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UNITED STATES GENERAL ACCOUNTING OFFICE
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STATEMENT OF
ELMER B. STAATS, COMPTROLLER GENERAL OF THE UNITED STATES
BEFORE THE
MONOPOLY SUBCOMMITTEE
SELECT COMMITTEE ON SMALL BUSINESS
UNITED STATES SENATE

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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 and reimbursement for prescription drugs by the Federal Government and related matters.

Among the matters we will comment on are:

--Actions taken to assure that only effective and low cost equivalent drugs, when available, are procured by the Government or paid for under Government sponsored medical programs.

Drugs
Government procurement
Food and drug law

--Information sources used by physicians in selecting drugs.

Quality assurance

--Use of Government specifications in the procurement of drugs.

Inspection
relations
Interagency

--Quality assurance and inspection procedures of Federal agencies.

Medicaid programs
Medicare programs
Military procurement

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--Coordination and cooperation between Federal agencies which buy drugs.

--Procurement of drugs of foreign origin.

--Policies and practices pertaining to furnishing drugs under the Medicare and Medicaid programs.

Estimates indicate that direct Federal procurements of prescription drugs amounted to about $240 million for fiscal year 1971. Most of these procurements were made by the Defense Supply Agency, through the Defense Personnel Support Center (DPSC), and the Veterans Administration (VA).

DPSC manages about 1,100 drug items on a centralized basis and spent about $95.5 million for drugs in fiscal year 1971. The VA manages about 450 drug items on a centralized basis and procured for central stock drugs valued at $27.4 million in fiscal year 1971. The VA also administers Federal Supply Schedule contracts under which Federal agencies can satisfy their drug requirements by direct purchases from drug manufacturers. Purchases under these contracts by all Government agencies for fiscal year 1971 amounted to about $64 million. The Public Health Service centrally manages about 600 drug items and spent an estimated $14.2 million for drugs in fiscal year 1971. About 50 percent of this amount was spent under contractual arrangements made by VA.

A substantial portion of Federal expenditures for prescription drugs are indirect, consisting principally of the Federal share of the cost of drugs provided to beneficiaries under the Medicare and Medicaid programs. The Department of Health, Education, and Welfare (HEW) estimates that Medicaid expenditures for prescribed drugs for fiscal year 1971 amounted

to about $485 million, of which about $246 million represented the Federal share and the remaining $239 million the State and local share. Expenditures for prescription drugs under part A (hospital services) of Medicare for fiscal year 1971 were estimated at $541 million. No information is available on expenditures under part B (physician services) of Medicare.

Although we have not completed our work with respect to examining into the effectiveness of administration and management of Federal programs for procurement and distribution of drugs, it is already clear that standardized procedures and improved cooperation and coordination among the Federal procurement agencies currently involved in (1) procuring and distributing drugs, (2) financing the supply of drugs to beneficiaries under the Government's social programs, and (3) evaluating the effectiveness of drugs, would be beneficial in reducing costs and providing service.

ACTIONS TAKEN BY FEDERAL AGENCIES TO ASSURE THAT ONLY EFFECTIVE DRUGS ARE PROCURED AND THAT FEDERAL PROGRAMS MINIMIZE USE OF HIGH COST DRUGS

As of January 19, 1972, the Food and Drug Administration (FDA) had published 2,339 reports as to the effectiveness of drug preparations for the indications claimed in their labeling, and had reported them in the Federal Register. At that time FDA recognized that several problems pertaining to drug efficacy remained. Briefly they concerned:

--Conflicting reports relating to several drugs;

--Speeding up the progress on follow-up actions for drugs requiring evidence to be rated "effective";

--Completing compliance activities currently in process pertaining to "ineffective" drugs;

--Completing the review, which FDA expects to publish by June 30, of the remaining drug study reports; and

--Pursuing plans for evaluating the effectiveness of over-the-counter drugs.

Actions taken by the Department of Defense

As of November 18, 1971, the Defense Medical Material Review 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 have emphasized through instructions to medical

organizations the DOD policy on such drugs, which became effective January 21, 1971. This policy provides that for "ineffective" items subsequently withdrawn from the market, remaining stocks are to be destroyed or other appropriate action taken to remove them from the inventory. For items categorized "ineffective" but awaiting final determination by FDA, further use of remaining stocks is suspended until the final status is announced. Pharmacy and Therapeutic Agents Committees are required to question all prescriptions for "possibly effective" items, but local procurement of such items may be made if no alternative means of therapy is available.

No "ineffective" drugs have been purchased by DPSC for central stocks since the pertinent pronouncements in the Federal Register, but we are aware of a Federal Supply Schedule purchase of one item, Darvon (32 milligram), for initial treatment of seriously underweight geriatric patients. Also, 24 procurements valued at $1.5 million have been made of "possibly effective" drug items by DPSC for central stock since the FDA pronouncements. Twenty of these buys, valued at over $1.4 million, were made before the DOD policy prohibiting further procurements of "possibly effective" drugs was issued in January 1971.

