage centrally, and (2) centrally-managed drugs for which it currently has no specifications.

--The Department of Defense should revise DOD policy to insure that drugs will be obtained centrally whenever savings would result.

--The Department of Defense and the VA should consider jointly developing specifications which would satisfy all Federal agencies' requirements.

--The Department of Defense should (1) develop, for reporting local drug purchases, a uniform reporting

system aimed at requiring all military activities with individual drug purchases exceeding specified criteria to report their purchases, and (2) require centrally-managed drugs purchased from other than a central manager to be reported.

--The VA should require that VA's Central Office Supply Service (1) prepare lists of summary and exception data from the information reported, (2) require local field stations to report their purchase data correctly and consistently, and (3) see that all vendors report detailed sales data when required by contracts.

--The Department of Defense and the VA should consider using a standardized coding system, such as the National Drug Code, for identifying local purchases of drugs not having Federal stock numbers.

--The Departments of Defense and HEW and the VA should review the frequency and type of inspections required and the related changes needed to facilitate the transfer to FDA of all quality assurance responsibilities pertaining to purchases of drugs by Federal agencies.

OMB, in commenting on our final report by letter dated January 14, 1974, stated that the study group has completed its report and has made recommendations which are currently under review by the principal agencies involved. OMB stated also that the findings and recommendations of the study closely parallel those set out in GAO's report.

In its letter commenting on our final report, DOD stated that it subscribes in general to the goals and principles set forth in the report. DOD stated also that, although agencies' actions to improve Federal coordination regarding specific aspects of drug procurement and management have been limited to informal coordination between agencies pending evaluation of the OMB report, advice as to positive actions concerning our recommendations would be furnished to us as they are implemented. Also, a clarifying DOD policy concerning adapting medical items for central procurement is expected to be released within 60 days.

In its letter dated January 16, 1974, VA indicated general agreement with the thrust of our report and discussed the status of actions to implement the recommendations. For example, VA:

--has authorized its marketing centers and supply depots to accept orders from DOD field installations;

--will initiate a control system with DOD to assure that drug specifications are either developed jointly or coordinated; and

--is willing to rely on FDA to provide quality assurance for VA drug purchases, provided that FDA makes the necessary data available in a timely manner.

HEW agreed with the rationale for consolidating all quality assurance responsibilities pertaining to purchases of drugs by the Federal agencies and stated that a single organization should inherently be more efficient and uniformly equitable in administering a quality assurance program.

HEW stated that, in view of the comments from other Departments on the draft report, it believes the immediate objective should be the development of a consolidated quality assurance program which satisfies the needs of all interested parties. The Food and Drug Administration is currently developing an initial concept for that consolidated program based on its assessment of quality assurance requirements.

STATUS OF FEDERAL EFFORTS TO PROMOTE THE USE OF FORMULARIES AND ENCOURAGE THE USE OF LOWER PRICED DRUGS

We will now discuss briefly Federal efforts to reduce drug costs by promoting the use of formularies and encouraging, the use of lower priced drugs, including generics.

Department of Defense

Military medical regulations require that Pharmacy and Therapeutic (P&T) Committees be appointed by the commanders of U.S. military hospitals. Among the primary functions of P&T Committees are the development and periodic review and revision of the hospitals' drug formularies. In making decisions concerning the addition or continuation of formulary items, the P&T Committees consider the relative costs of therapeutic alternatives.

In addition to the general use of formularies by the services, the Surgeons General and subordinate administrative levels issue monthly newsletters or special letters to health facilities highlighting comparative prices of drugs maintained in central inventories and encouraging the use of less expensive drugs when they are considered to be therapeutically equivalent to more expensive items. Prescriptions written

by military physicians and filled in military hospitals for brand-name products may be filled with generic equivalent products except when the physicians specifically require that such substitutions not be made.

Under CHAMPUS, a DOD-supported program for providing medical care benefits from civilian sources to retired military personnel and military dependents, DOD has not established regulations requiring the use of formularies. Also, it has not encouraged the use of generic drug products for either the inpatient or outpatient portions of the CHAMPUS program.

Veterans Administration

VA requires that each of its medical facilities have a P&T Committee which develops and maintains a drug formulary. This formulary generally consists of monographs on those products selected by the P&T Committee for use in the facility. Generally, prescriptions will not be filled for drug items not included in the formulary. However, exceptions may be made with special permission. These monographs include the nonproprietary names of the drug, therapeutic classification, dosage, and instructions regarding product usage. VA has also instructed its physicians that generic identification of prescribed medications is preferred to the use of brand names.

