CIRCULAR 10-70-286
DECEMBER 30, 1970

TELEGRAPHIC MESSAGE

NAME OF AGENCY	PRECEDENCE	SECURITY CLASSIFICATION
VACO WASH DC	ACTION: P INFO:	
ACCOUNTING CLASSIFICATION	DATE PREPARED 12/22/70	TYPE OF MESSAGE ☐ SINGLE ☐ BOOK ☒ MULTIPLE-ADDRESS
FOR INFORMATION CALL		
NAME R.E. DEARDORFF	PHONE NUMBER 3784	

THIS SPACE FOR USE OF COMMUNICATION UNIT

MESSAGE TO BE TRANSMITTED *(Use double spacing and all capital letters)*

TO:

DIRECTORS, VA HOSPITALS, VA DOMICILIARY, VA OUTPATIENT CLINICS AND REGIONAL OFFICES WITH OUTPATIENT CLINICS AND MANAGER, VA MARKETING CENTER

DM&S CIRCULAR 10-70-286 - SUBJ: DM&S CIRCULAR 10-70-237 DATED DECEMBER 4, 1970. IMPLEMENTATION OF NAS/NRC DRUG EFFICACY STUDIES INFORMATION.

00/134 1. THIS CIRCULAR CONTAINED A LIST OF DRUGS PUBLISHED BY THE FOOD AND DRUG ADMINISTRATION. PRESCRIPTION DRUGS ON THIS LIST WILL NO LONGER BE PURCHASED AS POSTED ITEMS AND STOCKED IN THE WAREHOUSE.

2. ISSUES OF STOCKS OF SUCH ITEMS WILL BE MADE TO THE PHARMACY ON SPECIFIC REQUEST. AFTER STOCKS ARE EXHAUSTED ITEMS WILL BE PURCHASED BY SUPPLY ONLY AS UNPOSTED ITEMS TO SATISFY SPECIFIC REQUESTS FROM THE PHARMACY SERVICE.

3. STOCKS OF LISTED DRUGS IN BOTH PHARMACY AND WAREHOUSE WHICH HAVE BEEN WITHDRAWN FROM USE BY THE STATION THERAPEUTIC COMMITTEE WILL BE HELD PENDING RECALL BY THE MANUFACTURER OR INSTRUCTIONS FROM THE MARKETING CENTER 134/10A

CIRCULAR EXPIRES DECEMBER 3, 1971.

CONCURRENCE:
DISTRIBUTION: (119)
COB (10) only
SS (10C5A)
REDEARDORFF:SLM 134

PAGE NO.	NO. OF PGS.	SECURITY CLASSIFICATION
1	1	ATTACHMENT C

STANDARD FORM 14
REVISED AUGUST 1967
GSA FPMR (41 CFR) 101-35.306

GPO 1967 O-300-456 (9-H1)

Dr. WELLS. This latter circular directed that if any stocks did exist of any of these items, they would not be replenished. This was further strengthened by Department of Medicine and Surgery Circular——

Senator NELSON. Excuse me. When you say these items, what does that refer to?

Dr. WELLS. This refers to the list we have already distributed from FDA; the ineffective drug list that we have distributed from the FDA.

Now, circular 10–71–16 of January 20, 1971, herewith submitted for the record, directed that procurement action would not be initiated under any circumstances without the prior approval of our central office.

(The information above-referred to, follows:)

CIRCULAR 10-71-16
January 20, 1971

TELEGRAPHIC MESSAGE

NAME OF AGENCY	PRECEDENCE	SECURITY CLASSIFICATION
VACO, WASH DC	ACTION: R INFO:	
ACCOUNTING CLASSIFICATION	DATE PREPARED: 1/8/71	TYPE OF MESSAGE: ☐ SINGLE ☐ BOOK ☒ MULTIPLE-ADDRESS
FOR INFORMATION CALL		
NAME: C.C. COOK	PHONE NUMBER: 2247	

THIS SPACE FOR USE OF COMMUNICATION UNIT

MESSAGE TO BE TRANSMITTED *(Use double spacing and all capital letters)*

TO: DIRECTORS OF HOSPITALS, DOMICILIARY, OUTPATIENT CLINICS, REGIONAL OFFICES WITH OUTPATIENT CLINICS; MANAGERS OF VA SUPPLY DEPOTS AND VA MARKETING CENTER

DM&S CIRCULAR 10-71-16 — SUBJ: PROCUREMENT OF DRUGS CLASSIFIED BY FDA AS LACKING SUBSTANTIAL EVIDENCE OF EFFECTIVENESS OR WITH AN UNFAVORABLE BENEFIT TO RISK RATIO.

RE DM&S CIRCULARS 10-70-237 AND 10-70-286, DRUGS CONTAINED IN LIST PROVIDED BY FDA DATED 11/1/70 WILL NOT BE PROCURED BY VA WITHOUT PRIOR APPROVAL OF CENTRAL OFFICE ON EACH INDIVIDUAL PROCUREMENT ACTION. THIS MODIFIES PREVIOUS INSTRUCTIONS WHICH RELATED TO PROCUREMENT OF POSTED ITEMS FOR STOCK ONLY. VA WILL NO LONGER PURCHASE THESE ITEMS ON EITHER A POSTED OR UNPOSTED BASIS. STATION PERSONNEL ARE CAUTIONED TO BE ALERT FOR ADDITION OF INDIVIDUAL ITEMS IN THIS CATEGORY WHICH WILL BE PUBLISHED IN THE FEDERAL REGISTER AS AN ITEM IS DETERMINED TO LACK EVIDENCE OF EFFECTIVENESS OR FAVORABLE RISK TO BENEFIT RATIO. INFORMATION ON THESE ITEMS WILL BE DISSEMINATED FROM CENTRAL OFFICE. THIS CIRCULAR EXPIRES JAN. 1, 1972. 134/10A

DISTRIBUTION: COB (10) only
SS (10CSA)

CONCURRENCES: R.A. Stotler (119) (11)

CCCOOK:SLM 134

PAGE NO.	NO. OF PGS.	SECURITY CLASSIFICATION
1	1	ATTACHMENT E

Dr. WELLS. Here we are stepping in actively to prevent the use of these drugs or the procurement of them.

Senator NELSON. "Procurement action would not be initiated under any circumstances without prior approval of the central office."

Will you clarify that for me? Are you referring to procurement that they do at the local level on their own or what?

Dr. WELLS. This would be procurement not only locally but also through the central contacts. As a matter of fact, the next sentence I think helps to clarify it. I do not envision at this time circumstances under which we would approve purchase of any of these drugs, even as exceptions, unless the manufacturer submits further evidence to Food and Drug Administration as required and permitted by regulation, which would result in reconsideration of previous findings.

Senator NELSON. But when you say "these drugs," you are referring to those that NAS has said are ineffective?

Dr. WELLS. Ineffective.

Senator NELSON. Do you get down to the question of "possibly effective?"

Dr. WELLS. If not, we will do so anyway off the document.

This subcommittee is aware that a number of these products have not been removed from the market, and it is conceivable that further evidence might be presented which would establish efficacy or changes made in the product to render it acceptable. In any event, we have taken the actions described pending further developments which will either result in these drugs being removed from the market or perhaps in revised form being determined to be effective.

As far as the effective or the possibly effective drugs, we are at a disadvantage at the moment not knowing exactly how this is going to appear from FDA's decision. We are going to take action to discourage the use of the possibly effectives where effective drug treatment is known.

Mr. WHITWORTH. Senator, we have stopped procurement of all possibly effective drugs at the national level, totally.

Senator NELSON. All "possibly effective" drugs?

Mr. WHITWORTH. Yes, sir.

Senator NELSON. And they would not, then, be put back on your list of drugs unless at some stage adequate evidence was submitted to the FDA so that their classification was changed to effective; is that right?

Mr. WHITWORTH. Precisely, sir.

Senator NELSON. What does that do about their procurement at the local level, whatever procurement they do?

Mr. WHITWORTH. They will satisfy whatever requirements are placed upon them, that is, the procurement people.

Senator NELSON. Pardon?

Mr. WHITWORTH. The procurement people will satisfy whatever requirements are placed upon them.

Senator NELSON. About half of your drugs are purchased locally, aren't they?

Mr. WHITWORTH. A little over half, yes, Senator.

Senator NELSON. If at the national level you have made the decision that you wouldn't purchase or stock possibly effective drugs until and unless their classification was changed, what are you doing about purchases of possibly effective drugs at the local level?

Mr. WHITWORTH. This decision was made anticipating further developments. We don't want to be caught with a lot of hoards of stock in our depots. Therefore, this is a first step. There indeed will be additional steps, I am certain, in this area.

Mr. STATLER. Obviously this passes on down to the hospital. They will cut out their supply of possibly effectives. If they find it is not being centrally procured, they will be faced with a decision whether they need it to fill prescriptions for physicians or not, and physicians will be contacted about all other alternative drugs available for use, the more effectives, and so forth having a higher classification.

Senator NELSON. But we really didn't get down to settling this question of the use of possibly effective drugs procured at the local level yet.

Dr. WELLS. I would say at this point in time, Senator Nelson, I don't believe this is settled in our own mind. We are going to have to go at this drug by drug as we face this problem of the possibly effectives and the possible alternates that will be offered.

Mr. STATLER. You see, an official listing of the possibly effectives has not been put out by FDA. As soon as that is available, it will be presented to the executive committee on therapeutic agents for a policy decision as to what restrictions, if any, will be imposed upon use of these drugs.

Senator NELSON. Reports on these drugs appeared in the Federal Register. Isn't that sufficient?

Mr. STATLER. It has been published continually in the Federal Register, different classifications but there is no single compilation of drugs only on the possibly effective list. Most of the ones we have been reviewing in the Federal Register have several classifications.

Senator NELSON. But you don't think that you can simply take them from the Federal Register and act on that?

Mr. STATLER. There is such a backlog of Federal Register publications and, of course, there are 700 more to be published by June 30th, that we feel it would duplicate a lot of efforts that are being made by different Government agencies on this, the one official agency recognized—FDA is the one to provide all Federal agencies with this single compilation. As Dr. Edwards testified the other day, he feels that they are the one source of most knowledgeable information on the relative efficacy of the drugs. We have asked him to provide this information to us and they are in the process of doing this.

Senator NELSON. Do you know of any instance of a classification by the National Academy of Science-National Research Council that has been rejected by the FDA?

Mr. STATLER. Not rejected. They have made a decision that they have published—it is either in one of the four categories of classification. However, there are some changes. By this we mean, for example, ineffective listing. We had attempted to get the ineffective

listing for several months prior to the official listing of November 1st which you all have. We had lists signed by knowledgeable officials from the FDA dated September 23d and prior to publication and release to our field stations, we were advised that there were several errors on that list. So drugs had to be deleted and some others had to be added. So rather than subject our physicians in the hospitals to erroneous listings and then causing a traumatic episode of having to change the information that went out, we are waiting for an official publication that we can stand behind.

Dr. WELLS. This is a very key point of decision, because there were a number of additions and deletions on that ineffective list. I think it was this experience, more than anything else, that made us feel that at this point in time we had best not go along with anything other than an officially declared listing of the possibly effectives.

Mr. GORDON. Dr. Wells, may I interrupt for just a moment. Mr. Statler just quoted Dr. Edwards, and I am going to quote Dr. Edwards again: "that we are the only reliable source which the practicing physicians should be able to look to to obtain some of this relative efficacy type of information."

Mr. Statler, do you agree with the Food and Drug Administration on this?

Mr. STATLER. I agree, Mr. Gordon, and any information that the FDA puts out relative to efficacy and comparative efficacy of drugs is furnished to all of our hospitals. In part of this testimony, appendix A, we list information that is provided to our therapeutic committees. We mention, for example, all FDA releases on drugs such as clinical experience abstracts, adverse reaction reports, FDA's current drug information circulars, their dear doctor letters, their new drug approvals, their weekly recall reports are all provided to everyone of our hospitals for continued guidance.

Mr. GORDON. Do you consult with them before you put a drug on your formulary?

Mr. STATLER. We certainly would know whether it was on one of the possibly effectives or ineffectives.

Mr. GORDON. This is in the negative sense. Do you ever ask FDA, for example, as to whether one drug is more effective or safer than another drug when both may be effective and safe?

Mr. STATLER. They haven't made such a determination available. They don't have the comparative information.

Mr. GORDON. Did you ever ask them?

Mr. STATLER. Yes. We have been in discussion with many of their people on that.

Mr. GORDON. The wording that Dr. Edwards used was this: "* * * be able to look to obtain some of this relative efficacy type information." Have you consulted with him at all on whether, before you put a drug on the formulary, that particular drug or another one should be put on?

Mr. STATLER. We are in close contact constantly with their drug efficacy study implementation group, called DESI. This is what Dr. Edwards was referring to, that they are the only reliable source of relative efficacy of drugs and they are talking about the classification as a result of the NAS–NRC reviews.

Yes, we do have all the information as they publish it. For example, in preparing this testimony on Peritrate, we knew there had been a panel review on it but we had not seen anything published. I wanted to get the current information as to the relative efficacy.

They have not made their final determination and published it in the Federal Register. As soon as it is, then it will become information that is available to our agency.

Mr. GORDON. Can you tell us those drugs about which you have recently consulted with the FDA relative to putting a drug on one of your formularies?

Dr. WELLS. Normally I don't believe we do, Mr. Gordon.

Mr. GORDON. I don't mean taking off. I mean putting something on a formulary.

Dr. WELLS. We don't specifically consult with them. We use their publications. We use their generalized information, but our therapeutics committee in the central office actually executes this action to our stations. We don't consult with them relative to individual drugs. Is that correct?

Dr. CHASE. That is correct. We use the basis of their information where it is appropriate for us. If it is a question of therapeutic effectiveness we will go to the experts in the field who are actually involved with the controlled testing of these drugs. Either the literature or the individuals as persons.

Mr. GORDON. You do not consult with the FDA, then, on specific drugs, is that correct?

Dr. CHASE. Well, I personally do not, sir. As chairman of the committee.

Mr. GORDON. Does anybody in VA?

Mr. STATLER. We have continual contact on all these drugs you are talking about. Every one of these that was questioned during the testimony of the physicians during the fall months we have discussed with officials from FDA to find out drug efficacy study recommendations, and so forth. Yes, we try to get all available information that they have in their files that is made available to us, but I have to make it clear that they will not release anything that has not yet been published in the Federal Register. So information we get is also public knowledge.

Senator NELSON. Please continue.

Dr. WELLS. One of our most significant efforts to date has been the issuance of Department of Medicine and Surgery Circular 10–71–3, January 13, 1971, on rational drug use. This directive restates our long-standing policy of not rigidly restricting professional practice by administrative direction, but emphasizes that we want to assure that every effort is made to treat all Veterans' Administration patients with the most effective therapeutic agents, at the most favorable cost. It calls attention to previous major policy statements and reiterates the position that each hospital Therapeutic Agents and Pharmacy Reviews Committee should take necessary action in the context of agency policy to assure the rationality of drug use and to provide the most effective and economical treatment for the patient.

We also emphasize the role of each Therapeutic Agents and Pharmacy Reviews Committee in a continuing review of prescribing practices and drug usage in their hospital. The policy that the purchase of high cost drugs could not be justified when equally effective but less expensive preparations were available is emphasized.

We have also taken, or are taking, a series of further steps which I feel will contribute to our common objective of the most rational prescribing attainable. We are placing greater emphasis upon the importance of the role of our hospitals Therapeutics Agents and Pharmacy Reviews Committees. I am certain their efforts in establishing and maintaining good station formularies have been strengthened by the attention and emphasis focused upon this problem. The minutes of each Therapeutic Agents and Pharmacy Reviews Committee meeting that is held, at least once a month, are forwarded to our central office for review. This monitoring by central office assures that drugs considered ineffective have been deleted from the station formulary or are not approved for purchasing and inclusion in the formulary. The recent reports submitted to our central office have reflected major interest and attention from our hospitals throughout the country.

Our local Therapeutic Agents and Pharmacy Reviews Committees at each of our hospitals and our Executive Committee on Therapeutic Agents in central office have the primary responsibility for assuring rational drug selection and for monitoring the quality, safety and efficacy of drugs used in the Veterans' Administration. These committees bring together the principal medical and pharmacy staff members and are supported as required by the professional and administrative staffs of the hospitals and clinics. They include experts on various medical specialties to assure that information available from several sources is considered in the committee's actions. It is important that any examination of our Agency's drug selection and procurement program consider the mission, membership and scope of responsibilities of these committees. I am attaching to this statement as appendix A an outline of their composition and functions.

(The document referred to is as follows:)

Appendix A

STATEMENT OF COMPOSITION AND FUNCTIONS OF VETERANS' ADMINISTRATION THERAPEUTICS AGENTS AND PHARMACY REVIEWS COMMITTEES AND EXECUTIVE COMMITTEE ON THERAPEUTIC AGENTS

The composition and functions of our Therapeutic Agents and Pharmacy Reviews Committees in each hospital and clinic and our Executive Committee on Therapeutic Agents in the Central Office are:

Every Veterans Administration medical hospital and clinic has a Therapeutic Agents and Pharmacy Reviews Committee to assure that regular quality control reviews are established and carried out for therapeutic agents and Pharmacy programming.

The Committees are generally composed of members of the Medical Executive Committee of the hospital and clinic. This Committee includes the Chiefs of the major patient care services. The Chief Pharmacist serves as the recorder. In most hospitals and clinics, the Director or Chief of Staff serves as Chairman. The principal functions of the Therapeutic Agents and Pharmacy Reviews Committees are:

1. To serve in an advisory capacity to management on policies pertaining to the use of drugs.

2. To evaluate clinical data on drugs proposed for use in the hospital, outpatient clinic, or domiciliary, and make recommendations for stocking of those considered most useful and effective.

3. To prevent unnecessary duplication of drug products.

4. To establish and provide for continuous revision of the station formulary.

5. To review, advise on, and recommend procedures pertaining to the prescribing, dispensing, and administering of drugs to assure patient safety.

6. To receive from the Chief of Staff all reports of adverse drug reactions and assist the Chief of Staff in the collection of pertinent data, evaluation of each reaction and preparation of reports to Central Office.

In addition to the local aspects of committee functions, the actions and recommendations of the committees serve as guides in the selection of drugs for most advantageous central procurement. An additional function of the committee, therefore, will be to make its recommendations known to the Executive Committee on Therapeutic Agents (Central Office) through the committee meeting minutes, and to include the medical reasons for unusual committee actions (such as the approval for use of a specific brand drug if the same drug is in the Veterans Administration system by nonproprietary name).

The Executive Committee on Therapeutic Agents in Central Office is chaired by the Assistant Chief Medical Director for Professional Services and the Director of Pharmacy Service serves as Recorder. The other members are directors of patient care services and our Research and Education Service. The Committee's principal functions are:

1. To develop, recommend and promulgate policy and information on rational use of drugs in the Agency.

2. To review and act on reports from Veterans Administration hospitals and clinics for use of drugs not available in interstate commerce and for which an FDA New Drug Application has not been effected (investigational drugs) for clinical treatment in specific cases.

3. To evaluate reports of Adverse Drug Reactions prior to forwarding to FDA. (Veterans Administration reports are combined with reports from all hospitals, Government and non-Government, sending such information to FDA and the resulting compilation prepared by FDA is furnished to all Veterans Administration hospitals and clinics.)

4. To review minutes and recommendations of each Therapeutic Agents and Pharmacy Reviews Committee submitted by Veterans Administration activities to identify drugs which will be considered for centralized procurement.

5. To review and act on Quality Improvement Reports submitted by Veterans Administration hospitals and clinics indicating a dissatisfaction with a drug product. Appropriate information is then coordinated with FDA and USP officials.

To assist each Therapeutic Committee in selection of the best drugs for patient therapy, a multitude of leading publications are available in each hospital and clinic including Journal American Medical Association, New England Journals of Medicine, Annals of Internal Medicine, etc., and publications such as Medical Letter, Clin-Alert. In addition, all of FDA releases on drugs such as Clinical Experience Abstracts, Adverse Reaction Reports, FDA Current Drug Information circulars, Dear Dr. letters, New Drug Approvals, Weekly Recall Reports, are provided for guidance.

VA professional publications such as, "Drug Treatment in Psychiatry," "Cooperative Studies in Psychiatry," "Pulmonary Diseases Abstracts," etc., also provide supplemental information.

Mr. GORDON. May I ask another question. What are you going to do about the drugs classified as "probably effective"? Would you buy a probably effective drug if there is a known effective drug that could be used as an alternative?