Following this Subcommittee's hearings in 1970, DOD established a committee to conduct an item by item review of drugs, chemicals, and biologicals in the Federal Supply Catalog to identify high cost, possibly ineffective, or duplicate items, and to initiate action to minimize the use of high cost drugs where lower price equivalents are available.

Items so identified were to be reviewed by the military services to determine whether they should be deleted from the supply system. As of January 1972, seven items had been deleted and 57 items had been reclassified to a status prohibiting further procurements. Included in the 57 items were seven for which lower cost equivalent drugs were available in the supply system. Based on reported unit costs and demand, annual savings in excess of $1.1 million will be realized if the deleted items are not obtained via local purchase. Specific actions to stop local purchase of such items have not been taken because it would tend to dictate the drugs physicians can prescribe.

Actions taken by the Veterans Administration

A VA circular of December 4, 1970, transmitted to hospitals and clinics a listing of "ineffective" drugs and stated that the Executive Committee on Therapeutic Agents had recommended that VA hospital therapeutics committees remove these items from their formularies. If the hospitals and clinics wished to retain any of the drugs they were required to obtain approval from the Executive Committee. This has been done for certain drugs being used for research.

The hospitals were requested to advise fee basis physicians of VA's policy on these drugs and to attempt to get them to prescribe alternatives. Information on FDA pronouncements made after December 4, 1970, has been sent by the VA headquarters to its hospitals and clinics.

The VA policy for "possibly effective" drugs is that consideration should be given to using alternative products having a higher FDA effectiveness classification. The VA purchased seven "ineffective" drugs for central stock after

FDA pronouncements appeared in the Federal Register. Procurement of six of the seven items was discontinued after the VA policy was issued on December 4, 1970. The other item was purchased for over 2 years after the FDA pronouncement because it was inadvertently excluded from the list of "ineffective" drugs issued on December 4, 1970. The VA Marketing Center has now been instructed to suspend issuance of all "ineffective" drugs and to negotiate with manufacturers for return of existing stocks for credit.

The VA continues to purchase "possibly effective" drugs, apparently because of its philosophy that it should not take actions that would unduly restrict the prescribing practices of physicians.

On January 13, 1971, VA hospitals and clinics were advised to ensure that every effort be made to treat VA patients with the most effective therapeutic agents at the most favorable prices. Also, VA hospital therapeutic committees were requested to continually review prescribing practices--with due regard to the effectiveness and fluctuating prices of drugs--as patents expire, or competitive market conditions make price advantages available. Also, the hospital therapeutic committees were advised that the purchase of high cost drugs could not be justified when equally effective, but less expensive, items are available.

Actions taken by the Department of Health, Education, and Welfare

HEW has also acted to implement the FDA procurements related to the effectiveness of drugs. The Surgeon General on December 11, 1970, established the policy that the Department would not spend Federal funds for (1) "ineffective" drugs, except under approved clinical research projects, or (2) for "possibly effective" drugs, except under approved clinical research projects or when alternate

means of therapy are not available. On January 19, 1971, the Department instructed its agencies that provide direct patient care to stop the procurement and use of such drugs and to advise contract physicians of the Department's policy.

The December 1970 policy announcement stated that the policy also applies to Government financed programs and the Federal Register of October 16, 1971, contains the proposed regulation for Medicare. The Department planned to furnish Medicare carriers and intermediaries with listings of "ineffective" and "possibly effective" drugs to be excluded from reimbursement under the Medicare program. However we understand that the Department has recently undertaken a reevaluation of whether to extend the December 1970 policy to Government financed programs.

In January 1971, the Medical Services Administration of the Social Rehabilitation Service, HEW, notified all Associate Regional Commissioners for Medical Services of the departmental policy relating to purchases of "ineffective" and "possibly effective" drugs. The Medical Services Administration stated that program regulations were being amended to implement this policy for Medicaid. As of May 1, 1972, regulations have not been issued to implement the revised Federal drug policy for Medicaid.

Since 1966 HEW has required that Federal funds be expended only for the lowest priced drugs consistent with acceptable standards of identity, strength, quality, purity, and effectiveness. Information we have obtained on the Medicaid program in four states shows usage of "ineffective"

or "possibly effective" drugs. For example under the Medicaid program we found that in Mississippi during a 7-1/2 month period in 1970-71 nearly $90,000 was paid for two prescription drugs classified by FDA as "ineffective" and one as "possibly effective". In Ohio, during 4 months in 1970, about $138,000 was spent for 43 drugs classified as "ineffective" by FDA and in Illinois and New Jersey during 2 months in 1970 about $99,000 was spent on prescriptions for 10 randomly selected drugs classified by FDA as "ineffective". See Appendix I for a summary of such drugs paid for in Mississippi, Illinois, Ohio, and New Jersey.

INFORMATION SOURCES USED BY PHYSICIANS IN SELECTING DRUGS

In the 1971 hearings, the Subcommittee expressed interest in the sources of information considered by physicians in making their selections of prescription drugs.