Department of Health, Education, and Welfare

The HEW agencies that provide direct patient care, such as the Indian Health and Federal Health Program Services of the Public Health Service, require that all field installations be serviced by P&T Committees responsible for the development and maintenance of current formularies of accepted drugs. The formularies are required to list drug items by their official, generic or nonproprietary names and only formulary drugs are authorized for routine use by HEW installations providing direct patient care. Among the items the P&T Committees are required to consider in developing their formularies are comparative efficacy of formulary drugs with other drugs intended for the same use, evaluation of benefit/risk of formulary drugs and cost effectiveness.

Under Part A of the Medicare program, drugs are paid for by SSA--through fiscal intermediaries--as part of eligible recipients' total hospital bills. Under Part B of the program, Federal coverage for physicians and related services are provided through organizations known as "carriers." Coverage of drugs under Part B is limited to those drugs which are commonly furnished in physicians' offices and which cannot normally be self-administered.

The regulations for Medicare state that in order for a drug to be covered under Part A it must (1) represent a cost to the institution in rendering services to the beneficiary, and (2) either be included or approved for inclusion in specified drug reference volumes or approved by a P&T Committee (or equivalent) for use in the participating hospital. In order to be covered under Part B, costs of eligible drugs--like those of other medical services--must be accepted by the carrier as reasonable and necessary.

Under this system, SSA generally is not provided detailed information concerning the specific drugs that are being prescribed under Medicare. We were informed by an SSA official that there are currently no SSA regulations which encourage the use of generic drug products.

Under the Medicaid program, which is administered by State agencies with Federal guidance and reimbursed, in part, by the Social and Rehabilitation Service (SRS), the use of formularies and generic products is optional. The applicable Federal policy states that "where either is employed, there must be standards for quality, safety, and effectiveness under the supervision of professional personnel." Although SRS discusses the use of a formulary system as a means of reducing overall drug costs, the use of formularies is not

required. Presently 20 States use some type of formulary. SRS, in its Medical Assistance Manual, points out the arguments for and against the use of generic drugs but does not emphasize their use.

Although States generally accumulate data concerning the specific drugs being dispensed under the Medicaid program, the data is not normally provided to SRS.

As you know, Secretary Weinberger recently announced that HEW will be publishing regulations for public comment which, if adopted, would limit drug reimbursements under programs administered by the Department to the lowest cost at which the drug is generally available unless there is a demonstrated difference in therapeutic effect. The Secretary stated that this reimbursement policy will result in significant savings in the cost of providing prescription drugs under Medicare and Medicaid. The Secretary's announcement prompted the Chairman of the Senate Subcommittee on Health, Committee on Labor and Public Welfare, to hold another hearing on February 1, 1974, to provide representatives of the Administration and the drug industry the opportunity to clarify their positions concerning this significant new HEW policy. To date, the proposed regulations referred to by the Secretary have not been published.

STATUS OF ACTIONS TAKEN BY FEDERAL AGENCIES TO ASSURE THAT ONLY EFFECTIVE DRUGS ARE PROCURED WITH FEDERAL FUNDS

During our last appearance before this Subcommittee in May 1972, we commented on actions taken by DOD, HEW, and VA with respect to FDA's pronouncements regarding drug efficacy. As you are aware, FDA has categorized drugs as "effective," "probably effective," "possibly effective," and "ineffective" for one or more therapeutic indications claimed on the drug's labeling.

Legal action was brought against FDA in an effort to expedite FDA's completion of its determinations of drug efficacy under its Drug Efficacy Study Implementation (DESI). In October 1972, the Federal District Court for the District of Columbia:

--ordered FDA to meet specific target dates for various phases of DESI and to submit 6-month status reports to the Court concerning its progress.

--required FDA to make final determinations on drug efficacy or to rule on drug sponsors' request for hearings by October 1976.

As of January 1974, FDA's initial ratings on all but one of the more than 4,000 drug products included in the study have

been published in the Federal Register. However, in accordance with the procedures of DESI, FDA may--and has--revised its ratings for specific drugs as new information is submitted by the drugs' sponsors.

We inquired into the status of Federal agency actions to insure that only effective drugs are purchased with Federal funds and noted that, in general, definitive actions taken have been limited to direct Federal health care programs.