Dr. WELLS. We are looking forward to this list, this official publication, of the possibly effective drugs. At that point in time we will review these individually. We will publish the list to our field stations. We will get the advice from our field people and other experts as to exactly what we should do, drug by drug, what kind of alternatives are likely to be offered, and we will make the

best possible judgment we can in line with our basic goals which I think have been rather clearly stated.

Mr. GORDON. You say you are waiting for the FDA to bring together such a list? Is that it?

Dr. WELLS. Well, for the official publication of it, yes.

Mr. GORDON. Couldn't you put it together yourself since many have been published already in the Federal Register? I notice that you were waiting for the "possibly effective" list to be brought together by FDA. The Public Health Service drew up its own list. Could you have used the PHS list. Why do you have to wait?

Dr. WELLS. We are rather conservative about this.

Mr. STATLER. Mr. Gordon, we have been in close contact with FDA on this. The very first day we learned of the compilation of the listing by HEW of 159 drugs, we called FDA to find out if we could use this as the official listing, and they told us no, that there are errors on that list. We are not interested in having an erroneous list.

We also know Defense Department has a similar listing with more drugs on it than HEW has.

We asked in our letter to Dr. Edwards for the list of ineffective drugs, and in addition, advised him that we plan to also provide our hospitals with a list of drugs classified probably effective, possibly effective, and effective as a result of these panel reviews. We said we would appreciate receiving these lists of drugs considered officially by FDA in each of these four categories and an updating and subsequent listing of all drugs as they become available.

They are in the process of preparing such a listing. Just this morning in the green sheet I notice that FDA is, within the next 2 weeks, to publicize a new ineffective drug list which will have something like 400 on it rather than the original 359. So as you see, there is a continual review process.

One of the problems is they have new information—today in the Federal Register something may be listed as probably effective or possibly effective but additional information has been submitted by the manufacturers to FDA and they are making a different decision and putting it in a different classification. So something we take out of a Federal Register last year may not be current today in the eyes of FDA. That is why we are waiting for an official transmittal of the list to us.

Mr. GORDON. When you get the probably effective list what are you going to do?

Mr. STATLER. We will transmit it to all of our VA field stations so every therapeutic committee will have such a listing and as Dr. Wells indicated, we will make a drug-by-drug review to see if there should be any special action taken on any of the drugs on there.

Obviously if there is a drug on the possibly effective list and there are more effective drugs available and particularly at less cost, that information will be furnished to our hospitals for their use.

Mr. GORDON. What about the probably effectives?

Mr. STATLER. It looks like the probably effectives will eventually be put into the effective classification simply because of a change in certain claims of the manufacturer and they will then come out, be taken out, of the probably effective list.

Senator NELSON. Go ahead, Doctor.

Dr. WELLS. As an example of the problem that arises in selecting drugs for central purchasing and in obtaining complete agreement as to their acceptability for use, we have noted that a substantial number of our local therapeutic committees have changed to the macrocrystalline form of nitrofurantoin from the microcrystalline form. The decisions were apparently based upon concern that the microcrystalline form produced more unfavorable side effects than did the macrocrystalline form. This view has been challenged and some hold that there is insufficient clinical evidence to support it. Our Executive Committee on Therapeutic Agents has been examining this question to determine whether the microcrystalline form available from a foreign supplier would be satisfactory. The minutes of the Executive Committee on Therapeutic Agents discussion was disseminated to all hospitals. One of our chiefs of urology expressed his concern about Veterans' Administration's possible action, stating that in his practice of clinical medicine there is evidence of a fivefold greater incidence of nausea and vomiting when using the microcrystalline form than when using the macrocrystalline form. While recognizing the value of controlled clinical studies, we cannot ignore substantial evidence developed in routine clinical practice. In any event, we have reached no conclusion on this problem, nor have we purchased further stocks of nitrofurantoin in either form since our previous appearance before this subcommittee.

Our current policy with respect to those drugs whose effectiveness has not been questioned, but whose costs are significantly higher than other products which some authorities feel are equally effective, is to restrict the quantities purchased while our local Therapeutics Agents and Pharmacy Review Committees consider what controls they might wish to establish to assure they are used where indicated and not on a widespread basis just because of their popularity. It is possible that we will continue to purchase propoxyphene where its use is indicated. We will determine to what extent it is being used when there is no specific indication for it and when an effective and safe substitute is available. I believe that most of the distinguished witnesses which have appeared before your subcommittee generally agreed that there was no rationale for the use of propoxyphene instead of aspirin except in specific cases. As I interpret what they said and what our own experts tell me, there is a use for such products as propoxyphene; the problem lies in the general use of such products when a substantially lower cost, effective alternate is available. Our local committees are already reviewing the widely publicized examples. As a part of our agencywide review our Executive Committee on Therapeutic Agents will review, with our Supply Service, agency records which highlight substantial use of the more costly drugs and will provide this information to our local committees so that they can review their own decision, to assure themselves that they have adequately controlled the use of these drugs.

As we promised this subcommittee, we have examined our previous policy on soliciting foreign sources for our drug requirements. Our efforts to obtain world market prices or cost information were unsuccessful. We solicited the assistance of the Department of State, Department of Commerce, and both domestic and foreign drug firms.

In substance, we found that there are no fixed prices for purchase of drugs from foreign countries for importation into the United States.

Mr. GORDON. But you can get them to bid, can't you?

Dr. WELLS. On a large quantity, bulk quantities, but not for pharmaceuticals as such. We have been unsuccessful on them.

Mr. GORDON. What do you mean by that? You were able to get bids on meprobamate, for example.

Dr. WELLS. Yes, and we have indeed purchased meprobamate and tetracycline from foreign sources where we have been able to accomplish studies to assure ourselves through plant inspection, and so on, that we were getting quality, and to get a bid which was substantially lower than the domestic market. So we have indeed done this where we could.

Further, we have established that we cannot legally import into this country products for which an effective New Drug Application, approved by Food and Drug Administration does not exist at the time of import. At this moment, there are only three such instances of which we are aware, where the domestic suppliers are not competitive with foreign suppliers and for which there is an approved NDA in effect. One is for the product meprobamate, which we do purchase from foreign sources. Another is for nitrofurantoin, which we are studying before we reach a decision to replenish stocks. That is the matter to which we spoke a little earlier.

The third is for tolbutamide, a drug whose use is under study. We have talked with one foreign manufacturer with a potentially large capacity about what products he might offer. He tells us he is considering filing New Drug Applications on several products, but has not reached a decision to do so. We are carefully screening all announcements of New Drug Application approvals by FDA to determine if they might not offer us opportunities for expanded competition for our drug requirements.

We have selected 85 drugs which we now purchase on a sole-source basis and are studying the potential for expanding competition by seeking additional suppliers and determining if these suppliers are interested in competing for our requirements, and participating in our inspection program. Among those 85 items, we have selected 13 items for early and immediate action. We have already contacted potential suppliers to determine their interest and to determine that competition will result in lower prices.

Senator NELSON. Doctor, may I interrupt a moment. You are aware of the General Accounting Office survey of nine drugs purchased by the VA on a sole-source basis and by the Department of Defense on a competitive basis? The General Accounting Office found that VA paid 60 percent more than the Department of Defense for the same drugs.

What is your response to that?

Mr. WHITWORTH. These nine items, Senator, are among the 85 that have been chosen for generic—competitive procurement, and if I may say one more word about that, we have in our national distribution system some 544 different drug line items: 123 are now bought competitively; 336 are sole-source or as the military would say, single-source items. We can only get them from one manufacturer. This

leaves 85 items that there is a potential for competitive procurement on. This is the 85, sir, that have been selected and we are going to attempt to buy them competitively, put them in our national distribution system, and educate, if I may use the word, our prescribing physicians, if we can, to use these competitively procured items.

We have 13 of them under the first steps of the purchase action right now. The first invitations will go out February 15 on these 13 and the last invitations will go out around March 15.

What I am saying is that if we can do what we have started to do with 13 items, through 85 items, then we will have in the depot system all of those items that can be bought competitively, in fact, competitively bought.

Senator NELSON. How many did you say were single or sole-source?

Mr. WHITWORTH. 336.

Senator NELSON. 336 out of——

Mr. WHITWORTH. 544, sir.

Senator NELSON. These are 336 different drugs or does that include dosage forms of the same drug?

Mr. WHITWORTH. It includes dosage forms.

Senator NELSON. How many different compounds are involved, then?

Mr. WHITWORTH. I can submit it for the record, sir, but I don't know.

Senator NELSON. When you say sole-source for these 300-odd drugs, do you mean that there is no other similar compound in the marketplace or rather, that there is no other therapeutic agent that does the same thing? Or are you saying that among these sole-sources are certain brand names for which there are other generics available of the same compound?

Mr. WHITWORTH. Well, sir, they are all brand names, the 336. Whether there are other drugs available that will do the same job, I will have to defer to Mr. Statler.

Mr. STATLER. These are only available from a single manufacturer in the United States, Senator. In other words, an example would be chlordiazepoxide. No other manufacturer other than Roche manufactures that.

Senator NELSON. Maybe I am not making my question clear.

There are a whole list of tetracyclines. Obviously, if you order chlortetracycline, it will have only one source. You would call that a sole-source item?

Dr. WELLS. Yes. It would be a sole-source if you ordered that.

Senator NELSON. That is what I am getting at. Chlortetracycline, doxycycline, methacycline HCL—these are all members of the tetracycline family. Would you call each one of these a sole-source item? Is that what we are describing here?

Mr. COOK. In answering your question, Senator, yes. However, in the tetracycline family the only item we have in stock is the tetracycline hydrochloride.

Senator NELSON. But if you had these other ones you would consider that sole-source.

Mr. COOK. Yes, sir.

Senator NELSON. So what we are talking about here as sole-source is a number of items which have been selected by brand name that

therefore made them sole-source because there is only one company making that brand. Is that what we are saying?

Mr. COOK. Yes.

Senator NELSON. So if you were, for example, talking about prednisone, and you order Paracort or Meticorten or Deltra, you would consider each one of those sole-source items?

Mr. COOK. No. Not if they were identical chemical formulations. If they were similar we might consider them, everyone, sole-source but if they are identical, no.

Senator NELSON. If they are identical formulations with different brand names you don't consider that sole-source.

Mr. COOK. No, sir.

Senator NELSON. But if there is some slight difference, no matter how slight, and they have the same known therapeutic effect, you would consider that sole-source?

Mr. COOK. Yes, sir.

Senator NELSON. How many of them are there like that?

Mr. COOK. We will have to supply that.

Senator NELSON. Will you supply that for the record?

Mr. COOK. Yes, sir.

(Subsequently the Veterans' Administration supplied the following information:)

There are 137 brand name drugs which have different therapeutic effects and therefore considered sole-source.

VETERANS' ADMINISTRATION,
OFFICE OF GENERAL COUNSEL,
Washington, D.C., March 17, 1971.

Mr. BEN GORDON,
Majority Counsel,
Select Committee on Small Business,
Washington, D.C.

DEAR MR. GORDON: On March 5, you called Mr. Knapp of this office, referring to page 9286 of our testimony to the Subcommittee. You ask that the 137 brand name drugs we refer to as being bought by brand name be listed both by their trade and generic names and that the list be separated by therapeutic category.

Attached to this letter is the information requested.

You will note that the total of items is 140, rather than 137. This is a fluid figure as items are being dropped out and picked up constantly. At the time of our testimony, I am told it was 137. As of today, it is 140.

Sincerely yours,

JOHN J. CORCORAN,
General Counsel.

Attachment.

Analgesics

Acetaminophen tablets, NP, 325 mg. (5 gr.), 1000s. Scored, White. (Tylenol). McNeil Labs. Inc ..... BT

Butalbital, aspirin, caffeine, and phenacetin tablets, 1000s. Uncoated, White. (Piorinal). Sandoz Pharm., Div ..... BT

Fentanyl citrate and droperidol injection. Each ml. contains 0.05 mg. Fentanyl (as the Citrate) and 2.5 mg. Droperidol. (Innovar). McNeil Labs., Inc:

2 ml ..... AM

5 ml ..... AM

Meperidine hydrochloride injection, USP, 50 mg. per ml., 30 ml. Multiple-Dose Vial. (Demerol). Winthrop Labs., Div VI

Oxyphenbutazone tablets, 100 mg., 1000s. Sugar Coated, Tan. (Tandearil). Geigy Pharm., Div ..... BT
Pentazocine hydrochloride tablets, 50 mg., 100s. Peach, Scored. (Talwin). Winthrop Labs., Div ..... BT
Pentazocine lactate injection, NF, 30 mg. per ml. Sterile. (Talwin). (Talwin). Winthrop Labs., Div.:
1 ml ..... AM
10 ml VI
Phenacetin, aspirin, hyoscyamine, and phenobarbital capsules, 1000s. (Phenaphen). A. H. Robins Co ..... BT
Phenylbutazone tablets, USP, 100 mg., 1000s. Sugar Coated, Red. (Butazolidin). Geigy Pharm., Div ..... BT
Potassium aminobenzoate, ascorbic acid, and potassium salicylate tablets, 500s. (Pabalate-Sodium Free). A. H. Robins Co., Inc ..... BT
Propoxyphene hydrochloride, aspirin, caffeine, and phenacetin capsules, 500s. Eli Lilly & Co.:
32 mg. (Darvon Compound) ..... BT
65 mg. (Darvon Compound-65) ..... BT
Propoxyphene hydrochloride capsules, USP, 500s. (Darvon Pulvules). Eli Lilly & Co.:
32 mg ..... BT
65 mg ..... BT
Sodium aminobenzoate, sodium salicylate and ascorbic acid tablets, 500s. Enteric Coated. (Pabalate). A. H. Robins Co., Inc ..... BT

Anorexics

None.

Antibacterial and anti-infectives

Aminosalicylic acid, USP, 1 Lb. Powder. (Rezipas). E. R. Squibb & Sons, Inc ..... BT
Antiseborrheic liquid, 4 Oz. For treatment of seborrhea capitis and seborrheic dermatitis. (Sebulex). Westwood Pharm., Div ..... BT
Benzalkonium chloride solution, USP, Concentrated, 17%, Gal. (Zephiran Chloride). Winthrop Labs., Div ..... BT
Cycloserine capsules, USP, 250 mg., 500s. No. 1 Light-Gray Opaque Body, Red Opaque Cap. (Seromycin). Eli Lilly & Co ..... BT
Detergent, surgical, Plastic Bottle. Liquid. Contains 3% Hexachlorophene. (Phisohex). Winthrop Labs., Div:
5 Oz ..... BT
1 Pt ..... BT
1 Gal ..... BT
Ethionamide tablets, 250 mg. Red, Sugar Coated. (Trecator-SC). Ives Labs., Inc:
100s ..... BT
500s ..... BT
Nitrofusazone ointment, NF, 1;500, 1 Lb, (453.6 Gm). Water Soluble. (Furacin Soluble Dressing). Eaton Labs., Div ..... JR
Nitrofurazone solution, NF, 0.2%, 473 ml. (1 Pt.) in Water Miscible Liquid of Polyethylene Glycols, Octylphenoxy Polyethoxyethanol, NF, and Water. Antiseptic, Topical. (Furacin Solution). Eaton Labs., Div ..... BT
Povidone-iodine solution, NF, 1 Gal. The Purdue Frederick Co:
(Betadine Antiseptic). For Preoperative and Postoperative Prepping of Operative Site ..... BT
(Betadine Surgical Scrub). Microbicidal Cleaner for Preoperative and Postoperative Scrubbing ..... BT
Salicyazosulfapyridine tablets, 0.5 Gm., 500s. Brownish Yellow, Scored, Uncoated. (Azulfidine). Pharmaica Labs., Inc ..... BT
Selenium sulfide detergent suspension, NF, 2.5%, 4 Oz. (Selsun). Abbott Labs ..... BT
Sulfamethizole tablets, NF, 0.5 Gm., 100s. Scored, White. (Thiosulfil Forte). Ayerst Labs., Div ..... BT
Sulfamethoxazole tablets, NF, 0.5 Gm., 500s. Green, Scored. (Gantanol). Roche Labs., Div ..... BT
Sulfisozazole tablets, USP, 0.5 Gm., 1000s. (Gantrisin). Roche Labs., Div ..... BT

Antibiotics

Cephaloridine for injection, 1 Gm., 10 ml. Dry Powder, Sterile. (Loridine). Eli Lilly & Co ..... AM

Colistin sulfate, hydrocortisone acetate, neomycin sulfate, thimerosal and thonzonium bromide suspension, otic, 5 ml. dropper-bottle. (Coly-mycin S Otic). Warner-Chilcott Labs., Div ..... BT

Demeclocycline hydrochloride capsules, NF, 150 mg., 100s. Two-Toned Coral. (Declomycin). Lederle Labs., Div. ..... BT

Erythromycin estolate capsules, NF, 250 mg., 100s. (Ilosone Pulvules). Eli Lilly & Co ..... BT

Erythromycin tablets, USP, 250 mg., 100s. (Erythrocin Stearate). Abbott Labs ..... BT

Gentamicin sulfate cream, USP, 0.1%, (1 mg. per Gm.), 15 Gm. (Garamycin). Schering Corp ..... TU

Gentamicin sulfate injection, 40 mg. per ml., 2 ml. (Garamycin). Schering Corp VI

Lincomycin hydrochloride capsules, USP, 500 mg., 100s. Two-toned Blue. (Lincocin). The Upjohn Co ..... BT

Lincomycin hydrochloride injection, USP, 300 mg. per ml., 10 ml. For intramuscular or intravenous use. (Lincoin). The Upjohn Co VI

Neomycin sulfate, hydrocortisone, and polymyxin B sulfate suspension. Dropper-bottle. Sterile, Otic Administred. (Cortisporin). Burroughs Wellcome & Co., Inc.:

5 ml ..... BT

10 ml ..... BT

Nystatin, gramicidin, neomycin sulfate, and triamcinolone acetonide cream, 15 Gm. (Mycolog). E. R. Squibb & Sons, Inc ..... TU

Polymyxin B-bacitracin ointment, 1 oz. antibiotic. (Polysporin). Burroughs Wellcome & Co., Inc ..... TU

Polymyxin B sulfate, sterile, USP, 500,000 units (50 mg. Polymyxin Standard), 20 ml. capacity multi-dose vial. Powder. For parenteral use. (Aerosporin). Burroughs Wellcome & Co., Inc VI

Potassium phenoxymethyl penicillin tablets, USP, 250 mg. (400,000 units), 100s. Scored, White. (V-Cillin K). Eli Lilly & Co ..... BT

Sodium cephalothin, sterile, USP. Rubber stoppered vial. Dry powder. For parenteral use. (Keflin). Eli Lilly & Co.:

1 Gm., 10 ml VI

4 Gm., 50 ml VI

Sodium colistimethate and dibucaine hydrochloride for injection, 150 mg. (Coly-Mycin M). Warner-Chilcott Labs., Div VI

Troleandomycin capsules, NF, 250 mg., 60s. (Tao). J. B. Roerig & Co., Div ..... BT

Zinc bacitracin, neomycin sulfate, and polymyxin B sulfate ointment. (Neosporin). Burroughs Wellcome & Co., Inc.:

½ oz ..... TU

1 oz ..... TU

Antidiabetics

Acetohexamide tablets, NF, 500 mg., 500s. Capsule-Shaped, Scored, Yellow. (Dymelor). Eli Lilly & Co ..... BT

Chlorpropamide tablets, USP, 250 mg., 250s. Scored, Unocated. (Diabinese). Pfizer Labs., Div ..... BT

Phenformin hydrochloride capsules, 50 mg., 1000's. Time Disintegrating. (DBI/TD). USV Pharm. Corp ..... BT

Tolazamide tablets, USP, 250 mg. Scored, White. (Tolinase). The Upjohn Co.:

50's ..... BT

1,000's ..... BT

Tolbutamide tablets, USP, 0.5 Gm. (Orinase). The Upjohn Co.:

50's ..... BT

500's ..... BT

Antiemetics

None.