Two studies, one by Milton S. Davis, Ph.D. and Lawrence S. Linn, Ph.D., under a Social Security Administration grant and the other by a Professor of Pharmacy and Pharmaceutical Chemistry, University of California, shows that detail men were the most important source of information to physicians.

The American Medical Association (AMA) in 1971 published a manual entitled "AMA Drug Evaluations" to provide physicians with a convenient source of information for the sound use of drugs. This manual contains an evaluation by the AMA Council on Drugs regarding the effectiveness of drugs, information on the pharmacology and therapeutic indications of drugs, and preparations available, dosage, and generic and proprietary names.

The manual was distributed free to all members of the AMA--about 300,000, of which 170,000 are practicing physicians. Large numbers have also been purchased by the Government, pharmacists, physicians in residence and intern training, nurses, and medical students. In 1972, the AMA began a survey of 2,000 physicians to determine the extent to which this manual has been used. The AMA hopes to complete the survey in June 1972.

We understand that a second edition of the manual is scheduled for publication shortly and will include changes designed to make it more useful including dosage guidelines, ingredients of over-the-counter drugs, and additional trade name items.

GOVERNMENT SPECIFICATIONS FOR DRUGS

One requirement of an efficient supply system for prescription drugs is the development of specifications which can be used to encourage competition and assure controlled quality production of drugs with the desired therapeutic effect.

Both DPSC and VA develop specifications for items they intend to buy competitively. These items account for about 25 percent of all VA centrally managed drug items and 99 percent of all DPSC centrally managed drug items. The remaining items procured centrally by the agencies are designated for purchase from preselected sole sources. Data for preparation and development of DPSC specifications is obtained primarily from the manufacturers of drug products.

Although DPSC attempts to purchase virtually all of its drug items competitively, it has been able to do so for only about 51 percent of its approximately 1,100 drug items. The

remainder, about 535 items, have been supplied by single sources. Of these, competitive procurement of 386 is limited by patents or by FDA regulatory requirements which preclude marketing without an approved new drug application or antibiotic certification. The remaining 149 items have no apparent legal or regulatory restrictions that would preclude interested firms from submitting bids on DPSC requirements.

In 1969 and 1971 DPSC made a widespread effort to develop competition on a large number of drug items but the responses were few and disappointing.

Basically DPSC's specifications require full compliance with the product standards and requirements set forth in the United States Pharmacopeia (USP) or National Formulary (NF). But additional requirements are often included to provide assurance that items manufactured will have needed characteristics for such requirements as potency and purity, from the time of manufacture to use. Only about 50 percent of the drug items managed centrally by DPSC and 65 percent of those managed centrally by VA are monographed in the USP and NF.

The use of manufacturers' data by DPSC in the development of its specifications could result in including requirements which are not essential to producing a comparable product or which do not contribute to its medical usefulness. However, DPSC includes in its solicitation packages a Specification Analysis Sheet for potential suppliers to submit comments on the specification requirements and those that bidders claim are unnecessary or unduly restrictive are evaluated by DPSC.

We found that it was common for manufacturers to add requirements to those in the compendia (USP and NF) for products they sell to the general public. Comments by manufacturers and compendia officials and statements in professional publications explain that the additional requirements are added for controlling manufacturers' production processes and to ensure product quality and uniformity.

The DoD practice of establishing a specification for every drug item in its central supply system, while commendable for purposes of broadening and equalizing the competitive base and assuring the receipt of acceptable products, results in unnecessary technical and administrative effort when the policy extends to drug items which, because of legal or regulatory restrictions, are obtainable from only one source.

The VA, after its appearance before your Subcommittee in 1970, began developing specifications for 115 sole source items for which competition appeared feasible. We were informed on May 1, 1972, that 36 final specifications had been issued as a result of this effort.

QUALITY ASSURANCE

In our last appearance before the Subcommittee we reviewed the quality control activities of FDA, DPSC, and the VA. We have noted (1) apparent overlap of these activities, (2) the acceptable results obtained by VA from its minimal inspection efforts supplemented with the use of FDA's testing services, and (3) that substantial military procurements are made each year from Federal Supply Schedules and local vendors--about $21 million in fiscal year 1970--based

only upon the quality assurance work of the FDA. We suggested in our statement that consideration should be given to assigning sole responsibility to FDA for inspecting drug contractor plants and testing products and quality control procedures.

So far as we are aware no action has yet been taken to consider the advisability and feasibility of centralizing drug inspection along these lines. The estimates of manpower requirements and administration costs, including inspection activities, involved in the DoD and VA procurement systems for drugs are provided in Appendix II.

COOPERATION AND COORDINATION AMONG AGENCIES MAKING DIRECT PROCUREMENT OF DRUGS

In our previous statement we suggested that closer cooperation between VA and DPSC could result in substantial savings in the procurement of drugs. Our subsequent review work confirms that improvements can be made.