Actions Taken by the Department of Defense

We testified in May 1972, that as of November 18, 1971, the Defense Medical Materiel Board had initiated action to stop further procurement and to eliminate from the supply system all items that FDA had then pronounced "ineffective" or "possibly effective." Also, the Surgeons General of the military departments had emphasized through instuctions to medical organizations the DOD policy on such drugs, which became effective January 21, 1971. This policy provided that remaining stocks of "ineffective" drugs withdrawn from the market were to be destroyed or other appropriate action was to be taken to remove them from the inventory. For items categorized "ineffective," but awaiting final determination FDA, further use of remaining stocks was

suspended until the final status was announced by FDA. P&T Committees were required to question all prescriptions for "possibly effective" items, but local procurement of such items could be made if no alternative means of therapy was available.

On June 11, 1973, the Office of the Assistant Secretary of Defense (Health and Environment) announced a revised policy which is a bit less stringent with respect to the use of "ineffective" and "possibly effective" drugs. According to DOD, the original policy was revised because the completion schedule for the DESI had been substantially extended from that originally anticipated and because some of FDA's more recent drug classifications would be revised following only minor changes in labeling or formulation of certain widely-used items.

The revised policy provides that procurement of items classified by FDA as "ineffective" and ordered withdrawn from the market continues to be prohibited. However, for items which FDA has classified as "ineffective" but has permitted to remain on the market pending final resolution of the items' classification, the policy permits the Defense Medical Materiel Board, in conjunction with the Surgeons General, to determine whether centrally-procured stocks are

to be discontinued. Additionally, the policy authorizes the services to make similar decisions concerning locally-procured drugs in this category or to delegate their authority to local P&T Committees.

The policy also authorizes the procurement of "possibly effective" drugs when no alternative means of therapy is available and final FDA determinations on their efficacy are expected to require a long period of time. However, both central and local procurements of these items are to be minimized to take into account the possibility that they may be finally determined by FDA to be ineffective and ordered removed from the market.

Shortly after June 1973, the military departments included the revised policy in their instructions for field installations together with up-to-date consolidated listings of FDA drug safety and effectiveness data for use by military medical personnel.

Under CHAMPUS, DOD has placed no restrictions on the drugs that may be prescribed and is not supplied detailed data concerning the specific drugs that are being paid for. Therefore, DOD could be paying for drugs under CHAMPUS which could not be procured for its direct care activities.

Actions Taken by the
Veterans Administration

Since December 1970, VA's policy has continued to be that all "ineffective" drugs must be removed from VA hospitals except where special approval of the Central Office Executive Committee on Therapeutic Agents has been obtained. Also, VA's policy concerning "possibly effective" drugs continues to require that consideration be given to using an alternative product having a higher FDA effectiveness classification.

To strengthen the policy's implementation, the VA is furnishing a list of drugs ordered to be withdrawn from the market to the P&T Committees at each VA facility which buys or dispenses drugs. Further, a current statement of VA policy on the use of drugs is now being developed by the Central Office Executive Committee on Therapeutic Agents for distribution to all VA facilities.

Actions Taken by the Department
of Health Education and Welfare

As we testified in May 1972, HEW's policy was that Federal funds shall not be spent for "ineffective" drugs except under approved clinical research projects, or for "possibly effective" drugs, except under similar projects or when alternative means of drug therapy are not available. In October 1971, HEW agencies involved in direct patient care were instructed to stop procurement and use of such drugs and to

advise their contract physicians of the Department's policy. These instructions remain in effect.

Although the policy was intended for use in all of the Department's programs, it has not yet been implemented for the Medicare and Medicaid programs. The Department, SSA, and SRS have each drafted proposed regulations to address this matter. We understand that the drafts of the proposed regulations are under review in the Department and that notices of proposed rule making will be published for comments by interested parties in the near future.

You may recall that we issued a letter to the Administrator, SRS, in May 1972 bringing the matter to his attention and asking him to advise us concerning SRS plans for implementing the Department's policy. In June 1972, the Administrator told us that a draft of a regulation implementing the Surgeon General's 1970 policy had been cleared in SRS and was being prepared for transmittal to the Office of the Secretary for publication as a proposed rule. The regulation was not published.

As part of our continuing review efforts concerning Medicaid activities, we have recently initiated a survey of the administration of the Medicaid drug program. We have

already noted that States were continuing to pay for "ineffective" and "possibly effective" drugs.

For example, in one month--September 1973--three States paid an estimated $692,000 for such drugs. Also, we contacted officials of two additional States--which were included in our 1972 review--and were informed that these States had not changed their policy concerning payment for "ineffective" and "possibly effective" drugs and would not do so until SRS issues its final regulations concerning this matter.

We have again brought this matter to the attention of HEW in a letter to the Secretary, dated February 15, 1974.

Mr. Chairman, this concludes my statement. We shall be happy to answer any questions that you or other members of the Subcommittee may have.