Antifungals

Tolnaftate solution, USP, 1%, 10 mg. per ml., 10 ml. plastic squeeze bottle. For dermatological use only. (Tinactin). Schering Corp ..... BT

Antihistamines

Bropheniramine maleate, phenylephrine hydrochloride, and phenylpropanolamine hydrochloride tablets, 500s. Extended Action, Sky Blue, Sugar Coated. (Dimetapp Extentabs). A. H. Robins Co., Inc ..... BT

Brompheniramine maleate tablets, NF, 12 mg., 500s. Coated, Unscored. (Dimetane Extentabs). A. H. Robins Co., Inc ..... BT

Chlorpheniramine maleate tablets, modified, 1000s. Repeat-Action. (Chlor-Trimeton Maleate Repetabs). Schering Corp.:
- 8 mg., Yellow ..... BT
- 12 mg., Orange ..... BT

Dexbrompheniramine maleate and pseudoephedrine sulfate tablets, 60s. Sugar Coated, Sustained Action. (Drixoral). Schering Corp ..... BT

Dexchlorpheniramine maleate tablets, NF, 6 mg., 1000s. (Polaramine Repetabs). Schering Corp ..... BT

Diphenhydramine hydrochloride capsules, USP, 50 mg. (¾ gr.), 1000s. (Benadryl). Parke, Davis & Co ..... BT

Tripelennamine hydrochloride tablets, USP, 50 mg., 1000s. (Pyribenzamine). Ciba Pharm. Co., Div ..... BT

Antihypertensives

Guanethidine sulfate tablets, USP. Scored, Uncoated. (Ismelin). Ciba Pharm. Co., Div.:
- 10 mg., Yellow:
  - 100's ..... BT
  - 1000's ..... BT
- 25 mg., White:
  - 100's ..... BT
  - 1000's ..... BT

Hydralazine hydrochloride tablets, NF, 1000's. Dry-Coated. (Apresoline). Ciba Pharm. Co., Div.:
- 25 mg. (⅜ gr.), Blue ..... BT
- 50 mg. (¾ gr.), Lilac ..... BT

Reserpine, hydralazine hydrochloride, and hydrochlorothiazide tablets, 1000's. Each tablet contains Hydralazine Hydrochloride 25 mg., Hydrochlorothiazide 15 mg., and Reserpine 0.1 mg. Salmon Pink. (Ser-Ap-Es). Ciba Pharm. Co., Div ..... BT

Tolazoline hydrochloride tablets, 25 mg., 1000's. (Priscoline). Ciba Pharm. Co., Div ..... BT

Cardio tonics/heart prep.

Digoxin tablets, USP, 0.25 mg. (1/250 gr.), 1000's. Scored, White. (Lanoxin). Burroughs Wellcome & Co., Inc ..... BT

Procainamide hydrochloride Capsules, USP, 0.25 Gm., 1000's. Yellow. (Pronestyl). E. R. Squibb & Sons, Inc ..... BT

Quinidine sulfate tablets, USP. White. 300 mg., 250's. Coated, Sustained Action. (Quinidex Extentabs). A. H. Robins Co., Inc ..... BT

Coronary and systemic vasodialators

Cyclandelate capsules, 200 mg., 100s. Capsule Size No. 1, Blue, Opaque. (Cyclospasmol). Ives Labs., Inc ..... BT

Cyclandelate tablets, 100 mg., 100s. Orange-Buff, Sugar Coated. (Cyclospasmol). Ives Labs., Inc ..... BT

Dipyridamole tablets, 25 mg., 1000s. Orange, Sugar Coated. (Persantin). Geigy Pharm., Div ..... BT

Isosorbide dinitrate tablets. Ives Labs., Inc.:
- 5 mg., 100s. Pink. (Isordil Sublingual) ..... BT
- 10 mg., 500s. Scored, White. (Isordil) ..... BT
- 40 mg., 100s. Light Green, Scored, Sustained Action. (Isordil Tembids) ..... BT

Isoxsuprine hydrochloride tablets, NF, 10 mg., 1000s. (Vasodilan). Mead Johnson Labs., Div---- BT
Nicotinyl alcohol tablets, 150 mg., 500s. Red, Sugar-Coated, Sustained Release, Tartrate. (Roniacol Timespan). Roche Labs., Div---- BT
Nitroglycerin capsules, 2.5 mg., 100s. Micro-Dialysis Cells, Sustained Release. (Nitrospan). USV Pharm. Corp---- BT
Nylidrin hydrochloride tablets, NF, 6 mg., 1000s. (Arlidin). USV Pharm. Corp---- BT
Papaverine hydrochloride capsules, 150 mg., 1000s. Long Acting, Brown and White. (Pavabid Plateau). Marion Labs., Inc---- BT
Pentaerythritol tetranitrate tablets, 80 mg., 1000s. Sustained Action. (Peritrate-SA). Warner-Chilcott Labs., Div---- BT
Pentaerythritol tetranitrate tablets, NF, 1000s. (Peritrate). Warner-Chilcott Labs., Div.:
10 mg---- BT
20 mg---- BT

Diuretics

Acetazolamide capsules, 500 mg., 100s. Orange, Soft Shell, Sustained Release. (Diamox Sequels). Lederle Labs., Div---- BT
Acetazolamide tablets, USP, 250 mg., 1000s. Scored, White. (Diamox). Lederle Labs., Div---- BT
Chlorothiazide tablets, NF, 0.5 Gm., 1000s. Scored, White. (Diuril). Merck Sharp & Dohme, Div---- BT
Chlorthalidone tablets, USP, 100 mg. Scored, White. (Hygroton). Geigy Pharm., Div.:
100's---- BT
1000's---- BT
Furosemide injection, 10 mg. per ml., 2 ml. (Lasix). Hoechst Pharm. Co., Inc---- AM
Furosemide tablets, USP, 40 mg., 500s. Scored, White. (Lasix). Hoechst Pharm. Co., Inc---- BT
Meralluride injection, USP, 2 ml. Ampul, 100s. For intramuscular, intravenous or subcutaneous use. (Mercuhydrin Sodium). Lakeside Labs., Inc---- BX

Hormone/steriod

Betamethasone valerate cream, 0.1%. (Valisone). Schering Corp:
15 Gm---- TU
45 Gm---- TU
Chlorotrianisene capsules, NF, 12 mg. (¼ gr.), 500s. Soft Gelatin, Green. (Tace). The Wm. S. Merrell Co., Div---- BT
Estrogenic substances, conjugated, for injection, (Equine) Powder, 20 mg. Secule, with 5 ml. Vial of Sterile Diluent. For Intravenous use. (Premarin). Ayerst Labs., Div---- PG
Estrogenic substances, conjugated, tablets, (Equine), 1.25 mg., 100's. Yellow. (Premarin). Ayerst. Labs., Div---- BT
Fluocinolone acetonide cream. For topical use. (Synalar). Syntex Labs., Inc.:
0.01 percent, 45 Gm---- TU
0.025 percent:
15 Gm---- TU
425 Gm---- JR
Flurandrenolide cream, NF. For topical use. (Cordran). Eli Lilly & Co.:
0.025 percent, 60 Gm. (Half Strength)---- TU
0.05 percent:
15 Gm---- TU
60 Gm---- TU
225 Gm---- JR
Hydrocortisone sodium succinate for injection, USP, 100 mg., Sterile, 2 ml. Powder and Sterile Water in separate compartments of vial. For intravenous and intramuscular use. (Solu-Cortef, Mix-O-Vial). The Upjohn Co---- VI

Methandrostenolone tablets, 5 mg., Greenish-Blue, Round, Scored. (Dianabol). Ciba Pharm. Co., Div:
100's ..... BT
1,000's ..... BT
Methylprednisolone acetate suspension, sterile, NF, 40 mg. per ml., 5 ml. For intramuscular, intrasynovial, soft tissue injection, and intrarectal use only. (Depo-Medrol). The Upjohn Co VI
Methylprednisolone sodium succinate for injection, NF, Powder. For intravenous or intramuscular use. (Solu-Medrol, Mix-O-Vial). The Upjohn Co:
40 mg., 1 ml. Sterile Water in Separate Compartment of Vial VI
125 mg., 2 ml. Sterile Water in Separate Compartment of Vial VI
Methylprednisolone tablets, NF, 4 mg. (1/15 gr.), 500s. Scored, White. (Medrol). The Upjohn Co ..... BT
Triamcinolone acetonide cream, USP, 0.1 percent. For dermatologic use only. (Kenalog). E. R. Squibb & Sons, Inc.:
15 Gm ..... TU
5 Lb ..... JR

Psychotherapeutic agents

Acetophenazine maleate tablets, NF, 20 mg., 1000's. (Tindal). Schering Corp ..... BT
Chlordiazepoxide hydrochloride capsules, NF, 500's. (Librium). Roche Labs., Div.:
5 mg., Green and Yellow ..... BT
10 mg., Green and Black ..... BT
25 mg., Green and White ..... BT
Chlordiazepoxide hydrochloride for injection, NF, 100 mg., 10's. Duplex package consisting of 5 ml. ampul dry powder and 2 ml. ampul of diluent. For intramuscular or intravenous use. (Librium Ampul). Roche Labs., Div ..... BX
Chlorprothixene tablets, NF, 500's. Round-Convex. (Taractan). Roche Labs., Div.:
25 mg., Light Beige ..... BT
50 mg., Medium Beige ..... BT
100 mg., Dark Beige ..... BT
Desipramine hydrochloride capsules, NF, 25 mg., 1000's. Pink. (Pertofrane). Geigy Pharm., Div ..... BT
Desipramine hydrochloride tablets, NF, 1000's. Biconvex, Round. (Norpramin). Lakeside Labs, Inc.:
25 mg., Lemon-Yellow ..... BT
50 mg., Light Green ..... BT
Diazepam injection, NF, 5 mg. per ml., 2 ml. Ampul, 10's. (Valium). Roche Labs., Div ..... BX
Diazepam tablets, NF, 500's. (Valium). Roche Labs., Div:
2 mg. (1/30 gr.), White ..... BT
5 mg. (1/12 gr.), Yellow ..... BT
10 mg. (1/6 gr.), Blue ..... BT
Fluphenazine enanthate injection, NF, 25 mg. per ml., 5 ml. (Prolixin Enanthate). E. R. Squibb & Sons, Inc ..... BT
Fluphenazine hydrochloride tablets, NF, 500's. Sugar Coated. (Prolixin). E. R. Squibb & Sons, Inc:
2.5 mg., Yellow ..... BT
5 mg., Light Green ..... BT
Haloperidol solution, NF, 2 mg. per ml., 120 ml. Colorless, Unflavored. For oral use. (Haldol). McNeil Labs., Inc ..... BT
Haloperidol tablets. Scored. (Haldol). McNeil Labs., Inc:
1 mg., Yellow:
1,000's ..... BT
5,000's ..... BT
2 mg., Pink:
1,000's ..... BT
5,000's ..... BT
5 mg., Green:
1000's ..... BT
5,000's ..... BT

Hydroxyzine hydrochloride injection, NF, 50 mg. per ml., 10 ml. (Atarax). J. B. Roerig & Co., Div VI
Hydroxyzine hydrochloride tablets, NF, 25 mg., 500s. Coated, Green. (Atarax). J. B. Roerig & Co., Div ..... BT
Hydroxyzine pamoate capsules, NF, 500s. (Vistaril). Pfizer Labs., Div.:
50 mg ..... BT
100 mg ..... BT
Imipramine hydrochloride tablets, USP. Coated, Coral, Round. (Tofranil). Geigy Pharm., Div.:
25 mg.:
100's ..... BT
1,000's ..... BT
5,000's ..... BT
50 mg., 1,000's ..... BT
Meprobamate capsules, 400 mg., 100s. Sustained-Release. (Meprospan). Wallace Pharm., Div ..... BT
Methylphenidate hydrochloride tablets, NF, 1000s. Uncoated. (Ritalin). Ciba Pharm. Co., Div.:
10 mg., Pale Green ..... BT
20 mg., Peach ..... BT
Nortriptyline hydrochloride capsules, NF, 500s. Yellow and White. (Aventyl HCL Pulvules). Eli Lilly & Co.:
10 mg ..... BT
25 mg ..... BT
Perphenazine solution, 16 mg. per 5 ml., 120 ml. with dropper. Oral. (Trilafon Concentrate). Schering Corp ..... BT
Perphenazine tablets. (Trilafon). Schering Corp.:
2 mg., 500's ..... BT
4 mg
500's ..... BT
5,000's CX
8 mg.:
500's ..... BT
5,000's CX
16 mg.:
500's ..... BT
5,000's CX
Phenelzine sulfate tablets, 15 mg., 100s. (Nardil). Warner-Chilcott Labs., Div ..... BT
Thiothixene capsules, 1000s. (Navane). J. B. Roerig and Co., Div.:
2 mg ..... BT
5 mg ..... BT
10 mg ..... BT

Sedative/hypnotics

Chloral hydrate capsules, USP, 500 mg., (7½ gr.), 100s. Unimatic (100 to Strip Pack), each individually sealed. (Noctec). E. R. Squibb & Sons, Inc. CT
Ethchlorvynol capsules, NF, 500 mg., 100s. Soft Gelatin, Red. (Placidyl). Abbott Labs ..... BT
Glutethimide tablets, NF, 0.5 Gm., 1000s. (Doriden). Ciba Pharm. Co., Div ..... BT
Methyprylon capsules, 300 mg., 500s. Amethyst and White. (Noludar). Roche Labs., Div ..... BT
Primidone tablets, USP, 0.25 Gm., 1000s. (Mysoline). Ayerst Labs., Div ..... BT
Sodium diphenylhydantoin capsules, USP, 0.1 Gm. (1½ gr.), 1000s. White Capsule with Orange Band. (Dilantin). Parke, Davis & Co ..... BT

Skeletal muscle relaxants

Carisoprodol tablets, 350 mg., 100s:
Sugar Coated, Pink. (Rela). Schering Corp ..... BT
Uncoated, White. (Soma-350). Wallace Pharm., Div ..... BT
Carisoprodol, caffeine and phenacetin tablets, 100s. Orange, Uncoated. (Soma Compound). Wallace Pharm., Div ..... BT
Chlorphenesin carbamate tablets, 400 mg., 500s. (Maolate). The Upjohn Co ..... BT

Chlorzoxazone and acetaminophen tablets, 500s. Each tablet contains Acetaminophen 250 mg., Chlorzoxazone 300 mg. Light Green, Scored. (Parafon Forte). McNeil Labs., Inc ..... BT
Methocarbamol tablets, NF, 500s. A. H. Robins Co., Inc.:
500 mg. (Robaxin) ..... BT
750 mg. (Robaxin–750) ..... BT
Orphenadrine citrate, aspirin, caffeine and phenacetin tablets, 500s. Each compressed three-layer tablet colored green, white, and yellow contains Aspirin 225 mg., Phenacetin 160 mg., Caffeine 30 mg., and Orphenadrine Citrate 25 mg. (Norgesic). Riker Labs ..... BT
Orphenadrine citrate tablets, 100 mg., 50s. Timed, White. (Norflex). Riker Labs ..... BT
Succimylcholine chloride, sterile, USP, 1000 mg. Powder. (Anectine, "Flo-Pack"). Burroughs Wellcome & Co., Inc ..... BT

Sugars

None.

Urinary tract

Methenamine hippurate tablets, 1 gm., 500s. yellow. (Hiprex). Ricker Labs ..... BT
Methenamine mandelate oral suspension, USP. Warner-Chilcott Labs., Div:
50 mg. per ml., 1 Pt. (Mandelamine) ..... BT
100 mg. per ml., 8 Oz. (Mandelamine Suspension Forte) ..... BT
Methanamine mandelate tablets, USP, Enteric coated. (Mandelamine). Warner-Chilcott Labs., Div:
0. 5 Gm. (500 mg.), Chocolate, 1000's ..... BT
1 Gm. (1000 mg.), Purple:
100's ..... BT
1000's ..... BT
Nalidixic acid tablets, 500 mg., 1000s. (Neggram Caplets). Winthrop Labs., Div ..... BT
Nitrofurantoin capsules, 1000s. (Macrodantin). Eaton Labs., Div:
50 mg ..... BT
100 mg ..... BT
Nitrofurantoin tablets, USP, 1000s (Furadantin). Eaton Labs., Div:
50 mg ..... BT
100 mg ..... BT
Phenazopyridine hydrochloride tablets, 0. 1 gm., 1000s. (Pyridium). Warner-Chilcott Labs., Div ..... BT

Vasoconstrictors

Levarterenol bitartrate injection, USP, 1:1000 (0. 2%), 4 ml. Ampul, 10s. (Levophed). Winthrop Labs., Div ..... BX

Anticoagulants

None.

Senator NELSON. When you select by a brand name, do you look at the literature to find out whether there are other therapeutic agents which do the same thing and, if so, which one is the most economical to purchase?

Dr. WELLS. This is a problem back in the hands of our professional people and referred back to the hospital committee, or comes into central office for review. But I wouldn't want to stick our pharmacists and supply people with this answer, because this really comes back to our professional services.

Mr. STATLER. Senator, if an item is put into the supply, central procurement depot system, and as you say brand name, it is only because we are able to achieve a much more favorable price by negotiation for depot stocking of this item. It is already being procured because therapeutic committees have standardized it and

it is being prescribed by physicians. The reason it is in our depot system is because we are getting a more favorable price through that channel, rather buying it on the open market under the Federal supply contract or from the manufacturer itself, so considerable savings is achieved.

Senator NELSON. For the exact formulation of that?

Mr. STATLER. For that particular formulation, right. Let's say Darvon. If they want Darvon and continue to prescribe it, if the best price we can get is to negotiate with the manufacturer and depot stock this, then the very fact we have to continue furnishing Darvon, the best thing to do is get the best possible price through our depot system, so we are able to achieve significant savings in that manner.

Senator NELSON. How do you know you achieve a saving if you selected a brand name for which there is no competitor?

Mr. STATLER. Because we know what the market price is, what it is to the outside pharmacists, what it is to other hospitals.

Senator NELSON. But all you are able to say about that is that you get a price more favorable than the wholesaler?

Mr. WHITWORTH. Sometimes, yes, sir. Very often.

Senator NELSON. But you don't know whether that is a fair price. All you know is that it is a somewhat better price than somebody else is paying.

Mr. WHITWORTH. Relatively, sir, we know that it is a very good price.

Senator NELSON. We have had many examples, you know—and I am sure you are familiar with this—where the retail price of a brand name has been 10, 20, 30 times higher than the bid price a company will make to DOD or some other agency because then they have to compete; whereas in the retail market place, if they have a well-known brand name, they aren't really competing. The doctors are writing that brand name. So they can charge some astonishing prices but when they move to compete on a bid we find them dropping the price to one-tenth or one-twentieth.

Mr. WHITWORTH. Sometimes a great deal more than that.

Senator NELSON. Sometimes more than that. So you really don't know, do you, that it is a particularly good price if you just find out that it is better than the wholesaler is getting?

Mr. WHITWORTH. Of course, we are making quantity buys that most wholesalers do not make and the companies will give us a better price because of these quantity buys. Very often the larger the quantity the better the price.

Senator NELSON. GAO's comment about that is:

Without effective competition it is a question of the Government assuring itself that prices being obtained are fair and reasonable under negotiated procurements.

We had some astonishing cases of AID paying 2,000, 10,000, and 12,000 percent over the world market price on a particular drug because it was a sole source procurement. So what I am getting at is—if you have several drugs or molecular modifications of the same drug and if the therapeutic value of each is found to be the same, do you then evaluate the costs between the two therapeutic agents or are you ordering it simply because the formulary committee at the local level says we want this particular drug with this brand name?

Mr. WHITWORTH. We depend on the therapeutics committee to select the drugs that are to be stocked, sir, and we make no professional judgments.

Dr. WELLS. They make no professional judgments, we do—I mean the purchasing staff doesn't.

Now, Dr. Haber, you wanted to add something.

Dr. HABER. I would like to point out a function of these therapeutics committees at the local level. They exercise a parsimony, if you will, of additional drugs to their formulary because they have to live within a budget. The local station people recognize when they meet that if they prescribe more effective drugs, this has the effect of reducing the amount of therapy that they can administer to our veteran patients. They can't regard this as an open-ended procedure under which they can introduce new drugs ad infinitum without regard to the expense. So there is a very disciplined effort there, and the whole structure of these therapeutic committees is to match the greatest therapeutic effectiveness with the greatest economy, and this is under surveillance of the central office committee which has the same discipline in effect.

Senator NELSON. Well, I still don't know how that would be done at the local level. If you have a selection of drugs that all have the same alleged therapeutic effect and all have passed the same standards, but there is a great variety in their price, and then the doctors at the local level simply believe that a particular brand name is much better though it costs much more, how do you handle that?

Dr. HABER. Sir, this is not in accordance with our procedures. You see, the people who are on the therapeutics committee include the pharmacist, and the chief of staff in the station who are intensely aware of the cost of drugs and part of the substantiation for new drug requests that Dr. Wells mentioned relates to the cost. If a physician at a hospital, the chief of the gastroenterology service, let's say, is suddenly made aware of a new antibiotic, for amebiasis, say, or something of that condition, he sends his submission to the Therapeutics Agents Review Committee, supports the use of this drug on a comparative basis with other known effective agents and usually such substantiation must include the cost of the drug. The therapeutics committee at the local level then is faced with a choice of adopting this drug if it appears to be so much more effective and if it is more effective, they must recognize this will inhibit their ability to purchase other drugs. So they have a builtin mechanism for practicing economy in addition to their major effect which would be to see that therapeutic effectiveness is beyond question.