We found little exchange of requirements data or coordination of procurements for drugs which are centrally stocked by both organizations, or those centrally stocked by one system but procured from either Federal Supply Schedule contracts or from local vendors by the other system. The VA negotiates several special contracts which exclude military activities and, in some cases, other civilian agencies from using them. The military uses Federal Supply Schedule contracts for its requirements for items in these special contracts and pays prices higher than those in the contracts. The lack of adequate cooperation and coordination has resulted in increased drug costs to the Government.

The VA has an agreement with DPSC under which it can buy drugs from DPSC for its central stocks. In fiscal year 1970 purchases from DPSC were only about $206,000. One drawback to this agreement is the add-on of surcharges by DPSC and the VA Marketing Center for drugs supplied to VA field stations. DPSC charges the VA Marketing Center its standard price (cost plus 7 percent) plus a 3-1/2 percent surcharge for packing, handling, and crating costs for medical items shipped from DPSC depots; a total add-on of 10-1/2 percent. For items shipped directly from a vendor to the VA depot, DPSC adds a one percent surcharge, for administration, to the cost of the items. The VA Marketing Center adds an 8 percent surcharge on all items bought from DPSC to recover its operating costs.

VA field stations do not order directly from DPSC because the VA requisitioning system requires the stations to submit requisitions, other than for local procurements, via the VA Marketing Center. As a result, certain drug items are purchased by the field stations from either the Federal Supply Schedule contractors or local vendors at substantially higher prices than they could obtain them from DPSC. The flow of drug items from DPSC depots or manufacturers to VA depots and then to VA field stations is cumbersome and results in extra handling and added transportation costs.

Even though the addition of surcharges discourages procurement from, or through DPSC, we found many cases where ultimate prices to the VA stations would have been significantly lower than the prices paid by these stations. For example, if VA field stations had purchased Aristocort

(8 ounce jar) directly from DPSC the cost would have been $39.85 per jar, with all surcharges, instead of $46.07 paid on the Federal price list. Total savings for this drug item alone during calendar year 1970 would have amounted to over $4,600. Further, even with the 8 percent surcharge of the VA Marketing Center a savings of $3.03 per jar would have been realized.

The military has made no formal arrangements to allow its activities to purchase from VA depots drug items which are not centrally managed by DPSC. During the period July 1, 1970, to December 31, 1971, military hospitals purchased about $550,000 of the drug Macrodantin from the Federal Supply Schedule at about $275,000 more than it would have cost to buy from VA at the contract price. This item has now been approved for inclusion in the DOD central supply system and a contract has been awarded by DPSC at prices comparable to those negotiated by the VA. But, until delivery is received under the DPSC contract, military hospitals will continue to purchase the item at the higher Federal Supply Schedule price.

Our examination of invoices and sales records for purchases totaling about $6.2 million from four manufacturers during a recent two-year period showed that the Government incurred excess costs of about $721,000 because (1) many drugs were purchased by local installations at prices which ranged as much as 100 percent higher than prices available to DPSC and VA Marketing Center, (2) prices paid for the same drugs differed between DPSC and VA Marketing Center, and (3) there were purchasing weaknesses at VA and DPSC field stations.

Our review of DPSC and VA procurement records for 43 identical drug items purchased by both agencies within 30 days of each other during fiscal years 1970 and 1971 showed excess costs of at least $246,000--split approximately equally between the VA and DPSC--resulted from the differences in prices paid for these items.

From 1964 to 1971 several studies have been made by the Defense Supply Agency and the General Services Administration, separately and jointly, to determine the feasibility of a single agency having Government-wide responsibility for management of various categories of supplies including medical materials. The studies indicated differences of opinion on the feasibility of consolidating the procurement and management of medical items. Decision on this has been deferred pending the outcome of a current study.

The Office of Management and Budget in January 1972 initiated a joint study by DOD, the General Services Administration, HEW, and VA to determine the lowest cost system or combination of systems to achieve maximum economy in meeting Government-wide needs for medical material, including drugs.

We believe that procurement costs can be reduced significantly by better cooperation and coordination between the VA and DPSC. However, the differences in their procurement practices, such as the respective volumes of procurements of brand-name and generic items, use of specifications, and inspecting and testing requirements, must be reconciled to ensure that drugs will be purchased at the lowest possible cost to the Government.

PROCUREMENT OF DRUGS OF FOREIGN ORIGIN

Studies by HEW covering world drug prices in 1970 and 1971 show that prices charged by manufacturers to druggists in the United States were generally higher than prices charged to druggists in other countries for the same drug. Recent comparative data is provided in Appendix III.

Although drugs of foreign origin are frequently priced lower than comparable drugs of domestic origin the following factors influence procurement of the cheaper drugs:

1. FDA's New Drug Application (NDA) requirements. DoD and VA normally will not procure drugs which require an NDA approval from firms which do not have them. Foreign firms sometimes do not have the required NDA approval.

2. Inability of some foreign firms to satisfy American manufacturing standards for such matters as quality control and good housekeeping.

3. Possible legal action on patent infringements.

4. Implementation of the Buy American Act (41 U.S.C. 10 a-d).

For evaluating bids or offers of foreign firms for their products against offers of domestic products, civilian agencies are required by the Federal Procurement Regulations, which implement the Buy American Act, to add to the foreign bids or offers a price differential equivalent to 6 percent, inclusive of import duties, or 12 percent, inclusive of import duties, if the low domestic bid is a small business or distressed labor area concern. Military departments generally add a price differential of 50 percent to bids or offers of foreign products, exclusive of import duties, for evaluation

purposes, when a 6 or 12 percent differential, plus import duties, does not result in a greater evaluated price for the foreign products.

The effect of adding these price differentials can be seen in a procurement of 310,464 units of tetracycline hydrochloride tablets by DPSC in April 1971. The low foreign bid was $.85 a unit, excluding duty, and the low domestic bid was $1.19 a unit. After an evaluation using the 12 percent factor plus duties, the foreign bid was still low. But, an evaluation using the 50 percent differential resulted in the domestic bidder being low and receiving the contract. After considering discount and freight, this procurement cost almost $107,000 more than it would have from the foreign source.

Because of the above influences neither DPSC nor VA normally make any special effort to develop foreign sources for their drug requirements even though prices of drugs of foreign origin, as a general rule, are lower than domestic prices. Efforts to obtain bids from foreign sources are limited to the actions normally taken to obtain bids from any source, that is, solicitations are sent to the few foreign firms on the bidders list at the time they are sent to other potential suppliers and the proposed procurements are announced in the Commerce Business Daily. The VA also sends copies of its solicitations for items to be procured competitively to publishers of a number of marketing publications.

In November 1971 VA wrote to several Canadian firms inquiring whether they marketed three specific drug items in the United States. Four of the eight replies said that the

firm did not yet have the necessary NDA approval and the others said that they did not market or manufacture the items.

Appendix IV shows the drug items procured from foreign firms in the years 1968 through 1971 by DPSC and VA.

POLICIES, REGULATIONS, AND PRACTICES PERTAINING TO FURNISHING DRUGS UNDER THE MEDICAID AND MEDICARE PROGRAMS

Medicaid

The current HEW policy for the payment for prescription drugs under the Medicaid program does not require uniform procedures and practices to be followed by the States. Also, the use of a formulary is optional, but where one is used standards for quality, safety, and effectiveness must be set and supervised by professionals. The Social and Rehabilitation Service is responsible for administering the Medicaid program.

The formulary system should be broad enough to enable physicians and pharmacists to select high quality drugs of recognized therapeutic value for the treatment of any medical situation. Approximately 20 States have attempted to control the cost of drugs in their Medicaid programs through the use of formularies. Attempts have also been made by the States to limit certain drugs in their formularies to generic names.

In November 1970 we reported to the Congress that significant savings could be available to the States and the Federal Government if physicians were to prescribe lower-priced, chemically equivalent drugs instead of higher-priced

brand-name drugs. We pointed out that the HEW Task Force on Prescription Drugs reported in December 1968 that of the 409 brand-name drugs most frequently prescribed for elderly persons in 1966, chemical equivalents for 63 of these were available at lower costs. These 63 drugs accounted for about one-fourth of the prescriptions for the 409 drugs, and the task force computed that prescribing the lower cost chemical equivalents would have resulted in annual savings of $41.4 million.

The HEW task force reported also that physicians were not always aware of low-cost, chemically equivalent drugs produced by competing manufacturers or were reluctant to prescribe such drugs until their safety and effectiveness had been proven.

Medicare

Regulations for part A of Medicare set forth two basic requirements that must be met in order for a drug or biological to be included as a covered hospital service. 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 the USP, the NF, the U.S. Homeopathic Pharmacopoeia, or New Drugs or Accepted Dental Remedies (except for those unfavorably evaluated), or approved by the pharmacy and drug therapeutics committee (or equivalent) of the medical staff of the hospital for use in the hospital. There are no Medicare regulations concerning the use of generic versus brand-name drugs.

Payments for drugs under part A are made on the basis of reasonable cost. Payments are audited by fiscal intermediaries under contract to the Social Security Administration in accordance with the "prudent buyer concept". Under this concept the Government pays the amount a prudent and cost-conscious buyer would pay for a given item or service.

Under part B of Medicare, coverage of drugs and biologicals is limited to those drugs and biologicals (except for insulin) commonly furnished in physicians' offices which cannot, as determined by regulations, be self-administered. Thus, a drug or biological is reimbursable under part B of Medicare only if it is of a type which is normally not self-administered.

Medicare carriers are responsible for determining whether the services in a given case are reasonable and necessary. In making its evaluation, the carrier is expected to take into account accepted standards of medical practice in its service area. Because accepted standards of medical practice vary from one area to another, the Social Security Administration has issued general guidelines leaving it to the carrier to develop more detailed guidelines which reflect accepted patterns of care in its service area.