Senator NELSON. I realize that formularies and therapeutics committees are relatively new as a practice, and there can be lots of argument about it, but one of the problems that bothers me is, for example, the fixed combination anti-infectives. All the experts that I know of in the United States said that they were ineffective as fixed combinations even before 1957; 13 years ago. All the experts in the country said this and knew this and it was true of your own experts in the VA, Department of Defense, in private practice, in teaching hospitals and all the pharmacologists and clinicians all agree. It was so universal that a major editorial was run in the American Medical

Association signed by 10 or 11 distinguished clinicians, including Dr. Harry Dowling, and Dr. Maxwell Finland.

Despite that, all these formularies which are supposed to be based on scientific knowledge, included these fixed combination antibiotics.

If you are planning a rational scientific method to your selection, how do you explain that, and if that can't be explained, how do we have some assurances that, in fact, these therapeutics committees are using the best available scientific knowledge since a year ago they were violating all of the best scientific methods we know of to date in this country?

Dr. WELLS. I would like to approach the answer to that, Mr. Chairman, strictly on an historical basis. I think your history is correct. I think that we have done many things that were questionable and some of them quite incorrect in medicine. As time goes on we corrected these. I would be surprised if we are not doing many things now that are incorrect that we know not of. We will learn about them, and try to correct them as best we can later.

Beginning in 1946, in VA, we did establish this type of committee just to try to prevent as far as we humanly could this type of recurring error or at least to identify it as early as possible and make the corrections. But in the last analysis the whole practice of medicine is not really a totally scientific matter, but is in part an art of practice and there are many things that we do that do require correction.

I wish we had some way of anticipating those and also of acting on them more expeditiously and perhaps more totally at any point in time. But I think really what you are recounting there is a rather unusual type of thing over the entire history of the practice of medicine in the world.

I think it can be safely said that it was the middle of the first half of this century before a patient going to a physician had an even break as to whether he would come out better or worse. Now, we are gradually improving this situation and hopefully it will be much better in the next generation. But I think we have to face the fact that historically we have done things like going on with Panalba and other things for years and not be able to correct our fault until it was really quite late in the day.

Senator NELSON. But the problem of fixed combination antiinfectives wasn't an issue in dispute among the experts. They were in agreement, whether they were right or wrong, or are even now right or wrong. They were all in agreement for at least 5 years—and your own experts would say that. So far as I know, there is no dispute over the issue. When they finally got the Kefauver bill in 1962 and finally put together the NAS–NRC panels, that is what they came up with. They just reaffirmed what the best people in medicine had known for years and years.

So all I am saying is how come, then, that if that were the agreed-upon fact without dispute in the whole profession, these fixed combinations continued to be in the formulary. Mysteclin F and Panalba were still in there a year ago.

Dr. WELLS. I think what you say is very true, but it is also quite characteristic of the practice of medicine that it simply does not

respond at any point in time to the consensus of its experts. We deal with a very large number of individuals, with individual notions about the practice of medicine. At this point in time we are not really prepared to tell them we are absolutely certain we are right and they are wrong. So we encounter these problems that require a very carefully made judgmental decision on the part of the physician who indeed has the responsibilities at the local level.

Senator NELSON. His responsibility is first to his patient.

Dr. WELLS. Right.

Senator NELSON. And therefore he ought to be applying the best knowledge available.

Dr. WELLS. But known to whom? Known to many?

Senator NELSON. No. Known to the profession, since at least within a hospital that is run by the Government we don't need to subsidize bad medical practice.

Dr. WELLS. I agree but again I think you enunciate our basic problem of education and evolution. We have to educate these people over a long period of time, and we have to be forebearant in the evolution of the practice.

Senator NELSON. Well, I guess we went through that before. It would seem to me in any event, and I will conclude arguing with you about it, if you have a position that is universally held by all the experts in the field then somebody who is not an expert shouldn't be permitted, at least in a Government hospital, to override the experts. You say to him, "Sir, all the medical experts in this country say this. You have a contrary position. You bring to us the controlled clinical studies or the evidence that overrides the position of the experts and we will accept the drug that you are using." All you have to do is to apply the rule of reason and science to the doctor. If you can't do it, you shouldn't permit the drug in your hospital and the taxpayers shouldn't fund it and the patients shouldn't have to suffer through it either.

Dr. WELLS. I would have to say that at this point in time, I would simply not be prepared to make that kind of recommendation to the Administrator of Veterans' Affairs which would mean that we would indeed be administering the practice of medicine from Washington. I doubt the expediency, the value, the ultimate worth of that judgment at this point in time.

Senator NELSON. All right. Go ahead.

Dr. WELLS. In reference to the 13 items under special study and beginning at the top of page 6, we anticipate issuing invitations for bid on these items in a few weeks. Our experience with these 13 items will determine how we proceed with the remainder. We have also directed that a continuous review be made for all items procured on a non-competitive basis to determine if there are potential competitors who can meet our requirements. I must emphasize, however, that this does not mean that we, in any way, are cutting our quality standards. We recognize that the area of quality standards employed in the manufacture and control of drugs is in some instances a matter of subjective judgment. We intend to do the best we can. We plan additional training for our plant inspectors. We likewise will use the facilities of other Federal agencies insofar as

feasible to augment our own efforts and to reduce duplication of effort.

In recent testimony before this subcommittee it was recommended that the Food and Drug Administration assume the responsibilities now discharged by the procuring agencies for plant inspection and quality control surveillance. The Veterans' Administration would favor such action, provided that such inspections were conducted in a timely and comprehensive manner relating to our procurement requirements, and provided that sufficient data to support our determinations on responsibility of bidders is made available to us. At present, detailed inspection reports of the Food and Drug Administration on specific manufacturers' facilities where products are manufactured for us under contract are not made available to us. Federal Procurement Regulations, subpart 1–14, place the responsibility for inspection and acceptance of supplies, including drugs, upon the contracting agency. We have extensively used the facilities of Federal inspection services such as those provided by the Department of Agriculture, Department of Defense, National Bureau of Standards, Department of Interior, when those agencies performing these services for us provide us with sufficient information to assure that we are discharging our responsibilities. There are no statutory exemptions from the requirement that Government procurement agencies must assure themselves by such means as inspection that the product being procured meets essential Government requirements, even though the industry may be operated under controls of a Federal regulatory agency.

It was also brought out in recent testimony that there was a need for greater cooperation and exchange of information among the Federal agencies engaged in drug procurement, quality control and product safety. The Veterans' Administration had exchanged information with Defense Supply Agency on vendors, plant inspections, pricing and quality control data on a widespread basis. Recently this exchange had been limited to pricing and market data and to adverse findings as the result of plant inspections. We also report to the Food and Drug Administration adverse drug reaction information. All the Federal agencies having an interest in drug procurement, regulation and control are members of the Intra-Governmental Professional Advisory Council for Drugs and Devices. We have asked that council to immediately request its member agencies to expand their exchange of information and to study and develop means for broadening and improving this exchange. I have been informed that both actions have been initiated.

We previously reported that a substantial number of the drugs used in our medical care program are available only from one source because of patents. These drugs account for about 80 percent of our dollars. It was suggested that the Federal Government can use a patent without the permission of the patent holder and without subjecting itself to damages for such use. While it is true that the Government cannot be held liable for a patent infringement as such, it is not held free from any financial liability to the patent holder. Title 28 USC 1498 provides that such a patent holder may bring suit in the U.S. Court of Claims for remuneration for the use of his

patent by the Government. At least one such suit is currently pending in the Court of Claims involving the Veterans' Administration purchase of the drug meprobamate. In addition to the questions of suits for the use of patents, there are several other major policy questions to be considered if a drug is to be procured from foreign sources. In any procurement action we are governed by statutes and regulations and national policy regarding balance of payments, the Buy American Act, special assistance to economically depressed areas. It is difficult to arrive at a rational judgment as to when to purchase drugs from someone other than the patent holder and especially from foreign sources when weighing these considerations against purchase cost alone. As we mentioned previously, even though a product is marketed from foreign sources at a significant price differential, we are still not free to procure it unless the Food and Drug Administration has approved an effective New Drug Application for its importation into and use in this country. Title 21, Code of Federal Regulations 130 extends this requirement to Federal agencies as well as to individuals and organizations.

I believe the actions we have described today will bring about a continuing, long-range improvement in the selection process of those drugs we include in our hospital formularies and which we purchase. It could result in some economies in drug procurement; it should result in assuring that our policy of rational drug selection and use is carefully and thoughtfully followed. As the Administrator of Veterans' Affairs testified to this subcommittee on August 11, 1970, this subject is both complex and complicated, and one in which there is continual controversy. We do not feel that the physicians practicing in and for the Veterans' Administration have a callous and cavalier attitude toward the cost of drugs prescribed and purchased from public funds. We do not believe cost is the primary factor in selecting the drug of choice, nor do we believe it should or can be. The physician, in selecting the drug for treatment of his patient, chooses the one which he considers the most effective. In making his choice, he is confronted with a large number of drugs, for which there are sometimes conflicting claims, a division of opinion among the experts, contradictions between his own clinical experience and judgment and the reported controlled test results. You may be interested to know that Veterans' Administration facilities have established policies restricting detailing activities of pharmaceutical representatives. Generally, these policies prohibit indiscriminate detailing and sampling of physicians. Provisions are made for appointments between physicians and representatives where specific information is desired.

We are very much interested in the forthcoming publication by the American Medical Association of a drug compendium. We feel much greater efforts along this line are needed to assist the physician in his selection of drugs. We believe that while some data are now available from some publications, there is not always a sufficiently broad consensus to persuade the physician that his choice is clear. One of the National Academy of Science/National Research Council panelists testified before this subcommittee that the black and white of expert testimony with respect to drug effectiveness is simply not

that clear. Another panelist agreed and brought out that many of the decisions of NAS–NRC panels represented majority views rather than unanimous decisions. This, in our opinion, may account for the continued use of drugs which have been classified by FDA, at some point, as other than effective for all indications claimed. In examining our position in the Veterans' Administration, a specific example illustrates the reason for such choices. The question has previously been raised about the value of chlordiazepoxide compared with barbiturates. We talked about this at our last hearings. Although quite disparate in cost, some experts share the view that they are equally effective and free from adverse side effects. Other experts, including those in the Veterans' Administration who had done very extensive clinical evaluations, disagree that they are equally desirable alternative drugs of choice for all manifestations. I also believe that the three panelists from the NAS–NRC panel on psychiatric drugs testified before your subcommittee that there were conditions in which either drug was a suitable drug of choice, but there were other conditions, notably moderate to severe psychosis or long-term therapy requirements in which they do not agree that barbiturates were comparable to chlordiazepoxide in therapeutic effect or safety. In this Agency, both barbiturates and chlordiazepoxide are used in our psychiatric program.

In conclusion we feel the problem is one that can best be solved by education and by a meaningful and timely flow of information to the prescribing physician. We cannot reasonably expect our physicians to base their medical decisions on the opinions of one expert or one publication or to reasonably choose between the divergent opinions of several experts without a sufficient battery of information to support their decisions. Compendia, digests of drug information and probably some educational programs not now in existence offer, in our opinion, greater hope for improvement than formularies compiled in Washington, often remote from the actual practice of medicine, if such formularies propose to restrict the availability of drugs contrary to the expert and enlightened opinion of the physician who has the actual responsibility for the health of the patient. It is our job to see that his opinion is an enlightened one, not to direct his selection of drugs for his patient, but rather to see that he makes an informed and knowledgeable choice and that he has readily available to him data on which to base this choice. We feel that such an approach will enhance rational prescribing more effectively than one which proposed to regulate judgment. We reaffirm our policy that the administrative process does not dictate the selection of drugs which will be prescribed and dispensed in our Veterans' Administration hospitals and clinics. We recognize that our own system for assisting our physicians in rational choices can be improved. We believe the deficiencies which exist in our system in this respect, are the same deficiencies found in the entire Nation's health care system. We have a problem in which the dissemination of information is not keeping pace with the need for that information. Perhaps the efforts of this subcommittee, in focusing attention on this problem, will stimulate more intensive efforts and speed up needed improvement.

Mr. Chairman, this concludes my statement. We will be happy to continue with members of the panel here.

Senator NELSON. After you have negotiated a contract, have you ever asked the General Accounting Office to examine the company's production costs so that you can find out whether or not the price you paid was a fair price?

Dr. WELLS. No. The answer is no.

Mr. WHITWORTH. No, we have not.

Senator NELSON. Why not?

Mr. WHITWORTH. Well, as Mr. Staats testified, they don't have to be asked. They can come in and do it at their own instance.

Senator NELSON. If I understand Mr. Staats correctly, since the law authorized the GAO to examine cost in a contract that you have negotiated, even if they haven't initiated on their own, why hadn't you requested them to do that so you could find out whether or not you were paying a fair price?

Dr. WELLS. That sounds like a good idea to me, Senator Nelson. I really don't know. If our procurement people don't, I am sure I don't, why we haven't literally sought this type of review. GAO does review a lot of procurement practices and certainly contract practices, but I don't know about this.

Senator NELSON. You are buying repeatedly, year after year, on a negotiated basis, as are other agencies, and the law authorizes GAO to go in and examine the company's production costs. It seems to me that it would be an obligation for you to request this.

Mr. WHITWORTH. The fact remains, Senator, that I have behind me the manager of our marketing center in Chicago and he tells me we have never done so.

Senator NELSON. Well, do you intend to consider doing so?

Dr. WELLS. I think we should explore this as one possible avenue to shore up our purchasing techniques and contract compliance, yes.

Senator NELSON. As one further method of checking reasonableness of your negotiated contracts, do you check the prices in the foreign countries for the same product sold by either our own or by foreign countries?

Mr. WHITWORTH. You mean the prices of American manufacturers' products sold in foreign countries?

Senator NELSON. Either one.

Mr. WHITWORTH. We do our best to get the information from domestic companies. I think we asked 48 companies in the last—since the hearings in August to give us the foreign prices. Three only gave us those prices.

Senator NELSON. Three? You asked them in August?

Mr. WHITWORTH. After the hearings in August. It was between September and the middle of October.

Now, as far as the foreign drug prices are concerned, we do have a number of catalogs from foreign drug manufacturers that we can make spotty comparisons, sir. But we have not made any or been able to make any organized comparison except in the Canadian market, and since the last hearings we have made rather an extensive comparison of Canadian prices versus our own and we are in a better position most of the time. We have a better price. But that is the Canadian market.

Now, we asked 48 firms; 23 did not reply. Twelve don't sell their products on the foreign market. Eight didn't give us a definitive price. One firm dealt in bulk sales only. We received price lists from three firms.

Senator NELSON. Twenty-three didn't reply at all?

Mr. WHITWORTH. No reply at all.

Senator NELSON. Well, I hope that you would consider having the GAO examine the costs of negotiated contracts. If I understand the law correctly, it has to be done after the contract is negotiated, but in any event, that would inform you for future negotiations.

Mr. WHITWORTH. Well, Senator, we will consider that, yes, sir.

Senator NELSON. Thank you very much.

We will meet in this same room tomorrow at 10 o'clock and the witness will be the Department of Defense.

Thank you very much, gentlemen.

(Whereupon, at 12:20 p.m., the Subcommittee on Monopoly of the Select Committee on Small Business adjourned, to reconvene the following morning at 10 a.m., Wednesday, February 3, 1971.)

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

(Present Status of Competition in the Pharmaceutical Industry)

WEDNESDAY, FEBRUARY 3, 1971

U.S. SENATE,
SUBCOMMITTEE ON MONOPOLY OF THE
SELECT COMMITTEE ON SMALL BUSINESS,
Washington, D.C.

The subcommittee met, pursuant to recess, at 10:12 a.m., in room 1318, New Senate Office Building, Senator Gaylord Nelson (chairman of the subcommittee) presiding.

Present: Senator Nelson.

Also present: Benjamin Gordon, staff economist; Elaine C. Dye, clerical assistant; and Keith A. Jones, minority counsel.

Senator NELSON. Our witness today is Brig. Gen. George J. Hayes, Medical Corps, U.S. Army, Principal Deputy Assistant Secretary of Defense (Health and Environment).

General, the committee is pleased to have you here this morning. Your statement will be printed in full in the record. You may present it however you wish and if your associates wish to comment, they may feel free to do so, but should identify themselves for the reporter so the record will be clear.

Please proceed, General.

STATEMENT OF BRIG. GEN. GEORGE J. HAYES, MEDICAL CORPS, U.S. ARMY, PRINCIPAL DEPUTY ASSISTANT SECRETARY OF DEFENSE (HEALTH AND ENVIRONMENT); ACCOMPANIED BY COL. M. E. McCABE, MC, USA, OFFICE OF THE SURGEON GENERAL, DEPARTMENT OF THE ARMY; CAPT. L. M. FOX, MC, USN, CHIEF, MEDICAL SERVICE, NAVAL HOSPITAL, BETHESDA, MD., AND CHAIRMAN, PHARMACY AND THERAPEUTIC DRUG COMMITTEE; COL. E. J. CLARK, MC, USAF, OFFICE OF THE SURGEON GENERAL, DEPARTMENT OF THE AIR FORCE; CAPT. R. F. C. MacPHERSON, MC, USN, DIRECTOR OF MEDICAL MATERIEL, DEFENSE PERSONNEL SUPPORT CENTER; COL. A. J. SNYDER, MSC, USA, CHIEF, DIVISION OF MEDICAL MATERIEL, DIRECTORATE OF PROCUREMENT AND PRODUCTION, DEFENSE PERSONNEL SUPPORT CENTER; AND MAX FEINBERG, ASSISTANT CHIEF, DIVISION OF TECHNICAL OPERATIONS, DIRECTORATE OF MEDICAL MATERIEL, DEFENSE PERSONNEL SUPPORT CENTER

General HAYES. Mr. Chairman, it is my pleasure to appear before you today to bring you a further report on the procurement of drug products by the Department of Defense. I should like to introduce my colleagues.

Col. Marshall E. McCabe, MC, USA, Office of the Surgeon General, to my right; Capt. L. M. Fox, MC, USN, Chief, Medical Service, Naval Hospital, Bethesda, Md., and Chairman, Pharmacy and Therapeutic Drug Committee, far right; Col. E. J. Clark, USAF, MC, Office of the Surgeon General; Capt. R. F. C. MacPherson, MC, USN, Director of Medical Materiel, Defense Personnel Support Center (DPSC); Col. A. J. Snyder, MSC, USA, Chief, Division of Medical Materiel, Directorate of Procurement and Production, DPSC; and Mr. Max Feinberg, Assistant Chief, Division of Technical Operations, Directorate of Medical Materiel, DPSC.

Probably no other event in recent years has had an impact on the practice of medicine in the United States equal to that of implementation by the Food and Drug Administration (FDA) of the National Academy of Science-National Research Council (NAS–NRC) study on drug effectiveness. Results first became apparent in federal agencies because their hierarchal organizational structures foster rapid communication with subordinate activities through a variety of media. Consequently, we in Government have been able to take the first definitive steps to reap the medical and economic benefits of the study. We have implemented our actions at three levels: DOD, Defense Medical Materiel Board (DMMB), and in the services themselves.

The Assistant Secretary of Defense (Health and Environment) has issued a memorandum to the Surgeons General of the Services outlining DOD policy as it applies to drug products categorized as other than "effective." Our policy prohibits further procurement or issue of ineffective products, and directs appropriate disposal of existing stocks. We have similarly terminated procurement of "possibly effectives," with one minor exception, but will withhold disposal

until final FDA regulatory action is directed. We contemplate few problems with the "probably effective" category, but here, too, we have established controls.

Senator NELSON. May I interrupt a moment, General?

General HAYES. Certainly.

Senator NELSON. What is the exception to the "possibly effective" drugs?

General HAYES. That is where no other drug for this purpose exists at this time, similar to the HEW Public Health Service position.

Senator NELSON. When there is no other drug that treats the condition which the "possibly effective" drug purports to treat. Is that what you are saying?

General HAYES. That is correct.

Senator NELSON. You say you have established controls for the "probably effective" drugs. What kind of controls? What do you mean by that?

General HAYES. Well, much the same as with the possibly effectives.

Senator NELSON. Pardon?

General HAYES. Much the same as with the possibly effective. Limited procurement here rather than total nonprocurement, directing a very careful evaluation of the utilization of the items both by the individual prescriber himself, by the Pharmacy and the Therapeutic Agents Board.

Senator NELSON. So you are saying again that if there is a drug that is effective for treating a particular condition, that you will not authorize the use of a "possibly" or "probably" effective drug for the same condition?