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

LISTING OF DRUGS PURCHASED UNDER THE MISSISSIPPI MEDICAID PROGRAM DURING THE PERIOD 7-1-70 - 2-19-71 WHICH WERE CLASSIFIED EITHER AS "INEFFECTIVE" OR "POSSIBLY EFFECTIVE" BY FDA

Drug name	Classification	Date of FDA classification	Number of prescriptions	Amount paid
Antivert Tablets	Ineffective	3-27-70	13,952	$52,425
Equagesic Tablets	Possibly effective	1-10-70	4,305	20,541
Rautrax-N Tablets	Ineffective	9- 5-69	3,372	15,938
			21,629	$88,904

LISTING OF DRUGS PURCHASED UNDER THE ILLINOIS AND NEW JERSEY MEDICAID PROGRAMS DURING JULY AND OCTOBER 1970 WHICH WERE CLASSIFIED AS "INEFFECTIVE" BY FDA

Drug name	Date of FDA classification	Illinois		New Jersey		Total	
		Prescriptions	Amount	Prescriptions	Amount	Prescriptions	Amount
Alertonic	9-12-69	6,070	$26,021	637	$ 2,271	6,707	$28,292
Terramycin SF capsules	4- 2-69	3,421	18,521	656	3,571	4,077	22,092
Antivert tablets	3-27-70	4,039	17,891	851	3,120	4,890	21,011
Mysteclin F capsules	12-24-68	2,272	11,858	358	1,309	2,630	13,167
Robaxisal tablets	2-11-70	1,346	7,372	-	-	1,346	7,372
Rautrax-N tablets	9- 5-69	804	4,722	-	-	804	4,722
Rautrax tablets	9- 5-69	203	1,314	20	117	223	1,431
Panalba capsules	12-24-68	86	688	-	-	86	688
Esidrix-K tablets	9- 5-69	138	518	-	-	138	518
Panalba-KM drops	12-24-68	25	115	-	-	25	115
Total		18,404	$89,020	2,522	$10,388	20,926	$99,408

LISTING OF DRUGS PURCHASED[1] UNDER THE OHIO MEDICAID PROGRAM DURING THE MONTHS OF JANUARY, APRIL, JULY, AND OCTOBER 1970 WHICH WERE CLASSIFIED AS INEFFECTIVE BY FDA

Drug name	Date of FDA classification	Ohio Prescriptions	Ohio Amount
Alertonic	9-12-69	10,009	$ 40,707
Terramycin SF Capsules	4- 2-69	2,675	17,090
Achrocidin Tablets	9-12-69	2,278	14,253
Hydropres KA Tabs	9- 5-69	2,272	12,808
Rautrax N Tablets	9- 5-69	980	7,494
Panalba Capsules	12-24-68	942	7,271
Declostatin 300 Tabs	4- 2-69	648	5,642
V-cillin Sulfa Pediatric	4- 2-69	1,316	5,183
Azotrex Caps	4- 2-69	445	3,158
Achrocidin Syrup	9-12-69	518	2,941
Ritonic Capsules	9-12-69	552	2,919
Mysteclin F Syrup	12-24-68	557	2,206
Signemycin Caps "375"	4- 2-69	144	1,426
Declostatin Caps	4- 2-69	204	1,369
Esidrix K Tablets	9- 5-69	360	1,286
Terrastatin Caps	4- 2-69	145	1,260
Tetrex APC w/Bristamin	9-12-69	232	1,171
Rautrax Tablets	9- 5-69	177	1,130
Rutorbin Tablets	1-27-68	165	1,110
CVP w/Vitamin K	1-23-68	182	842
Tetrex AP Syrup	9-12-69	188	806
Frenquel Tabs 100 mg.	4- 2-69	65	801
Hydrodiuril KA Tabs	9- 5-69	211	701
Duo CVP w/Vitamin K	1-23-68	82	526
Ruhexatal w/Reserpine	7-10-68	78	467
Achrostatin V Caps	4- 2-69	98	454
Frenquel Tabs 20 mg.	4- 2-69	62	411
Tetracydin Caps	9-12-69	93	359
Mesulfin Tablets	9-27-69	41	289
Rautrax N Modified Tablets	9- 5-69	70	287
TAO - AC Capsules	9-12-69	52	275
Pentid Sulfas "400" for Syrup	4- 2-69	65	219
Panalba Half STG Caps	12-24-68	41	177
Ilosone Sulfa Tabs	4- 2-69	35	152
Paredrine - SulfaThizole	9- 9-69	90	152
Lutrexin Tabs	5-24-68	16	131
Piptal Ped w/Phenobarb	9-27-69	49	103
Wycillin Sm Inj 600	4- 2-69	15	95
V-cillin K Sulfa Tabs	4- 2-69	22	84
V-Kor	9-12-69	34	84
Neopenzine 150 Tabs	4- 2-69	18	67
Mysteclin F	12-24-68	34	64
Comycin Capsules	4- 2-69	8	62
Total		26,268	$138,032

[1]Purchases of $50.00 or more.

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-146857

AUG 11 1971

Dear Mr. Chairman:

During testimony before your Subcommittee on January 19, 1971, concerning competitive problems in the drug industry and specifically the present status of competition in the pharmaceutical industry, you requested that we obtain information on the number of personnel and cost of purchasing drugs at the Veterans Administration and at the Defense Supply Agency.

By letters dated January 26 and 29, 1971, we asked the Administrator of Veterans Affairs and the Director of Defense Supply agency to furnish estimates of manpower requirements and administrative costs involved in the operation of their procurement systems for drugs. The information furnished is summarized below.

Veterans Administration
Drug Procurement Activities
Costs and Personnel
Fiscal Year 1970

Activity	Operations Included in Activity	Average Number of Personnel	Annual Cost
Marketing Center	Contracting (including Federal Supply Schedule), procurement, and control of stock.	13	$160,716
Depot Operations	Warehousing, distribution, accounting, and cataloging	61	572,380
Miscellaneous	Transportation, testing, inspection, etc.	13	574,421
	Total	87	$1,307,017

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Defense Supply Agency
Costs and Manpower for Providing
Drug Support
Fiscal Year 1971

Activity	Operations Included in Activity	Personnel Equivalents	Cost
Defense Personnel Support Center	Procurement (excluding contract administration)	50	$ 619,000
	Materiel management (item supply studies and accountability procurement requests, requirements determinations, and requisition processing)	32	368,000
	Technical support (cataloging, specification development and revision, quality assurance, laboratory analyses, and coordination with other Government agencies and professional activities)	44	640,000
Defense Contract Administration Services	Preaward surveys, postaward planning, contract administration, quality control and product inspection	32	438,000
Storage	Warehousing and distribution	479	3,689,000
	Total	637	$5,754,000

Neither agency separately identifies and accumulates costs related to all elements of their drug procurement systems. Accordingly, certain assumptions were made by each agency for the purpose of allocating costs to the above operations. The agencies' replies specify their assumptions and allocation methods used. It should be noted also that the estimated

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costs shown do not include costs incurred at the user activity level. Copies of the agencies' responses are enclosed.

We trust this information will serve the purpose of your request.

Sincerely yours,

(SIGNED) ELMER B. STAATS

Comptroller General
of the United States

Enclosures

The Honorable Gaylord Nelson
Chairman, Subcommittee on Monopoly
Select Committee on Small Business
United States Senate

Comparison of Selected Pharmaceutical Prices - 1971[1]
(Bottles of 100)

Product	USA	Australia	New Zealand	India
Analgesic:				
Propoxyphene HCL (65mg.)	$ 7.02 Darvon Lilly	$ 3.24 Doloxene Lilly	$ 2.50[11] Official Price	$ 4.75 Dolcxene Lilly
Antibiotics:				
Ampicillin (250 mg.)	22.75 AWP Polycillin Bristol	12.29 Penbritin Beechan	10.06[12] Official Price	26.81[23] Ampicillin CIPLA
Demethylchlortetr-cycline HCL (150mg.)	19.79 AWP Declomycin Lederle	9.53 Ledermycin Lederle	4.16 Official Price	12.32 Demethychlor-tetrcycline Tablets PVT LTD
Erythromycin (250mg.)	26.12 AWP Erythrocin Abbott	11.83[3] Erythrocin Abbott	13.60 Official Price	15.80 Erythrocin Abbott
Oxytetracycline HCL (250mg.)	20.48 AWP Terramycin Pfizer	6.99[4] Terramycin Pfizer	3.76 Official Price	7.82 Terramycin Pfizer
Potassium phenoxy-methyl pencillin (250mg.)	8.95 V. Cillin K Lilly	6.13[5] Pencillin VK Knoll	3.18 Official Price	3.08 Pencillin V Tablets PVT LTD
Tetracycline HCL (250mg.)	5.27 Achromycin-V Lederle	6.99[6] Achromycin-V Lederle	4.16 Official Price	7.56 Achromycin-V Lederle
Antidepressant:				
Amitriptyline HCL (25mg.)	8.55 Elavil Merck	2.95 Tryptanol Merck	2.82[13] Official Price	——— ——— ———
Antidiabetic:				
Tolbutamide (500mg)	8.70 AWP[2] Orinase Upjohn	3.26 Rastinon Hoechst	3.19 Official Price	1.93 Rastinon Hoechst
Antihistamine:				
Diphenhydramine (50 mg.)	2.92 AWP Benadryl Park-Davis	1.72[7] Benadryl Park-Davis	1.55[15] Official Price	1.80[25] Benadryl Park-Davis
Ataraxics:				
Chlordiazepoxide HCL	7.02 AWP Librium Roche	4.01 Librium Roche	2.06[16] Official Price	1.99[26] Librium Roche

1/ Prepared by the Office of Research and Statistics, Social Security Administration, Department of Health, Education, and Welfare.