General HAYES. That is correct. I could read, after I finish the whole statement, or here at your pleasure, the memo that Dr. Rousselot sent to the three Services which really outlines this pretty well.

Senator NELSON. How long a memo is it?

General HAYES. Page and a quarter.

Senator NELSON. Why don't you read that at the end of your statement.

General HAYES. Pending a decision on ultimate classifications, we are reducing our stock levels of these products to the minimum, and continually monitoring developments in FDA.

Also as a result of the study, Dr. Rousselot has appointed a study group to review our entire stock list of drugs, and make recommendations for their retention or deletion. The group is chaired by the staff director, DMMB, and has the advice and assistance of the professional consultants to the Surgeons General. The review is now in progress.

In addition to the actions generated by the study, DOD has directed the Surgeons General to emphasize the use of the most cost-effective medications whenever professionally appropriate.

DMMB has established an effective liaison with FDA which, for the first time, will ensure that our file of FDA actions is complete and accurate. This liaison has enabled DMMB to provide to the Services identical and validated data on the Study of Drug Effectiveness. The DMMB procedures eliminate duplication of effort by the Services, and insure that all Services will have all the information.

In a related action, DMMB has deleted all amphetamines and amphetamine-like drugs from military sets, kits, and outfits. Our concern was generated not by the study, but by a desire to minimize pilfering and misuse of these stimulants.

The Services are accelerating their programs of education and policy direction in the field of drug therapy. Service Pharmacy and Therapeutic Drug/Formulary Committees have been directed by their respective headquarters to review their formularies and their procedures. Since this activity has been stimulated by the Study on Drug Effectiveness, much of the material relates to the drugs so categorized. In addition to statements of policy in these matters, the Services disseminate to their professional staffs the listings of drugs released by FDA. These listings are used collaterally as another basis for emphasizing the necessity for cost-effective prescribing habits.

Mr. Chairman, we have analyzed some of the statistics resulting from the NAS–NRC study. As of January 21, 1971, our liaison with FDA, and our screening of the Federal Register, has resulted in lists of 359 drug products classified as "ineffective," and (as of January 12, 1971), 189 classified as "possibly effective." As of the date of publication in the Federal Register, DOD had in standard stock only five of the "ineffectives," and 16 of the "possibly effectives," from a total of 1,100 drug products.

Mr. GORDON. General, may I interrupt you a moment. Is there any indication as to how many of the "probably effective" drugs you have?

General HAYES. We have no information as yet on that.

Mr. GORDON. Could that be supplied for the record?

General HAYES. We can supply it for the record.

(The information above-referred to, follows:)

PROBABLY EFFECTIVE DRUGS

The Department of Defense has identified five centrally stocked pharmaceuticals as being classified "probably effective." They are:

Federal Stock Number	Description
6505-290-6032 (Fed Reg 24 Jun 70)	Bacitracin, USP, Powder for Topical and Intramuscular Use, 50,000 units
6505-122-6984 (Fed Reg 18 Aug 70)	Benzathine Penicillin G and Procaine Penicillin G Suspension, 300,000 units each, 1cc, 20s
6505-682-6538 (Fed Reg 18 Aug 70)	Benzathine Penicillin G and Procaine Penicillin G Suspension, 600,000 units each, 2cc, 20s
6505-890-1599 (Fed Reg 18 Aug 70)	Benzathine Penicillin G, Procaine Penicillin G, and Potassium Penicillin G for Injection, 300,000 units each, Powder
6505-687-8459 (Fed Reg 18 Aug 70)	Procaine Penicillin G and Potassium Penicillin G in Oil, 400,000 units, 1cc, 20s

Senator NELSON. As a related question, on page 2 you refer to a study group to be headed by Dr. Rousselot to review your entire stock list of drugs, and make recommendations for their retention or deletion, which I think is an appropriate step to take. But in dealing with the question of rational prescribing, you state:

> In addition to the actions generated by the Study, DOD has directed the Surgeons General to emphasize the use of the most cost-effective medications whenever professionally appropriate.

I notice that the Defense Department spent about $3 million in 1968–69—I don't have the 1970 figures—on a number of tetracyclines, demethylchlortetracycline, oxytetracycline, and chlortetracycline. If the Department had heeded the advice of the medical experts and used the drug of choice of that family of antibiotics, that is, plain tetracycline, our calculation is that $2,300,000 would have been saved. I am sure you realize it is the position of the Medical Letter that tetracycline HCL is an equivalent of the other members of the tetracycline group. Dr. Simmons of the Food and Drug Administration says the same thing.

Well, while counsel finds the comments of Dr. Simmons, Dr. Heinz Eichenwald, professor and chairman of the Department of Pediatrics, University of Texas, who was chairman of one of the NAS–NRC antibiotic panels, states, "Similarly, a large group of tetracyclines have been prepared. Basically none of them are superior to the parent molecule, tetracycline itself."

Dr. Simmons, Director of the Bureau of Drugs, FDA, states:

> At the present time—take tetracyclines which you had a lot of testimony on—there are about five different chemical formulations of tetracycline. Now, all of them have minor differences which present and old labeling have shown and on which advertising claims have been made. The important thing, however, is that these are minor differences, though they are clinically insignificant. And, therefore, there is no reason why a physician should choose one as opposed to the other.

Do you agree with the position of Dr. Eichenwald, Dr. Simmons, and the Medical Letter on the tetracyclines?

General HAYES. Essentially we do.

Senator NELSON. Well, what is the explanation?

General HAYES. I would like to answer that a little further and have Colonel Snyder respond to part of that question, what our actual proportion of procurement was at that time.

Colonel SNYDER. Mr. Chairman, there are approximately five major forms of tetracycline and during the period July 1, 1968, through last Friday we procured something over 300 million dose forms of the standard generic tetracycline. As opposed to that we procured about 45 million doses—of all other forms of tetracyclines. I have figures with me that we can provide for the record.

(The information referred to follows:)

TETRACYCLINE (and TETRACYCLINE-like) PROCUREMENT
(expressed in doses)

Federal Stock Number	Description	No. of Doses procured 1 Jul 68 to 29 Jan 71
6505-159-6575	Chlortetracycline HCI Capsules, 0.25 GRAM	22,808,400
	Demethychlortetracycline HCI Tablets:	
6505-890-2081	0.15 GRAM	3,168,000
6505-782-6485	0.30 GRAM	552,960
6505-142-9140	Doxycycline Hyclate Capsules, 50 MGM	691,200
6505-299-8276	Oxytetracycline Tablets 0.25 GRAM	17,669,600
	TOTAL Doses of "Tetracycline-type" items:	44,890,160
6505-286-7302	Tetracycline HCI Tablets, 0.25 GRAM	299,061,600
6505-782-6481	Tetracycline HCI Tablets, 0.25 GRAM	1,075,680
	TOTAL Doses of Tetracycline items:	300,137,280

Enclosure 3

Colonel SNYDER. The principal difference—there is a difference in cost and when you think in terms of dollars as opposed to terms of dose forms, it seems substantial, but we are buying in very large quantities and what seems to be an inordinate amount is a very small percentage of the total.

Senator NELSON. But if our figures are correct, you paid $3 million for these and other formulations of tetracycline HCL. You could have saved $2,300,000 or, in other words, bought tetracycline HCL for $700,000 instead of $3 million, which seems to me is substantial. I wonder what the justification is unless there is a medical justification.

Colonel SNYDER. I won't speak to the prescribing habits but actually 85 percent of the total prescribed is generic.

General HAYES. Mr. Chairman, I think we have to put in this somewhat proper time reference and the purchasing time, 1968 to last year—this kind of information was not available and this carefully reasoned study of the NAS–NRC type was not available to the people who were prescribing or purchasing.

Now I think if we put it in the proper time, I would like to get a little later on into what we are doing with the very useful tool that we have at the present time to accomplish what you are talking about.

Senator NELSON. The Medical Letter was dated 1968. Counsel says he is not sure. It might have been 1969.

The counsel reminds me that the NAS–NRC didn't cover these tetracyclines. They weren't part of this study on efficacy. I guess nobody is arguing about the efficacy of any of these variations of the tetracyclines. The only question is the price.

What the drug companies have done is taken tetracycline, made some modifications, put a brand name on them, and charged a higher price, while the Medical Letter and medical scientists are saying they all do the same thing. Why pay the higher price?

General HAYES. We will now turn from a discussion of what we have to why we have it, and how to get it. It is DOD policy that our stock list shall consist of quality drug products procured competitively on generic specifications; and at the most economical prices we can obtain.

We cannot procure competitively without a generic specification. Our standards are basically those of the USP and NF, supplemented with such additional standards as are necessary to insure suitability not only at the time of procurement, but also following possible long-term storage throughout the world in Artic, Temperate, or Torrid zones. Many of our specifications include standards which have been obtained from industry during the standardization procedure. If we are to obtain suitable materiel competitively, we must include these details in order to provide other than product originators with the necessary product information.

The specifications are developed, and procurement is effected by the Defense Personnel Support Center (DPSC). Each DPSC solicitation (other than an emergency purchase) is directed to all firms on the bidders list, and each solicitation for $10,000 or more is published in the Commerce Business Daily. In fiscal year 1970, 16.9 percent of

our purchase actions, representing 27.2 percent of our purchase dollars, resulted from competition between two or more bidders. Additionally, as was reported to you by Comptroller General Staats, in January of 1969 DPSC surveyed about 1,000 firms in an attempt to increase competition in the procurement of some 400 items, 290 of which were single source. As Mr. Staats noted, only 104 companies replied, and 88 of those replies were negative in nature. This low rate of positive response is another indication of the problems faced by DPSC in its continuing objective of expanding competition, and increasing the participation of small business.

It is appropriate to mention here that the solicitations mentioned previously are also provided to representatives of foreign drug industries. When we know of a specific foreign manufacturer or foreign licensee, DPSC makes overtures directly to that company. While we do successfully buy a few products in Europe, and we will continue to do so when permitted by law and administrative regulation, more frequently the attempt is frustrated. In a recent example, we learned that the price of chlorpromazine in Canada was materially lower than our then current contract price. The Canadian licensee refused to bid on our requirements, as their licensing agreement restricted their sales to Canadian customers.

Senator NELSON. May I ask a question there, General?

General HAYES. Certainly.

Senator NELSON. Hasn't the patent run out on chlorpromazine?

General HAYES. Yes.

Senator NELSON. What was the date of the Canadian company's refusal to bid?

Colonel SNYDER. This was a verbal inquiry by me, Senator Nelson, and at the time this was the answer given, the reason they did not submit an offer. I have talked to them as recently as last week. They say now that they will bid, that their license does not preclude participation. However, they do not have an NDA, which is one of the problems that we are faced with continually.

There is no patent now prohibiting—their license does not prohibit. The NDA is now the bar. We talked to the president personally, as a matter of fact, twice last week.

Senator NELSON. In any event, then, previously you had to buy chlorpromazine from the American licensee?

General HAYES. Yes.

Senator NELSON. Let me read you this. This is from a hearing held in 1968.

> Rhone-Poulenc, a French firm, discovered chlorpromazine. They licensed a company in the United States to produce it and they licensed a company in Canada to produce it, each of them with the exclusive market in their respective countries. So neither the company in the United States nor the company in Canada spent any money on research. It was just a question of each one of them having an exclusive market, both in the same Continent, with adjoining borders.
>
> The price charged by the U.S. licensee for 25-milligram tablets to the Defense Supply Agency was $32.62 a thousand. The price of the Canadian licensee to Canada's Department of Veterans Affairs was $2.60 a thousand.

Now, that was a figure we were using in 1968. I don't know what you had to pay in 1969 and in 1970. But are you aware of the statute referred to by Mr. Staats, the Comptroller General, in his testimony

to the effect that under the statute, after a negotiated contract has been completed, the GAO has the authority to go in and examine the production costs of the seller to find out whether the price charged is reasonable? I think I state the statute correctly. Are you aware of that?

General HAYES. Yes, we are.

Senator NELSON. Why shouldn't you ask the GAO to do that? This is such a dramatic difference when we have two licensees on the same continent with common borders, one selling for over $32—$32.62 for a 1,000 to our Defense Supply Agency and another company selling the same product as a licensee to Canada's Department of Veterans Affairs for $2.60.

It would seem to me that would be just exactly the kind of situation in which the statute ought to be used because certainly the cost of production can't be that great. If they can make a profit on the $2.60 in Canada, the profit made in this country must be very great. Why shouldn't the statute be used in that case?

Colonel SNYDER. Really this is a policy decision. I assure you it will be explored. We discussed this with the GAO people and they were going to look into it. We have not traditionally audited fixed price contracts on a post-contractual basis. We always audit cost-type contracts. We do not normally audit fixed price.

It is certainly something that warrants investigation and it will be done.

Senator NELSON. Well, it just seemed to me we have examples with such dramatic differences—this is a price differential of about 14 times—that with the statute there and the Department having to negotiate to buy, with no knowledge of whether it is reasonable or not, that this is the kind of occasion when we ought to have this kind of an audit, particularly when you know what the Canadian licensee is selling it for.

Colonel SNYDER. In almost every instance where you have a substantial price difference between a domestic and overseas or a Canadian supplier, there is also an added factor of an NDA or some FDA control that also limits it.

These are things that have to be explored and I am sure they will be.

Senator NELSON. Well, it works both ways. I have looked at prices in Canada and found a number of retail prices, that is, prices charged to the pharmacist for brand name drugs in Canada higher than the prices charged here in the United States. And substantially lower for the same product—perhaps one-fifth as much—in Switzerland and Italy by the same company. We end up with them charging $4 or $5 a hundred more for a product in Canada than they charge in the United States where it is made, or one-fourth or one-fifth as much in Europe after the company that made it in the United States shipped it over there.

So I don't see how anybody could claim that the price differential based upon cost of production and reasonable profit, could range from $2.60 a thousand in Canada to $32.62 in the United States.

Colonel SNYDER. I make no such claim.

Senator NELSON. Please proceed.

General HAYES. We inspect our successful bidders and monitor batch analyses of their output to insure that the Government gets what it pays for. Within the Defense Contract Administration Service (DCAS) are approximately 75 inspectors who have been trained in the drug field. The time spent by these inspectors working in the drug-related field, plus 11 DPSC employees who are at times requested to assist DCAS, equates to approximately 20 man-years per annum.

DOD performs these inspections on a product basis. While FDA periodically inspects drug plants to insure compliance with their good manufacturing practices (GMP), they neither register the products supplied by each manufacturer, nor, except for antibiotics, do they routinely test the products. As indicated previously, we must inspect and analyze these products to insure that they are useful and are what we pay for.

Mr. Chairman, that completes my formal statement. My colleagues and I will attempt to answer any further questions you may have.

Senator NELSON. You have that page and a half?

General HAYES. Right. I will read it.

Senator NELSON. Please read that into the record.

General HAYES. That is a memorandum to the Director of the Defense Supply Agency, to the Surgeons General of the Departments of the Army, Navy, and Air Force, and Chairman of the Defense Medical Materiel Board, subject: DOD implementation of the drug efficacy study, dated January 21, 1971.

The Food and Drug Administration, after review of the drug efficacy findings of the National Academy of Sciences/National Research Council on drug products approved by FDA between 1938 and 1962, has published notices in the Federal Register with the classification of "ineffective" and some "possibly effective." The NAS/NRC panel also classified some drug products as being "probably effective."

After careful review and consideration of these findings, it has been determined that Department of Defense policy regarding the procurement and prescribing of these three categories of drug items will be as follows:

1. **"Ineffective"**
   - (a) **No further procurement or issue is authorized for those items that have been withdrawn from the market. Remaining stocks of standard items will be destroyed or other appropriate action taken.**
   - (b) **Those items awaiting final determination by FDA will no longer be authorized for central or local procurement until final action is taken by the FDA. All present stocks are to be suspended until status is resolved.**
2. **"Possibly Effective"**
   - (a) **Standard and local procurement of these items are no longer authorized.**
   - (b) **Pharmacies and Therapeutic Agents Committees are to question all prescriptions prescribing these drug items.**
3. **"Probably Effective"**
   - (a) **Minimize all central and local procurement of these items.**
   - (b) **Continually monitor centrally these items and immediately notify all medical facilities as to change in classification by FDA.**

There are many high cost drugs being prescribed when equally effective but much less expensive drugs are available. Request you advise using medical facilities as to cost/effective ratio and direct use of most economical item when appropriate.

Request that the policy guidance outlined in the foregoing paragraphs be disseminated to all medical facility commanders worldwide.

(Signed) LOUIS M. ROUSSELOT, M.D., F.A.C.S.

Now, we do have the exception that we discussed, a possible use of a possibly effective where there is nothing else that can be found to satify the need at that time. We have already discussed that.

Senator NELSON. And the same is true of the " probably effective" drugs; is that correct?

General HAYES. Beg pardon?

Senator NELSON. And the same rule applies to the "probably effective" drugs?

General HAYES. We didn't delineate it that clearly for that because the probably effective group is sort of in limbo a little bit.

Senator NELSON. This is a continuation of the question I raised about the various tetracycline modifications that we were talking about a little while ago. Will it be or is it your policy at this time to review the purchase of so-called or what you might call "me-too" drugs, that is, drugs that perform the same function as another drug that is well established and is demonstrated to be just as effective? Will it be your policy to review these "me-too' drugs that cost more and perform the same function and eliminate them from your purchasing policy?

General HAYES. Well, as a result of the continuing actions resulting from these hearings, from the NAS–NRC studies, we talked this over with the Defense Medical Materiel Board and on January 25 further implementation of the memorandum I just read. The Chairman of the Board sent out a subject "Committee Review of Special Interest Items." It changed the review approach that I mentioned earlier of all line items, line by line in the standard pattern, to looking at certain areas of special interest.

Thirty areas have been identified at the present time. I will read just a little bit of this memorandum to give an idea of how we are going at it.

This is paragraph 3 of the memorandum:

An abbreviated item review report is given below as an example of Committee action. Number one is Declomycin, two is Aureomycin, three is Terramycin. In the discussion, medical authorities state that tetracyclines do not differ in any essential characteristics and are essentially identical in terms of antibacterial activity. The difference in pharmacologic activity due to molecular modifications are relatively minor in importance. Differences in costs are significant.

Recommendation. That items one, two, and three above be reclassified as limited standard with eventual deletion from the Federal Supply Catalog, retain generic tetracycline hydrochloride as a standard item.

Now, we have another enclosure to this which lists by what you might call class actions a similar approach to 30 different areas. I will list a few of them or all of them at your desire. Anti-infective drugs, antihistamines, coronary vasodilators, vasodilators, sedatives, hypnotics, gastrointestinal antispasmodics, antacids, skeletal muscle relaxants, antiemetics and analgesics.

In each of those major headings are varying numbers of specific items by line item.

Senator NELSON. Would you supply the committee with a copy?

General HAYES. We will be glad to.

(The information above-referred to, follows:)

DEFENSE MEDICAL MATERIEL BOARD
POTOMAC ANNEX, 2300 E STREET NW.
WASHINGTON, D.C. 20390

ADDRESS REPLY TO:
STAFF DIRECTOR, DEFENSE
MEDICAL MATERIEL BOARD
AND REFER TO:
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Serial: 86
25 January 1971

MEMORANDUM

From: Chairman, FSC Class 6505 Review Committee
To: Assistant Secretary of Defense (Health and Environment)

Subj: Committee Review of Special Interest Items; Report of

Ref: (a) ASD (H&E) Memo dated 27 Oct 1970

Encl: (1) List of 30 Items Proposed for Reclassification to "LIMITED STANDARD" with Eventual Deletion from the Federal Supply Catalog
(2) Committee Recommendations Covering "Special Interest" Items

1. In accordance with reference (a), a line item review of all FSC Class 6505 is being conducted. The modus operandi of the Committee will be review by therapeutic group as listed in the Federal Supply Catalog.

2. Because of the current interest in certain drugs, the Committee deviated from its planned order of review. Enclosure (1) is a list of 30 items considered to be of "special Interest", which was forwarded to the professional consultants on January 11 and 14 1971, with the proposal for reclassification to Limited Standard and ultimate deletion from the Federal Supply Catalog. Service position or appropriate comments were requested.

3. An abbreviated item review report is given below as an example of committee action:

1. 6505-890-2081 DEMETHYLCHLORTETRACYCLINE HYDROCHLORIDE TABLETS, 0.15 GRAM (DECLOMYCIN)

2. 6505-159-6575 CHLORTETRACYCLINE HYDROCHLORIDE CAPSULES, 0.25 GRAM (AUREOMYCIN)

3. 6505-299-8276 OXYTETRACYCLINE TABLETS, 0.25 GRAM (TERRAMYCIN)

DISCUSSION: 1. Medical authorities state that the TETRACYCLINES do not differ in any essential characteristics and are essentially identical in terms of antibacterial activity. The differences in pharmacologic activity, due to molecular modifications, are relatively minor in importance.