Comparison of Selected Pharmaceutical Prices - 1971 Contd.

Product	USA	Australia	New Zealand	India
Chlorpromazine HCL (50mg.)	$ 4.40 Thorazine SKF	$ 2.38 Largactil May & Baker	$ 2.03[17] Official Price	$ 1.78[27] Largactil May & Baker
Diazepam (5mg.)	7.90 Valium Roche	3.45 Valium Roche	2.51[18] Official Price	2.20 Calmpose Ranbaxy
Meprobamate (400mg.)	7.06 Equanil Wyeth	4.47 Equanil Wyeth	2.21 Official Price	2.37[28] Equanil Wyeth
Prochlorperazine malcate (10mg.)	7.86 Compazine SKF	4.76[8] Stemetil May & Baker	2.87[19] Official Price	2.10[29] Stemetil May & Baker
Trifluoperazine HCL (5mg.)	9.75 Stelazine SKF	4.54 Stelazine SKF	3.99[20] Official Price	3.72 Eskazine SKF
Cardiovascular:				
Digoxin (.25mg.)	1.03 Lanoxin B-W	.74 Lanoxin B-W	.56[21] Official Price	.98 Lanoxin B-W
Oral Contraceptive:				
Ethynodial diacetate with mestranol (1mg. 6x21)	8.10 Ovulen 21 Searle	4.53[9] Ovulen 21 Searle	3.97[22] Official Price	4.32[30] Ovulen 21 Searle
Sedative:				
Glutethimide (250mg.)	3.00 Doriden Ciba	2.26 Doriden Ciba	1.40 Official Price	2.68 Doriden Ciba
Sulfonamide:				
Sulfisoxazole (500mg.)	2.94 Gantrisin Roche	3.00[10] Gantrisin Roche	———	1.22[31] Gantrisin Roche

See Attached sheet for footnotes

Footnotes:

1/ Calculated from the direct sale price March 15, 1971.

2/ Converted from price of 4.35 per 50 tablets.

3/ Converted from wholesale price of 14.89 per 150, 250 mg. tablets.

4/ Converted from wholesale price of 8.81 per 150, 250 mg. tablets.

5/ Converted from wholesale price of 7.72 per 150, 250 mg. tablets.

6/ Converted from wholesale price of 8.81 per 150, 250 mg. tablets.

7/ Converted from wholesale price of .72 per 50, 50 mg.

8/ Converted from wholesale price of .50 per 25, 5 mg.

9/ Converted from wholesale price of 1.90 per 3x21.

10/ Converted from wholesale price of .90 per 40, 500 mg.

11/ Converted from official price of 10.44 per 500.

12/ Converted from official price of 42.11 per 500.

13/ Converted from official price of 11.80 per 500.

14/ Converted from official price of 13.35 per 500.

15/ Converted from official price of .65 per 50.

16/ Converted from official price of 8.61 per 500.

17/ Converted from official price of .85 per 50.

18/ Converted from official price of 10.54 per 500.

19/ Converted from official price of 3.00 per 250, 5 mg.

20/ Converted from official price of 1.67 per 50.

21/ Converted from official price of 4.65 per 1000.

22/ Converted from official price of 1.66 per 3x21

23/ Converted from official price of 27.75 per 16.

Footnotes: cont'd.

24/ Converted from official price of 2.16 per 4.

25/ Converted from official price of 6.43 per 50.

26/ Converted from official price of 1.41 per 10.

27/ Converted from official price of 1.27 per 10.

28/ Converted from official price of 42.25 per 250.

29/ Converted from official price of .75 per 10, 5mg.

30/ Converted from official price of 5.14 for 1 cycle.

31/ Converted from official price of 3.74 per 20.

Sources:

USA--Drug Topics Readbook, 1971, Topics Publishing Co., Inc., New York.

Australia--Suggested Prices of Prescription Proprietaries for Dispensing, Issued by the Federal Council of the Pharmacy Guild of Australia, August 16, 1971.

New Zealand--New Zealand Department of Health, Prescription Pricing Schedule, August 1, 1971.

India--Indian Pharmaceutical Guide, 1971.

PROCUREMENTS BY DPSC AND THE VA

FROM FOREIGN FIRMS FOR CALENDAR YEARS

1968 THROUGH 1971

Calendar year	DPSC	VA	Total amount spent (rounded)
1968	Tetracycline Hydrochloride Tab. Meprobamate Tab. Nitrofurantoin Tab. (two sizes) Tetracycline Syrup	Meprobamate Tab.	$3,002,000
1969	Tetracycline Hydrochloride Tab. Meprobamate Tab. Nitrofurantoin Tab.	Meprobamate	1,263,000
1970	Tetracycline Hydrochloride Tab.	None	633,000
1971	Tetracycline Hydrochloride Tab. Meprobamate Tab.	None	854,000