2. Differences in costs are significant.

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RECOMMENDATION: That Items 1, 2, and 3 above be reclassified as "LIMITED STANDARD" with eventual deletion from the Federal Supply Catalog. Retain generic TETRACYCLINE HYDROCHLORIDE 0.25 GM (FSN 6505-286-7302) as a standard item.

4. Enclosure (2) represents the complete detailed committee actions on the "special interest" items.

Wm. G. LAWSON

List of 30 Items Proposed for Reclassification to "LIMITED STANDARD" with Eventual Deletion from the Federal Supply Catalog

ANTI-INFECTIVE DRUGS

6505-853-8608 SODIUM CLOXACILLIN CAPSULES (TEGOPEN)
6505-890-2081 DEMETHYLCHLORTETRACYCLINE HYDROCHLORIDE TABLETS (DECLOMYCIN)
6505-782-6485 DEMETHYLCHLORTETRACYCLINE HYDROCHLORIDE TABLETS (DECLOMYCIN)
6505-159-6575 CHLORTETRACYCLINE HYDROCHLORIDE CAPSULES (AUREOMYCIN)
6505-299-8276 OXYTETRACYCLINE TABLETS (TERRAMYCIN)
6505-765-0582 SULFAMETHOXAZOLE TABLETS (GANTANOL)
6505-770-8345 NALIDIXIC ACID TABLETS (NEG GRAM CAPLETS)

ANTIHISTAMINES

6505-014-1028 CHLORPHENIRAMINE MALEATE, ISOPROPAMIDE IODIDE, AND PHENYLPROPANOLAMINE HYDROCHLORIDE CAPSULES (ORNADE)
6505-935-9818 CHLORPHENIRAMINE MALEATE, CARAMIPHEN EDISYLATE, ISOPROPAMIDE IODIDE, AND PHENYLPROPANOLAMINE HYDROCHLORIDE CAPSULES (TUSS-ORNADE)
6505-926-9019 DEXBROMPHENIRAMINE MALEATE AND PSEUDOEPHEDRINE SULFATE TABLETS (DISOPHROL CHRONOTABS)

CORONARY VASODILATORS

6505-764-9014 DIPYRIDAMOLE TABLETS, (PERSANTIN)
6505-597-7341 PENTAERYTHRITOL TETRANITRATE TABLETS (PERITRATE)
6505-584-4297 PENTAERYTHRITOL TETRANITRATE TABLETS (PERITRATE)
6505-680-2326 PENTAERYTHRITOL TETRANITRATE TABLETS (PERITRATE)

VASODILATORS

6505-943-4384 CYCLANDELATE CAPSULES (CYCLOSPASMOL)
6505-890-1321 ISOXSUPRINE HYDROCHLORIDE TABLETS (VASODILAN)
6505-299-8052 TOLAZOLINE HYDROCHLORIDE TABLETS (PRISCOLINE)

SEDATIVE-HYPNOTICS

6505-616-9068 GLUTETHIMIDE TABLETS (DORIDEN)

GASTROINTESTIONAL ANTISPASMODICS

6505-783-0242 GLYCOPYRROLATE TABLETS (ROBINUL)
6505-777-8911 GLYCOPYRROLATE AND PHENOBARBITAL TABLETS (ROBINUL-PH)

ANTACIDS

6505-890-1658 CALCIUM CARBONATE AND AMINOACETIC ACID TABLETS (TITRALAC)

SKELETAL MUSCLE RELAXANTS

6505-062-4833 CARISOPRODOL TABLETS (RELA)
6505-904-3256 CARISOPRODOL TABLETS (SOMA)
6505-890-1562 ORPHENADRINE CITRATE TABLETS (NORFLEX)

List of 30 Items Proposed for Reclassification to "LIMITED STANDARD" with Eventual Deletion from the Federal Supply Catalog (Cont'd.)

ANTIEMETICS

6505-754-0086 DICYCLOMINE HYDROCHLORIDE, DOXYLAMINE SUCCINATE, AND PYRIDOXINE HYDROCHLORIDE TABLETS (BENDECTIN)

ANALGESICS

6505-890-2024 PROPOXYPHENE HYDROCHLORIDE (DARVO-TRAN)
6505-913-7907 PROPOXYPHENE HYDROCHLORIDE (DARVON COMPOUND 65)
6505-784-4976 PROPOXYPHENE HYDROCHLORIDE (DARVON COMPOUND 65)
6505-958-2364 PROPOXYPHENE HYDROCHLORIDE CAPSULES (DARVON)
6505-687-7901 ASPIRIN AND ETHOHEPTAZINE TABLETS (ZACTIRIN)

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S4:0
Sheet 22
11 January 1971

[illegible]: REVIEW OF STANDARD STOCK-LISTED ANTI-INFECTIVE ITEMS

[illegible]:

1. [illegible]: 6505-852-0078 SODIUM CHLORAMBUCIL CAPSULES, 0.25 GRAM
[illegible]: 100s DZ/$10.60 [illegible]: $0.106
[illegible]: ARMY - 4,809; NAVY - 1,563; [illegible] - 2,317
[illegible]: "LEUKERAN"

2. [illegible]: 6505-226-1202 SODIUM CHLORAMBUCIL CAPSULES, USP, 0.25 GRAM
[illegible]: 48s DZ/$3.76 [illegible]: $0.0783
[illegible]: ARMY - 24,605; NAVY - 15,559; [illegible] - 13,271
[illegible]: "PROSTRACHLEN"

[illegible]:

1. [illegible] authorities state that "Leukeran" and "Prostrachlen" have [illegible] the same use, same effectiveness and the same safety [illegible] "Leukeran" is somewhat more expensive.

2. There appears to be a reduplication of similar items.

[illegible]:

1. That NSN 6505-813-[illegible] [illegible] CHLORAMBUCIL [illegible] be classified to "LIMITED STANDARD" with eventual deletion from the Federal Supply Catalog.

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SUBJECT: REVIEW OF STANDARD (BROAD-SPECTRUM) ANTI-ENTEROCOCCAL DRUGS

ENCLOSURE:

1. ITEM NAME: 6505-890-8091 DIMETHYLCHLORTETRACYCLINE HYDROCHLORIDE TABLETS, 0.15 GRAM
UNIT OF ISSUE/PRICE: 100s BT/$11.00 COST PER TABLET: $0.110
ESTIMATED ANNUAL USAGE: ARMY - 5,689; NAVY - 2,114; AIR FORCE - 2,904
GENERIC NAME: "DEMECYCLIN"

2. ITEM NAME: 6505-782-6485 DIMETHYLCHLORTETRACYCLINE HYDROCHLORIDE TABLETS, 0.30 GRAM
UNIT OF ISSUE/PRICE: 40s BT/$10.80 COST PER TABLET: $0.216
ESTIMATED ANNUAL USAGE: ARMY - 2,505; NAVY - 2,070; AIR FORCE - 3,424
GENERIC NAME: "DEMECYCLIN"

3. ITEM NAME: 6505-159-6575 CHLORTETRACYCLINE HYDROCHLORIDE CAPSULES, 0.25 GRAM
UNIT OF ISSUE/PRICE: 100s BT/$3.12 COST PER CAPSULE: $0.0312
ESTIMATED ANNUAL USAGE: ARMY - 62,913; NAVY - 900; AIR FORCE - 324
GENERIC NAME: "AUREOMYCIN"

4. ITEM NAME: 6505-299-0876 CHLORTETRACYCLINE TABLETS, 0.25 G
UNIT OF ISSUE/PRICE: 100s BT/$6.24 COST PER TABLET: $0.0624
ESTIMATED ANNUAL USAGE: ARMY - 116,566; NAVY - 11,100; AIR FORCE - 5,790
GENERIC NAME: "TETRACYCLN"

5. ITEM NAME: 6505-206-7302 OXYTETRACYCLINE HYDROCHLORIDE CAPSULES, USP, 0.25 GRAM
UNIT OF ISSUE/PRICE: 100s BT/$0.97 COST PER CAPSULE: $0.0097
ESTIMATED ANNUAL USAGE: ARMY - 668,127; NAVY - 174,256; AIR FORCE - 207,04
GENERIC NAME: "AUREOMYCIN" - "TETRACYN" and others

DISCUSSION:

1. Medical authorities state that the TETRACYCLINES do not d[iffer] in their essential characteristics and are essentially identical [in terms] of antibacterial activity. The differences in pharmacol[ogy], chiefly due to molecular modifications, are relatively minor in importance.

2. Differences in costs are significant.

RECOMMENDATION:

1. That FSCs 6505-890-8091, 6505-782-6485, 6505-159-6575, 6505-299-0876 OXYTETRACYCLINE CAPSULES, be type-classified as "LIMITED STANDARD" with eventual deletion from the Federal Supply Catalog.

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SUBJECT: REVIEW OF STANDARD STOCK-LISTED ANTI-INFECTIVE DRUGS

BACKGROUND:

1. ITEM 1 NOUN: 6505-765-0502 SULFAMETHOXAZOLE TABLETS, 0.5 GRAM
UNIT OF ISSUE/PRICE: 500s BT/$14.60 COST PER TABLET: $0.0292
ANNUAL REQUIREMENTS DATA: ARMY - 1,703; NAVY - 2,379; AIR FORCE - 1,997
TRADE NAME ITEM: "GANTANOL"

2. ITEM 2 NOUN: 6505-146-4425 SULFISOXAZOLE TABLETS, USP, 0.5 GRAM
UNIT OF ISSUE/PRICE: 1000s BT/$9.00 COST PER TABLET: $0.009
ANNUAL REQUIREMENTS DATA: ARMY - 81,290; NAVY - 6,846; AIR FORCE - 7,893
TRADE NAME ITEM: "GANTRISIN"

DISCUSSION:

1. Medical authorities state that "Gantanol", although somewhat different in terms of pharmacology, is basically useful for the same conditions as "Gantrisin" and is more than three times as expensive.

RECOMMENDATION:

1. That FSN 6505-765-0502 SULFAMETHOXAZOLE TABLETS (GANTANOL) be type-classified to "LIMITED STANDARD" with eventual deletion from the Federal Supply Catalog.

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[redacted]: REVIEW OF STANDARD STOCK-LISTED ANTI-INFECTIVE DRUGS

[redacted]:

1. [redacted]: 6505-770-8345 NALIDIXIC ACID TABLETS, 0.50 GRAM
[redacted]: 1000s DE/$30.00 [redacted]: $0.030
[redacted]: ARMY - 315; NAVY - 630; AIR FORCE - 870
[redacted]: "Neg Gram CAPLETS"

2. [redacted]: 6505-286-9869 NITROFURANTOIN TABLETS, USP, 100 mg
[redacted]: 100s DE/$2.10 [redacted]: $0.021
[redacted]: ARMY - 8,838; NAVY - 2,611; AIR FORCE - 1,699
[redacted]: "FURADANTIN" and others

3. [redacted]: 6505-685-4072 NITROFURANTOIN CAPSULES, USP, 100 mg
[redacted]: 100s DE/$10.80 [redacted]: $0.0108
[redacted]: ARMY - 917; NAVY - 1,129; AIR FORCE - 1,792
[redacted]: "FURADANTIN" and others

[redacted]:

1. Medical authorities state that there is no clinical evidence that Nalidixic Acid is as reliable as other drugs in the treatment of acute or chronic urinary tract infections. On the other hand, Nitrofurantoin is universally accepted as a highly useful agent for these conditions.

[redacted]:

1. That FSN 6505-770-8345 NALIDIXIC ACID TABLETS (Neg Gram Caplets) be type classified to "LIMITED STANDARD" with eventual deletion from the Federal Supply Catalog.

SUBJECT: REVIEW OF STANDARD STOCK-LISTED ANTIHISTAMINES

BACKGROUND:

SHORTACTING

1. ITEM IDENT: 6505-582-4868 DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES, USP, 50 mg
UNIT OF ISSUE/PRICE: 1000s BT/$3.31 COST PER CAPSULE: $0.0033
ANNUAL DEMAND DATA: ARMY - 5,631; NAVY - 2,480; AIR FORCE - 3,350
TRADE MARK NAME: "BENADRYL"

2. ITEM IDENT: 6505-116-8350 DIPHENHYDRAMINE HYDROCHLORIDE CAPSULES, USP, 50 mg
UNIT OF ISSUE/PRICE: 100s BT/$0.57 COST PER CAPSULE: $0.0057
ANNUAL DEMAND DATA: ARMY - 10,439; NAVY - 7,329; AIR FORCE - 2,221
TRADE MARK NAME: "BENADRYL"

3. ITEM IDENT: 6505-299-8610 CHLORPHENIRAMINE MALEATE TABLETS, USP, 4 mg
UNIT OF ISSUE/PRICE: 1000s BT/$0.55 COST PER TABLET: $0.0006
ANNUAL DEMAND DATA: ARMY - 22,176; NAVY - 3,016; AIR FORCE - 4,585
TRADE MARK NAME: "CHLOR-TRIMETON"

4. ITEM IDENT: 6505-584-3277 PROMETHAZINE HYDROCHLORIDE TABLETS, USP, 25 mg
UNIT OF ISSUE/PRICE: 1000s BT/$20.30 COST PER TABLET: $0.0203
ANNUAL DEMAND DATA: ARMY - 2,417; NAVY - 275; AIR FORCE - 386
TRADE MARK NAME: "PHENERGAN"

5. ITEM IDENT: 6505-148-9000 TRIPELENNAMINE HYDROCHLORIDE TABLETS, USP, 50 mg
UNIT OF ISSUE/PRICE: 1000s BT/$2.33 COST PER TABLET: $0.0023
ANNUAL DEMAND DATA: ARMY - 447; NAVY - 734; AIR FORCE - 1,849
TRADE MARK NAME: "PYRIBENZAMINE"

6. ITEM IDENT: 6505-753-9615 TRIPROLIDINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE TABLETS
UNIT OF ISSUE/PRICE: 100s BT/$1.37 COST PER TABLET: $0.013
ANNUAL DEMAND DATA: ARMY - 55,919; NAVY - 72,641; AIR FORCE - 67,901
TRADE MARK NAME: "ACTIFED"

7. ITEM IDENT: 6505-142-9206 TRIPROLIDINE HYDROCHLORIDE AND PSEUDOEPHEDRINE HYDROCHLORIDE TABLETS
UNIT OF ISSUE/PRICE: 1000s BT/$13.00 COST PER TABLET: $0.013
ANNUAL DEMAND DATA: ARMY - 6,723; NAVY - 5,853; AIR FORCE - 6,372
TRADE MARK NAME: "ACTIFED"

SUBJECT: REVIEW OF STANDARD STOCK-LISTED ANTIHISTAMINES (CONT'D).

BACKGROUND (CONT'D.)

SUSTAINED/TIMED ACTION

1. ITEM IDENT: 6505-014-1028 CHLORPHENIRAMINE MALEATE, ISOPROPAMIDE IODIDE, AND PHENYLPROPANOLAMINE HYDROCHLORIDE CAPSULES
   UNIT OF ISSUE/PRICE: 500s BT/$29.90 COST PER CAPSULE: $0.0598
   ANNUAL DEMAND DATA: ARMY - 36,539; NAVY - 15,878; AIR FORCE - 18,386
   TRADE MARK NAME: "ORNADE"

2. ITEM IDENT: 6505-935-9818 CHLORPHENIRAMINE MALEATE, CARAMIPHEN EDISYLATE, ISOPROPAMIDE IODIDE, AND PHENYLPROPANOLAMINE HYDROCHLORIDE CAPSULES
   UNIT OF ISSUE/PRICE: 500s BT/$36.00 COST PER CAPSULE: $0.72
   ANNUAL DEMAND DATA: Army - 741; NAVY - 707; AIR FORCE - 600
   TRADE MARK NAME: "TUSS-ORNADE"

3. ITEM IDENT: 6505-982-9594 CHLORPHENIRAMINE MALEATE AND PHENYLEPHRINE HYDROCHLORIDE TABLETS, TIMED
   UNIT OF ISSUE/PRICE: 250s BT/$8.29 COST PER TABLET: $0.0331
   ANNUAL DEMAND DATA: ARMY - 4,708; NAVY - 3,462; AIR FORCE - 5,689
   TRADE MARK NAME: "NOVAHISTINE"

4. ITEM IDENT: 6505-655-8460 CHLORPHENIRAMINE MALEATE TABLETS, MODIFIED, 8 mg
   UNIT OF ISSUE/PRICE: 1000s BT/$4.55 COST PER TABLET: $0.0045
   ANNUAL DEMAND DATA: ARMY - 2,431; NAVY - 2,960; AIR FORCE - 3,261
   TRADE MARK NAME: "CHLOR-TRIMETON REPETABS"

5. ITEM IDENT: 6505-890-1891 BROMPHENIRAMINE MALEATE, PHENYLEPHRINE HYDROCHLORIDE, AND PHENYLPROPANOLAMINE HYDROCHLORIDE TABLETS
   UNIT OF ISSUE/PRICE: 500s BT/$19.00 COST PER TABLET: $0.038
   ANNUAL DEMAND DATA: ARMY - 21,409; NAVY - 13,542; AIR FORCE - 18,316
   TRADE MARK NAME: "DIMETAPP EXTENTABS"

6. ITEM IDENT: 6505-926-9019 DEXBROMPHENIRAMINE MALEATE AND PSEUDOEPHEDRINE SULFATE TABLETS
   UNIT OF ISSUE/PRICE: 100s BT/$4.90 COST PER TABLET: $0.049
   ANNUAL DEMAND DATA: ARMY - 15,758; NAVY - 12,655; AIR FORCE - 21,412
   TRADE MARK NAME: "DISOPHROL CHRONOTABS"

7. ITEM IDENT: 6505-890-1112 BROMPHENIRAMINE MALEATE TABLETS, 12 mg
   UNIT OF ISSUE/PRICE: 500s BT/$17.60 COST PER TABLET: $0.0176
   ANNUAL DEMAND DATA: ARMY - 224; NAVY - 270; AIR FORCE - 810
   TRADE MARK NAME: "DIMETANE EXTENTABS"

8. ITEM IDENT: 6505-890-1902 CYCLOPENTAMINE HYDROCHLORIDE, METHAPYRILENE HYDROCHLORIDE, AND PYRROBUTAMINE PHOSPHATE CAPSULES
   UNIT OF ISSUE/PRICE: 1000s BT/$13.90 COST PER CAPSULE: $0.0139
   ANNUAL DEMAND DATA: ARMY - 1,397; NAVY - 2,524; AIR FORCE - 1,608
   TRADE MARK NAME: "CO-PYRONIL"

SUBJECT: REVIEW OF STANDARD STOCK-LISTED ANTIHISTAMINES (CONT'D.)

DISCUSSION:

1. Medical authorities state the indications for antihistamines are (1) to control the manifestations of allergy which may be attributed to histamine, and (2) to control nausea and motion sickness. Carefully controlled studies show that antihistamines neither shorten the duration nor reduce the severity of the common cold. It is stated that most physicians, expert in allergic diseases, confine their prescribing to a few drugs well established as to their effectiveness in allergy and motion sickness. A few combinations with decongestants would be convenient in allergic syndromes. The great bulk of antihistamines on the market, some of them highly priced, offer no detectable advantage over the antihistamines listed in the USP.

2. The Federal Supply Catalog lists a wide range of basic USP antihistamines plus a large number of antihistamine combinations, some of which appear to be inordinately expensive.

RECOMMENDATION:

1. That FSNs 6505-014-1028 CHLORPHENIRAMINE MALEATE, ISOPROPAMIDE IODIDE, AND PHENYLPROPANOLAMINE HYDROCHLORIDE CAPSULES (ORNADE), 6505-935-9818 CHLORPHENIRAMINE MALEATE, CARAMIPHEN EDISYLATE, ISOPROPAMIDE IODIDE, AND PHENYLPROPANOLAMINE HYDROCHLORIDE CAPSULES (TUSS-ORNADE), and 6505-926-9019 DEXBROMPHENIRAMINE MALEATE AND PSEUDOEPHEDRINE SULFATE TABLETS (DISOPHROL CHRONOTABS) be type classified to "LIMITED STANDARD" with eventual deletion from the Federal Supply Catalog.

SUBJECT: REVIEW OF STANDARD STOCK-LISTED CORONARY VASODILATORS

BACKGROUND:

1. ITEM IDENT: 6505-764-9014 DIPYRIDAMOLE TABLETS, 25 mg
UNIT OF ISSUE/PRICE: 1000s BT/$45.50 COST PER TABLET: $0.0455
ANNUAL DEMAND DATA: ARMY - 76; NAVY - 219; AIR FORCE - 153
TRADE MARK NAME: "PERSANTIN"

2. ITEM IDENT: 6505-597-7341 PENTAERYTHRITOL TETRANITRATE TABLETS, 10 mg
UNIT OF ISSUE/PRICE: 500s BT/$5.00 COST PER TABLET: $0.01
ANNUAL DEMAND DATA: ARMY - 1,100; NAVY - 1,024; AIR FORCE - 925
TRADE MARK NAME: "PERITRATE"

3. ITEM IDENT: 6505-584-4297 PENTAERYTHRITOL TETRANITRATE TABLETS, 20 mg
UNIT OF ISSUE/PRICE: 500s BT/$9.69 COST PER TABLET: $0.194
ANNUAL DEMAND DATA: ARMY - 239; NAVY - 110; AIR FORCE - 127
TRADE MARK NAME: "PERITRATE"

4. ITEM IDENT: 6505-680-2326 PENTAERYTHRITOL TETRANITRATE TABLETS, 80 mg
UNIT OF ISSUE/PRICE: 500s BT/$16.50 COST PER TABLET: $0.033
ANNUAL DEMAND DATA: ARMY - 1,637; NAVY - 1,814; AIR FORCE - 1,621
TRADE MARK NAME: "PERITRATE"

DISCUSSION:

1. Medical authorities state that among the coronary vasodilator drugs, Nitroglycerine appears to be the most effective despite its short duration; however, evidence of effectiveness of longer acting agents is lacking. Results of controlled studies that are available fail to provide evidence of effectiveness of such long acting preparations as DIPYRIDAMOLE and PENTAERYTHRITOL TETRANITRATE in the prevention of angina pectoris.

RECOMMENDATION:

1. That FSNs 6505-764-9014 DIPYRIDAMOLE TABLETS, 25 mg, 6505-597-7341 PENTAERYTHRITOL TETRANITRATE TABLETS, 10 mg, 6505-584-4297 PENTAERYTHRITOL TETRANITRATE TABLETS, 20 mg, and 6505-680-2326 PENTAERYTHRITOL TETRANITRATE TABLETS, 80 mg, be type classified to "LIMITED STANDARD" with eventual deletion from the Federal Supply Catalog.

SUBJECT: REVIEW OF STANDARD STOCK-LISTED VASODILATORS

BACKGROUND:

1. ITEM IDENT: 6505-943-4384 CYCLANDELATE CAPSULES, 0.2 GRAM
   UNIT OF ISSUE/PRICE: 500s BT/$29.50 COST PER CAPSULE: $0.59
   ANNUAL DEMAND DATA: ARMY - 367; NAVY - 397; AIR FORCE - 254
   TRADE MARK NAME: "CYCLOSPASMOL"

2. ITEM IDENT: 6505-890-1321 ISOXSUPRINE HYDROCHLORIDE TABLETS, 10 mg
   UNIT OF ISSUE/PRICE: 1000s BT/$32.10 COST PER TABLET: $0.032
   ANNUAL DEMAND DATA: ARMY - 918; NAVY - 729; AIR FORCE - 1,000
   TRADE MARK NAME: "VASODILAN"

3. ITEM IDENT: 6505-299-8052 TOLAZOLINE HYDROCHLORIDE TABLETS, 25 mg
   UNIT OF ISSUE/PRICE: 100s BT/$0.44 COST PER TABLET: $0.0044
   ANNUAL DEMAND DATA: ARMY - 459; NAVY - 1,016; AIR FORCE - 658
   TRADE MARK NAME: "PRISCOLINE"

DISCUSSION:

1. Medical authorities state that there is no acceptable evidence that the Peripheral Vasodilator drugs are effective in relieving symptoms associated with arteriosclerosis of the extremities or in the prevention or treatment of gangrene which may occur as the condition progresses. The only effective measures at present appear to be walking in the development of collateral circulation and the discontinuation of smoking. Further, it is stated that there is no evidence in form of controlled studies to indicate these drugs are useful in preventing symptoms associated with cerebral vascular disease.

RECOMMENDATION:

1. That FSNs 6505-943-4384 CYCLANDELATE CAPSULES, 0.2 GRAM (CYCLOSPASMOL), 6505-890-1321 ISOXSUPRINE HYDROCHLORIDE TABLETS, 10 mg (VASODILAN) and 6505-299-8052 TOLAZOLINE HYDROCHLORIDE TABLETS, 25 mg (PRISCOLINE) be type classified to "LIMITED STANDARD" with eventual deletion from the Federal Supply Catalog.

SUBJECT: REVIEW OF STANDARD STOCK-LISTED SEDATIVE-HYPNOTICS

BACKGROUND:

1. ITEM IDENT: 6505-616-9068 GLUTETHIMIDE TABLETS, NF, 0.5 GRAM
UNIT OF ISSUE/PRICE: 500s BT/$9.20 COST PER TABLET: $0.0184
ANNUAL DEMAND DATA: ARMY - 461; NAVY - 467; AIR FORCE - 491
TRADE MARK NAME: "DORIDEN"

DISCUSSION:

1. GLUTETHIMIDE is a barbiturate substitute which many pharmacologists consider to be highly dangerous, both in terms of its propensity for abuse and the extremely difficult problems in managing overdosage.

RECOMMENDATION:

1. That FSN 6505-616-9068 GLUTETHIMIDE TABLETS, NF, be type classified to "LIMITED STANDARD" with eventual deletion from the Federal Supply Catalog.

SUBJECT: REVIEW OF STANDARD STOCK-LISTED GASTROINTESTIONAL ANTISPASMODICS

BACKGROUND:

1. ITEM IDENT: 6505-783-0242 GLYCOPYRROLATE TABLETS, 1 mg
UNIT OF ISSUE/PRICE: 100s BT/$2.51 COST PER TABLET: $0.025
ANNUAL DEMAND DATA: ARMY - 3,810; NAVY - 1,346; AIR FORCE - 3,333
TRADE MARK NAME: "ROBINUL"

2. ITEM IDENT: 6505-777-8911 GLYCOPYRROLATE AND PHENOBARBITAL TABLETS
UNIT OF ISSUE/PRICE: 500s BT/$13.00 COST PER TABLET: $0.026
ANNUAL DEMAND DATA: ARMY - 130; NAVY - 168; AIR FORCE - 382
TRADE MARK NAME: "ROBINUL-PH"

DISCUSSION:

1. According to medical authorities, efficacy of GLYCOPYRROLATE has not been established. Further, there is no reason to use it in a fixed combination with Phenobarbital.

RECOMMENDATION:

1. That FSNs 6505-783-0242 GLYCOPYRROLATE TABLETS, 1 mg (ROBINUL) and 6505-777-8911 GLYCOPYRROLATE AND PHENOBARBITAL TABLETS (ROBINUL-PH) be type classified to "LIMITED STANDARD" with eventual deletion from the Federal Supply Catalog.

SUBJECT: REVIEW OF STANDARD STOCK-LISTED ANTACIDS

BACKGROUND:

1. ITEM IDENT: 6505-890-1658 CALCIUM CARBONATE AND AMINOACETIC ACID TABLETS
UNIT OF ISSUE/PRICE: 500s BT/$2.88 COST PER TABLET: $0.0058
ANNUAL DEMAND DATA: ARMY - 17,799; NAVY - 9,878; AIR FORCE - 11,149
TRADE MARK NAME: "TITRALAC" and others

DISCUSSION:

1. Medical authorities state that a mixture of CALCIUM CARBONATE AND AMINOACETIC ACID (GLYCINE) is not more effective than aluminum Hydroxide (the basic ingredient in most antacids). Furthermore, it is more expensive and is more likely to lead to alkalosis.

RECOMMENDATION:

1. That FSN 6505-890-1658 CALCIUM CARBONATE AND AMINOACETIC ACID TABLETS be type classified to "LIMITED STANDARD" with eventual deletion from the Federal Supply Catalog.

SUBJECT: REVIEW OF STANDARD STOCK-LISTED SKELETAL MUSCLE RELAXANTS

BACKGROUND:

1. ITEM IDENT: 6505-062-4833 CARISOPRODOL TABLETS, Sugar Coated, 0.35 Gram
   UNIT OF ISSUE/PRICE: 100s BT/$3.90 COST PER TABLET: $0.039
   ANNUAL DEMAND DATA: ARMY - 1,431; NAVY - 1,597; AIR FORCE - 1,402
   TRADE MARK NAME: "RELA"

2. ITEM IDENT: 6505-904-3256 CARISOPRODOL TABLETS, Uncoated, 0.35 Gram
   UNIT OF ISSUE/PRICE: 100s BT/$4.18 COST PER TABLET: $0.0418
   ANNUAL DEMAND DATA: ARMY - 512; NAVY - 1,839; AIR FORCE - 1,090
   TRADE MARK NAME: "SOMA"

DISCUSSION:

1. CARISOPRODOL, chemically related to both Mephenesin and Meprobamate Analgesic group of drugs. Authorities state that it has been found superior to Placebo in the treatment of various musculo-skeletal complaints, but it is uncertain whether its performance is superior to substantial doses of tranquilizers or sedatives.

RECOMMENDATION:

1. That FSNs 6505-062-4833 CARISOPRODOL TABLETS, Sugar Coated, 0.35 Gram (RELA) and 6505-904-3256 CARISOPRODOL TABLETS, Uncoated, 0.35 Gram (SOMA) be type classified to "LIMITED STANDARD" with eventual deletion from the Federal Supply Catalog.

SUBJECT: REVIEW OF STANDARD STOCK-LISTED SKELETAL MUSCLE RELAXANTS

BACKGROUND:

1. ITEM IDENT: 6505-890-1562 ORPHENADRINE CITRATE TABLETS, 100mg
UNIT OF ISSUE/PRICE: 50s BT/$5.10 COST PER TABLET: $0.102
ANNUAL DEMAND DATA: ARMY - 3,505; NAVY - 4,216; AIR FORCE - 6,095
TRADE MARK NAME: "NORFLEX"

DISCUSSION:

1. The skeletal muscle relaxants are basically sedatives, several being related to Meprobamate. Medical authorities doubt whether or not any of these agents offer any advantage over Meprobamate. ORPHENADRINE is a drug similar to agents used for treating rigidity and tremors of Parkinson's Disease. Medical authorities question the suitability of ORPHENADRINE for its customary usage, i.e., muscle pain and spasm such as back pain or stiff neck.

2. There is questionable effectiveness in addition to high cost in relation to other agents in this therapeutic group.

RECOMMENDATION:

1. That FSN 6505-890-1562 ORPHENADRINE CITRATE TABLETS, 100 mg (NORFLEX) be type classified to "LIMITED STANDARD" with eventual deletion from the Federal Supply Catalog.

SUBJECT: REVIEW OF STANDARD STOCK-LISTED ANTIEMETICS

BACKGROUND:

1. ITEM IDENT: 6505-754-0086 DICYCLOMINE HYDROCHLORIDE, DOXYLAMINE SUCCINATE, AND PYRIDOXINE HYDROCHLORIDE TABLETS
UNIT OF ISSUE/PRICE: 100s BT/$4.36 COST PER TABLET: $0.0436
ANNUAL DEMAND DATA: ARMY - 52,550; NAVY - 40,361; AIR FORCE - 46,303
TRADE MARK NAME: "BENDECTIN"

DISCUSSION:

1. The above agent, according to medical authorities, is an expensive mixture of ingredients,none with adequate evidence of efficacy.

2. Item is relatively expensive.

RECOMMENDATION:

1. That FSN 6505-754-0086 DICYCLOMINE HYDROCHLORIDE, DOXYLAMINE SUCCINATE, AND PYRIDOXINE HYDROCHLORIDE TABLETS (BENDECTIN) be type-classified to "LIMITED STANDARD" with eventual deletion from the Federal Supply Catalog.

SUBJECT: REVIEW OF STANDARD STOCK-LISTED ANALGESICS

BACKGROUND:

1. ITEM IDENT: 6505-890-2024 PROPOXYPHENE HYDROCHLORIDE, 32 mg, ASPIRIN, AND PHENAGLYCODOL CAPSULES
   UNIT OF ISSUE/PRICE: 500s BT/$13.80 COST PER CAPSULE: $0.0276
   ANNUAL DEMAND DATA: ARMY - 481; NAVY - 1,258; AIR FORCE - 1,126
   TRADE MARK NAME: "DARVO-TRAN"

2. ITEM IDENT: 6505-913-7907 PROPOXYPHENE HYDROCHLORIDE, 65 mg, WITH APC CAPSULES
   UNIT OF ISSUE/PRICE: 100s BX/$2.14 COST PER CAPSULE: $0.0214
   ANNUAL DEMAND DATA: ARMY - 2,534; NAVY - 215; AIR FORCE - 266
   TRADE MARK NAME: "DARVON COMPOUND 65"

3. ITEM IDENT: 6505-784-4976 PROPOXYPHENE HYDROCHLORIDE, 65 mg, WITH APC CAPSULES
   UNIT OF ISSUE/PRICE: 500s BT/$13.70 COST PER CAPSULE: $0.0274
   ANNUAL DEMAND DATA: ARMY - 24,198; NAVY - 26,388; AIR FORCE - 32,376
   TRADE MARK NAME: "DARVON COMPOUND 65"

4. ITEM IDENT: 6505-958-2364 PROPOXYPHENE HYDROCHLORIDE CAPSULES
   UNIT OF ISSUE/PRICE: 500s BT/$13.30 COST PER CAPSULE: $0.0266
   ANNUAL DEMAND DATA: ARMY - 12,728; NAVY - 5,459; AIR FORCE - 7,094
   TRADE MARK NAME: "DARVON"

DISCUSSION:

1. Medical authorities state that PROPOXYPHENE is a weaker analgesic than Codiene and no more effective than aspirin in equivalent doses.

2. There is a questionable advantage of PROPOXYPHENE over much less expensive and proven analgesics.

RECOMMENDATION:

1. That FSNs 6505-890-2024 PROPOXYPHENE HYDROCHLORIDE, 32 mg, ASPIRIN, AND PHENAGLYCODOL CAPSULES, 6505-913-7907 PROPOXYPHENE HYDROCHLORIDE, 65 mg, WITH APC CAPSULES, 6505-784-4976 PROPOXYPHENE HYDROCHLORIDE, 65 mg, WITH APC CAPSULES, and 6505-958-2364 PROPOXYPHENE HYDROCHLORIDE CAPSULES be type-classified to "LIMITED STANDARD" with eventual deletion from the Federal Supply Catalog.

SUBJECT: REVIEW OF STANDARD STOCK-LISTED ANALGESICS

BACKGROUND:

1. ITEM IDENT: 6505-687-7901 ASPIRIN AND ETHOHEPTAZINE TABLETS
UNIT OF ISSUE/PRICE: 1000s BT/$15.80 COST PER TABLET: $0.0158
ANNUAL DEMAND DATA: ARMY - 13,481; NAVY - 2,661; AIR FORCE - 3,188
TRADE MARK NAME: "ZACTIRIN"

DISCUSSION:

1. Medical authorities state that studies indicate that ETHOHEPTAZINE in clinically used doses has little or no analgesic activity.

RECOMMENDATION:

1. That FSN 6505-687-7901 ASPIRIN AND ETHOHEPTAZINE TABLETS be type-classified to "LIMITED STANDARD" with eventual deletion from the Federal Supply Catalog.

Senator NELSON. In your review of drug purchasing policy do you also intend to look into the fixed combination drugs of all kinds? I have a list of fixed combinations purchased by your Agency, and it is a long one. As you are aware, I am sure, the position taken by the National Academy of Sciences-National Research Council was against fixed combinations as a general proposition and those that they approved were simply exceptions to their general position.

When Dr. Edwards was before the committee I asked the question: "Is it not, however, correct that the NAS–NRC position thus far on fixed combination dosage form is that the fixed combinations that they have endorsed have been an exception to the rule?" Dr. Edwards said, "That is correct."

Dr. Simmons, Director of the Bureau of Drugs, FDA, commenting, stated: "No drug should be present in a fixed dose combination unless its presence clearly enhances safety or efficacy, and unfortunately most combination drugs to this point have not developed that type of efficacy."

Are you reviewing that question of fixed combinations, also?

General HAYES. We have reviewed this. We did not have for some time now any of the anti-infectives such as Panalba, and so on. We have some combination drugs such as Ornade, Tuss-Ornade. These are included in this review group that I just have been speaking about.

These are going out for review as to "do we include them"? Do we diminish their use? Do we control their use?

This will be a professional recommendation from our using professional people.

Mr. GORDON. General, Mr. Staats, the Comptroller General, said that there is no routine exchange of inspection information between the DSA and the Food and Drug Administration. Do you have any changes in mind or are you planning to get together with the FDA to exchange inspection information?

General HAYES. Mr. Feinberg will answer that question.

Mr. FEINBERG. Mr. Gordon, we do have extensive exchange of information through the IPADD organization—the Intra-Professional Advisory Council for Drugs and Devices. We exchange with—I will list some of the points that we cover—all specifications are sent to the FDA, the VA, GSA, Public Health Service, the NIH for biologicals, and we also exchange this information with the USP, NF, and HEW.

Insofar as the plant information is concerned, at one time we did prepare a list. We found that this list was antiquated by the time we finished typing it because of the surveys that we perform, the fact that we guided toward a product in a different determination, that the list in fact was never up to date and we felt that may be prejudicial to some of these companies who had been rejected and we may not have returned for a survey because they did not—they were not in contention for another award to have this as an indication to the other activities that they are a rejected company.

Now, we do, however, communicate on about a weekly basis with the VA as it pertains to qualification of companies. Before they go on the survey, they ask us by telephone what our last findings have

been, the types of deficiencies if there were any, and the types of items we were inspecting them for.

Conversely, before we go on the survey, we touch base with them, too. So although there has not been this formal list sent out as in the past, we have covered this in every way.

Senator NELSON. How many inspectors do you have in DOD?

Mr. FEINBERG. In 1970 we had 48 DCAS inspectors.

Senator NELSON. Forty-eight what?

Mr. FEINBERG. Forty-eight drug inspectors who were inspecting drug plants and products for us, but these 48 operate on a part-time basis. They inspect other commodities for DSA, and as the statement indicated, about twenty man-years are spent in inspection for drugs.

Senator NELSON. Annually?.

Mr. FEINBERG. Yes, annually.

Senator NELSON. Is there any particular advantage in having the FDA have its inspectors inspecting plants and the Veterans' Administration having its inspectors and the Department of Defense having its inspectors? Or to put it another way: Is there any reason why they shouldn't all be in the FDA?

Mr. FEINBERG. Well, Mr. Nelson——

Captain MACPHERSON. If I might, Mr. Nelson, there appears to be a difference in the philosophy involved concerning the approach to inspection and quality control by the two agencies. FDA's inspections are plant-oriented and ours are product-oriented.

Should FDA determine a plant to be in violation of good manufacturing practices, recourse would be through legal channels. When we inspect a plant, we look not only at the physical layout but the equipment and the personnel and the quality control in relation to a specific product which we are going to buy. The plant may be manufacturing a number of items in an acceptable manner except for the one product in which we have interest and this could be the cause for our rejection.

We as a contractual agency attempt to prevent the introduction into our system of defective medical material. FDA as a regulatory agency removes from commerce any material that it determines to be ineffective or defective at some time after it has reached the market place.

Senator NELSON. You inspect only for purposes of purchasing under a particular proposed contract?

Mr. FEINBERG. Yes, sir.

Senator NELSON. And do you inspect every time you are making a purchase?

Mr. FEINBERG. Well, our policy on that, sir, is that if a company had previously successfully supplied the item or the company is one which we know has the capability to produce the item, we do not perform an inspection for qualification of the company. Of course, we have product inspection when the material is manufactured and before it is accepted. Relocation, yes. But where a company is inspected and found to have minor deficiencies, we indicate what the corrections must be and if they show a desire to make these corrections, we will attempt to delay the procurement until they make these corrections and we can verify it.

Now, in those instances where the deficiencies are of a major nature and they could not possibly make these corrections within a timely fashion, or they may not have the desire to make the correction, then, of course, the company is disqualified for that particular procurement.

Senator NELSON. You say you make a product inspection. How is that done? Do you take a sample of something coming off the line and have it assayed to see whether it meets USP-NF standards?

Mr. FEINBERG. No, sir; we don't do that precisely. We inspect the plant for its total operation and this would include the personnel qualification, the plant arrangement, the line of equipment, the methods, systems and procedures used in manufacturing that item or proposed to manufacture that item, and, of course, the housekeeping and the stability that the company has developed for that product and, of course, stability is a very important point for us.

Senator NELSON. With respect to these items of inspection that you make, and that you have just recited, doesn't the FDA cover the same thing?

Mr. FEINBERG. Well, the FDA does, assumingly does, I don't know myself, but the FDA is in a different situation. They act from a point of view of regulation and the FDA by necessity, I assume, permits companies to manufacture in spite of the fact that they are not in compliance with the good manufacturing practices, and as I understand, in the testimony that Dr. Edwards gave before you, sir, he stated that there were—there was the intensified drug inspection for some 230-some-odd companies and that 147 I believe have gotten to the point now where they are willing to comply with the good manufacturing practices.

Well, during that period they were manufacturing but they were still not complying because FDA apparently cannot stop production within whatever regulations they operate.

Dr. Edwards also stated that there were 44 companies, and I believe he gave a list of the companies, that were presently under this intensified drug inspection and gave some statistics as to how many—what the categories were.

Well, we had an opportunity to review that list and of those 44, we had only contracted with one company and that one company contracted for us in a different location, different area, and which we had found at that time to be acceptable.

Senator NELSON. When you say only one out of 44, this 44 was in what category?

Mr. FEINBERG. Well, it is the one where Commissioner Edwards said:

> Since July 1968 FDA has initiated intensified inspection of 237 drug manufacturers and associated commercial testing laboratories. In 147 of the terminated cases, voluntary compliance with the GMP regulations was achieved through a dialogue between FDA district personnel and plant management. In the forty-four remaining cases are twenty-three which are now the subject of legal action and twenty-one firms which are going out of the drug business because of their inability to come into compliance.

Senator NELSON. Well, now this 21 and 23 are different firms. That makes your 44.

Mr. FEINBERG. That is right, sir. If I gave a different number, I was wrong.

Senator NELSON. No.

Mr. FEINBERG. Well, what I was pointing out, sir, was you made reference to FDA inspection. FDA does inspect. They apparently tell the companies what it is that is wrong and then await the action of the company during which time the company does produce on the market place.

In our case, if the company is not in compliance with the required pharmaceutical practices, they are not qualified to get—to be awarded a contract for that item.

Senator NELSON. Are your required manufacturing practices different from the FDA?

Mr. FEINBERG. Well, the FDA has just come out with its new good manufacturing practices which become effective this month and we have reviewed that and I would say that there are some areas of differences but there are none of much magnitude.

If you would like, I can review for you some of the differences.

Senator NELSON. What are the differences that you consider might be significant?

Mr. FEINBERG. The FDA good manufacturing practices do not require written procedures covering the receipt of new material, quality control, packaging, and inspection of raw material.

Senator NELSON. They do not require written what?

Mr. FEINBERG. Written procedures for this, whereas we do.

Senator NELSON. What is a written procedure for this? What do you mean?

Mr. FEINBERG. Well, this is where the quality control officials in this case would identify in writing what it is that their employees have to do, sort of like a check list. When material comes in, you sample by some specific sample procedure. You send it to the laboratory for testing. You await the report from the laboratory. These are systems methods and procedures that become necessary in order to continually produce in a uniformly satisfactory manner.

Senator NELSON. Now, what else is on that list that the FDA does not require?

Mr. FEINBERG. They do not require written procedure in this respect.

Senator NELSON. Does that mean that the company doesn't have a list of written procedures or that the company doesn't follow these procedures?

Mr. FEINBERG. It means that the company has not established—there is no doubt that many companies do have written procedures. It is just that as a minimum that the FDA is asking for, they are not saying that you have to have it. And for inspection purposes and to produce on a uniform consistent basis, particularly where you have people who are out sick, who go on vacation, you should have procedures so that the people in these various areas of manufacture know precisely what has to be done.

Senator NELSON. And you would not purchase from any company that didn't have these enumerated written procedures? Is that what you are saying?

Mr. FEINBERG. If they did not have these procedures, they would not be qualified. However, they would be asked if in fact they want to do this, and give them the opportunity to do so.

Senator NELSON. How do you find out whether or not they follow their own written procedures?

Mr. FEINBERG. We have—this is what our inspector does, one of the things he does, when he visits a plant to determine the qualifications of a low bidder.

Senator NELSON. What other significant differences are there?

Mr. FEINBERG. Well, we require, for example, calibration and standardization of equipment and instruments so that you would—so that it is established that the balances that are used and the instruments that are used are accurate, that the weights are. This is again a normal operating thing and it is required that they check it periodically.

Senator NELSON. Have you ever done any tests to find out whether or not the drugs that you are purchasing are superior in any way to those of other manufacturers—in other words, do you know whether yours meet certain standards, USP or NF standards, and others don't?

Mr. FEINBERG. We have not made comparisons with material on the market, no, sir. We have, of course, tested the material that we have purchased.

Senator NELSON. Well, let's assume that the FDA adopted these written procedures that you are talking about. Is there any reason why they shouldn't do the inspection for DOD and VA, then?

Mr. FEINBERG. Well, Mr. Nelson, we have not delved into the subject really at this point to discuss it at length.

General HAYES. I think I should answer part of that, Mr. Chairman. The FDA inspects for some things, and we set standards in some areas that are higher than the FDA's of necessity. As I mentioned in the statement, we have drugs that go all over the world, under adverse circumstances, and we have had to set certain standards of packaging, for instance, certain standards of stability under adverse circumstances.

Therefore, our standards are even, if you shifted all of this around, our standards would have to be somewhat different along the line.

Senator NELSON. What are some of the standards of stability? You say you are buying a drug in tablet form. It is going to go to some other country. What is it you require that is different?

General HAYES. Well, Mr. Feinberg is going to amplify but I am going to start it off a little bit.

If you decide that you want a tablet at the end-using site, if the case that the tablet started out in has been brought from the manufacturer to the depot, thrown from the depot into a truck, from the truck to a ship, from the ship to the dock, from the dock to a truck, the tablet off-loaded into something else, then juggled around in a jeep and finally set out in a field unit for awhile, you want to be sure at the end of all of that mechanical stress, and that is all we are talking about fundamentally in this discussion, you want to be sure that you still have an intact tablet, that it hasn't fallen apart and you have only an amorphous mass of powder in the bottle.

Senator NELSON. You aren't talking about a different quality tablet. It is the same tablet the company is selling to the general public in this country.

General HAYES. Not necessarily.

Senator NELSON. What do they do to the tablet to keep it from falling apart? What tests have been made to show that the tablet still retains its biologic availability?

General HAYES. That is another part of this also. I took the mechanical aspect for simplicity because it is dose-related. If you have a bottle of powder that is 100 tablets as it started, you don't know what you have for a dosage. On the other hand, we do have problems of extremes of temperature and you can imagine what the temperature, for instance, is in the storage depot at Cam Ranh Bay in Vietnam as opposed to the more ideal circumstances in a stateside drugstore. So we have to assure that the potency is not affected by the extremes of temperature, even if the tablet stays in one piece through all of this mechanical manhandling. So we have these two problems.

Senator NELSON. So you are saying that in a substantial number of the drugs that you buy and send overseas, their compositions differ somehow? Is that what you are saying? Not just packaging. It is a question of compounding, putting the compound together in a different form or making a tablet that somehow or another has a different physical characteristic and still retains its therapeutic value?

General HAYES. Mr. Feinberg will pick up now.

Mr. FEINBERG. Mr. Nelson, we require as a result of the conditions of temperature and long storage, as described by General Hayes, we introduced standards which are guided toward assuring that if material does or is subjected to these conditions, that they would still be suitable for use at the time that they ultimately have to be used. And some examples—water content in tablets. Tablets are made generally with granulations where syrup is added or water is added and depending upon the amount of water or moisture that remains in that tablet, and you do have some, will determine with some items, many items, whether hydrolysis will take place, whether the molecule will split up and whether you are going to have a suitable product after it is subjected to these various conditions.

So we would require in fact a tablet with a lower moisture content.

Now, when you get to that point, you have to consider tablet hardness. It may be so hard that it won't disintegrate. So we have to introduce sometimes varying limits for disintegration or for dissolution.

We have had in the past experiences dealing with excessive breakage because the tablets or the products are handled the way they have to be handled. We have in some instances bioavailability tests where you test in advance to determine whether the tablets will hold up under these conditions. And then wherever we can, we have what we call accelerated aging tests where we subject these same products to some higher temperature, like 120 degrees for 2 weeks, sometimes varying from that, and attempt to establish whether the material will hold up under those circumstances in the laboratory because if it doesn't do it in the laboratory, it certainly will not hold up in the field.

Now, when we do establish these kinds of information, we then include them as a requirement of the specification.

Senator NELSON. Do these special specifications apply only to the drugs you purchase for sending overseas or do you require that of everything you buy, for domestic consumption and overseas consumption?

Mr. FEINBERG. We have one system. We do not know which bottle will ultimately go from a depot to overseas versus a bottle going domestically.

Senator NELSON. How much does that add to the cost?

In other words, if you are having the manufacturer meet all kinds of special problems in the process of putting the tablet or injectable together that he doesn't have to do for the domestic market, what does that do to the cost of the drug you are buying?

Mr. FEINBERG. I don't know that, sir. But generally speaking, the standards that we have are utilized by the companies in their commercial market, too.

Senator NELSON. Oh, so what you are talking about is automatically done by them in their sales in the domestic market anyway.

Mr. FEINBERG. So far as we know.

Senator NELSON. Well, then, all this talk about these being specially designed tablets and drugs for Indonesia or elsewhere is all nonsense?

General HAYES. No. That is a non sequitur, Mr. Chairman.

Senator NELSON. Pardon?

General HAYES. That is a non sequitur.

Senator NELSON. What is?

General HAYES. What Mr. Feinberg really is saying here is that the specifications have been upped by the USP and the NF to come to these more stringent specifications that we have talked about in many areas because they have resulted in a better and more stable product.

Senator NELSON. Well, then, if that is the USP and NF standard——

General HAYES. But it is not universal.

Senator NELSON. Pardon?

General HAYES. It is not universal.

Senator NELSON. What is not universal?

General HAYES. The fact that these standards have come up. Captain MacPherson would like to say a few words.

Senator NELSON. If it is adopted by the USP and NF it is universal so far as the United States is concerned.

General HAYES. Not all products.

Senator NELSON. So what you are saying is USP and NF adopted these standards for some products but not for all products.

General HAYES. That is right.

Senator NELSON. I must say that is a bit puzzling. I had a long detailed explanation of how drug firms had to compound their drugs differently for possible overseas use; that that is the only kind you bought; and the company had to meet those standards or you couldn't buy them. Then I am told that these companies that you approve of are producing their products for the domestic market the same way. And now you are saying that they do it the same way for some of their products but not for all of them, is that it?

Colonel SNYDER. If I may, sir——

Senator NELSON. I am just trying to get something straight myself.

Colonel SNYDER. Again, I think we may not be communicating too well. The firms that we buy from do meet these standards but there are many products marketed and many products that we examine that do not meet these standards. This accounts for the rejection of some of the unsuccessful contenders for our procurements.

Senator NELSON. Are you saying that the firms you are dealing with meet these standards both for your requirements overseas and for the domestic market, too? Is that what you are saying?

Colonel SNYDER. Generally speaking. Again I don't think you can make a blanket statement but a firm that is involved in marketing a product under its brand name, where their total reputation is dependent upon that, has a greater interest in the quality than a firm which markets on an ad hoc basis for a particular segment of the market. No, sir——

Senator NELSON. A firm that—would you repeat that?

Colonel SNYDER. A brand name product, if you will, from any firm, and this can go through the entire industry—a firm whose name and reputation and continued success in business is dependent upon quality pays more attention to it than a firm that may be entering the market for a particular opportunity to produce for a specific contract.

Now, these conditions that Mr. Feinberg mentioned are met by these firms that are regularly engaged in marketing a product by anyone who does business with us, but there are many firms who apply whose products do not meet these standards.

This is not a universal condition. It is something that some people do and some don't. We try to do business with those that do.

Senator NELSON. Concerning your statement that those that market under brand name meet a higher standard because their reputation is at stake——

Colonel SNYDER. Generally speaking.

Senator NELSON. I am interested in that because we have been trying to get any piece of evidence for 4 years to show that that was true and the brand-name companies can't produce it. Dr. Edwards testifying a few weeks ago said it wasn't true. Do you have any evidence of that?

Colonel SNYDER. I think more in the negative rather than the positive. We do have substantial evidence of rejection of products that do not meet these standards. We also test on brand-name products and they usually do meet our standards.

Now, again, you are asking me for a blanket statement and this is not possible. Generally speaking—this is true of any brand-name product you buy, whether you buy an automobile or a suit. Someone whose reputation——

Senator NELSON. Well, I would like to have the evidence because, as I said, I have been asking for it for 4 years and you assert that it is there and so does the Pharmaceutical Manufacturers Association, but nobody produces it.

Dr. Edwards just recently testified:

> In today's drug scene the brand name and generic name drugs that are approved by the FDA are, for all practical purposes, equal drugs in terms of their potency, uniformity, et cetera.

This has been the testimony of a number of experts over the past years. As a matter of fact, the only massive test I am aware of was for potency, and included 4,600 drugs. About 2,600 drugs were sold by generic name and 2,000 were sold under brand names. I think these are the figures—7.8 percent of the generic name drugs were not of acceptable potency and about 8.8 percent of the brand names flunked the test of potency. That is, they were above or below.

Now, I know of no other large test on potency. So I am interested in what evidence there is because we have been told that there isn't any difference between the quality of drugs sold by brand or generic name in the marketplace.

Now, this might be the basis of your statement—let me read it to you. I think it is a rather interesting, if not shocking, statement by Col. W. V. Breyfogle, USA, former Chief, Division of Medical Materiel, Defense Personnel Support Center, Defense Supply Agency, 1968. This is in a speech he gave at the 21st Annual Meeting of the Defense Supply Association and it was reprinted in "The Review," November–December 1968.

Listen to what he says. Now, if this is the basis of your statement, then it is a good explanation because you have the brand name people supplying you the specifications and, of course, they are the only ones that can meet them:

> The first problem that has been bothering us for some time is our inability to procure competitively. The policy of the Department of Defense as it has been for many years is that we will obtain competition on our procurements to the maximum extent possible.
>
> The major problem in our failure to procure competitively is the nature of the specifications that we are using. It has been said in the past that our specifications are too restrictive in nature and thereby restrict competition. There is some validity in this statement.
>
> However, before you can understand why we have a problem in procuring competitively, you must understand how items are selected for standardization and stockage in our Defense Supply Depot system. Items that are standardized by the Defense Medical Materiel Board and stocked in the DSA Depot system were for the most part developed by industry or independent research for use by the civilian medical profession and for sale in the market place.
>
> These items were presented to the Board for study and the determination was that they would be stocked for use in our system.
>
> Therefore, the specifications that are developed of necessity describe a certain manufacturer's item. Most of the information used in writing the specifications was furnished by the developer. Therefore, even if we have a, pardon the expression, generic specification, in many cases it merely describes the generic equivalent of a brand name.

This is by Colonel Breyfogle, former Chief, Division of Medical Materiel, Defense Personnel Support Center, Defense Supply Center.

I think that is a very fine explanation why brand names meet your standards more frequently and why the generics fail it.

Do you want to comment on that?

Colonel SNYDER. No. I am very familiar with that.

Senator NELSON. I am sure you must be. We have used it a couple of times before, and I have been waiting for an explanation which I have never received.

Captain MACPHERSON. If I may, Senator, in our opinion our specifications are not restrictive and any knowledgeable drug manufacturer can in fact supply us with the items that we want. The military services are under no obligation to buy the drugs that we

stock. If we do not have the specific item they want at an acceptable price, they will purchase it from another source.

Senator NELSON. Who will?

Captain MACPHERSON. The military services. Detailed comprehensive specifications are required in order for us to procure a product on a generic basis which is as professionally acceptable as the brand name item which the physician has been accustomed to use and in which he has confidence.

As an example of the success of our system in meeting the desired objectives, when FDA announced the recall of 711 items as Commissioner Edwards mentioned in 1968, we had only four of these items in the system. In 1969 when they had 707, we had three. And in the current fiscal year when they had 951, we had only one.

Senator NELSON. Who are "they?"

Captain MACPHERSON. FDA. Commissioner Edwards gave these figures in his testimony.

Senator NELSON. I see. You mean they listed that number.

Captain MACPHERSON. Of drug recalls, yes, sir.

Senator NELSON. These were drug recall figures?

Captain MACPHERSON. Yes, sir.

Senator NELSON. Well, I didn't hear any satisfactory response to my statement but I guess the record will speak for itself.

Let me ask you this question: Is it correct that about half of your purchases are centrally purchased and the others are purchased locally?

General HAYES. More correctly 70–30.

Senator NELSON. 70–30.

General HAYES. Central versus local.

Senator NELSON. 70–30.

General HAYES. 70–30. As opposed to 50–50.

Senator NELSON. I see. Seventy percent central?

General HAYES. Central.

Senator NELSON. And the other 30 percent is purchased locally?

General HAYES. Yes.

Senator NELSON. So about $30 million of $150 million, is that about the total? $100 million centrally and $50 million locally? Is that it?

General HAYES. $94 million total and that would be about 25 percent local out of the $94 million.

Senator NELSON. So——

General HAYES. $25 million.

Senator NELSON. In any event, this one-third, one-fourth whatever is purchased locally, is not purchased under the standards that you establish for central purchasing?

General HAYES. That is correct.

Senator NELSON. Do you find any difference in all of those drugs that are purchased locally? Are they used locally?

General HAYES. They are used locally.

Senator NELSON. Do you find any problem with those which are different—for example, more doctors complain about them?

General HAYES. In view of the fact that they are used locally and rather rapidly, of course, we don't have the shipping and storage problems in a breakdown of that kind. If there are problems, these

are brought to the therapeutic agents board and ultimately reported up through the adverse reaction system.

Senator NELSON. Let me just conclude by saying, General, that it strikes me that the Defense Department is approaching the whole problem very sensibly and that, all in all, it looks to me as if you have had a good record and it seems to me the procedures you have established for examining the whole question of rational prescribing, purchasing, and utilization of drugs is a sound approach.

Maybe a year from now when we have a record based upon your new approach to the problem, you may wish to make a report to the committee at that time.

General HAYES. We would be glad to, Mr. Chairman.

Senator NELSON. Thank you very much, gentlemen.

General HAYES. Thank you.

(Upon the direction of the chairman, information pertinent to the hearings follows:)

DEPARTMENT OF THE AIR FORCE,
HEADQUARTERS, U.S. AIR FORCE,
Washington, D.C., November 27, 1970.

Reply to
Attn of: SGPAC
Subject: Rational Prescribing of Drugs
To: AAC, ADC, AFSC, AFLC, AFCS, ATC, AU, AFRES, CINCPACAF, CINCUSAFE, HQ COMD USAF, MAC, CINCSAC, TAC, USAFA, USAFSO, USAFSS.
(Surgeon)

1. All Air Force Medical Service officers should, by now, be aware of the National Academy of Sciences/National esearch Council drug efficacy study which was begun in 1966 at Hthe request of the Food and Drug Administration. The goal of this study was to review all marketed drugs for therapeutic efficacy. Some of the findings of this study have already been released, and others will be forthcoming after the study is completed. To insure that these findings are available to every Air Force medical facility, listings of all findings will be reported initially in an ALMAJCOM letter and thereafter in Air Force Medical Materiel letters (AFMML) as they are released. Additionally, professional guidance, policies, and therapeutic notes will appear regularly in the *USAF Medical Service Digest.* It is the responsibility of each therapeutic committee to insure that the professional staff is advised of all such information and guidance.

2. Drugs that are found to be ineffective will be removed from the stocklist and local purchase of such items will not be authorized.

3. In addition to those drugs determined to be ineffective, there is the matter of high cost drugs being prescribed when equally effective but much less expensive drugs are available. Many experts are convinced that Librium and Valium are vastly over-prescribed today. Similarly, Darvon probably has no greater analgesic effectiveness than aspirin and there are totally effective low cost alternates for Ornade. Therapeutic committees must regularly review their own drug consumption data to insure that formularies not only satisfy the needs of the staff but also accurately reflect the judgments of current medical literature and the harsh reality of austere finances. We cannot justify the purchase of high cost drugs when equally effective but less expensive preparations are available.

4. You are directed to take necessary action to insure that all medical service officers are aware of this guidance. Rational prescribing must become a matter of special interest to all of us in the future.

THOMAS H. CROUCH,
Major General, USAF MC,
For the Chief of Staff.

(Whereupon, at 11:35 a.m., the Subcommittee on Monopoly of the Select Committee on Small Business adjourned, to reconvene at the call of the Chair.)

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