COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

HEARINGS

BEFORE THE

SUBCOMMITTEE ON MONOPOLY

OF THE

SELECT COMMITTEE ON SMALL BUSINESS

UNITED STATES SENATE

NINETY-FIRST CONGRESS

SECOND SESSION

ON

PRESENT STATUS OF COMPETITION IN THE PHARMACEUTICAL INDUSTRY

PART 18

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COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

(Present Status of Competition in the Pharmaceutical Industry)

TUESDAY, AUGUST 6, 1970

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

The subcommittee met, pursuant to recess, at 10:10 a.m., in room 318, Old Senate Office Building, the Honorable Gaylord Nelson (chairman of the subcommittee) presiding.

Present: Senators Nelson and McIntyre.

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

Senator NELSON. The hearing will come to order.

Senator MCINTYRE. Will the chairman yield?

Senator NELSON. Yes. Be glad to, Senator McIntyre.

Senator MCINTYRE. Mr. Chairman, I would like to point out that our witness today is one of my most distinguished constituents. Governor Dwinell served as Governor of the State of New Hampshire for two terms, 1955 through 1959. He served previously as Assistant Secretary of State for Administration during the Administration of President Eisenhower. Lane Dwinell has been prominent in the New Hampshire and national business world, serving as president of the New Hampshire Manufacturers Association and director of the National Association of Manufacturers.

He has had as varied a wealth of public service in my State as anyone that I can think of, as president of the State Senate, speaker of the State House of Representatives, and member of the State Board of Education. Statesman, banker, manufacturer, and public servant—my State is proud of his record and I am delighted to welcome him here and introduce him to you on this committee.

Senator NELSON. Governor, I am pleased to have you here. If you decide to run again, I see whom you can get for campaign manager.

Governor, the committee is pleased to welcome you and your associates from the Department. Why don't you present your statement however you wish, and it will be printed in full in the record. I trust that if we have questions as you go along, you will not object to interruptions.

STATEMENT OF GOV. LANE DWINELL, ASSISTANT ADMINISTRATOR FOR ADMINISTRATION, AGENCY FOR INTERNATIONAL DEVELOPMENT, DEPARTMENT OF STATE; ACCOMPANIED BY NATHAN SALANT, RESOURCES POLICY ADVISER IN THE OFFICE OF PROCUREMENT; MATTANIAH EYTAN, ASSISTANT GENERAL COUNSEL FOR PROCUREMENT AND TRANSPORTATION; AND SEYMOUR BARONDES, CHIEF OF THE COMMODITY ELIGIBILITY AND PRICE BRANCH, OFFICE OF THE CONTROLLER

Mr. DWINELL. Thank you, Mr. Chairman. May I thank your colleague for his gracious introduction.

I have a statement which has been submitted to the committee, which I would like to read, if the Chair would permit.[1]

Senator NELSON. Of course, Governor.

Mr. DWINELL. I appreciate this opportunity to discuss AID programs which involve the procurement of pharmaceutical products. I have with me several colleagues who are prepared to discuss in detail specific aspects of our program, which have been of special interest to this committee.

On my right is Mr. Nathan Salant, Resources Policy Adviser in the Office of Procurement; on my immediate left is Mr. Mattaniah Eytan, Assistant General Counsel for Procurement and Transportation; on his left, Mr. Seymour Barondes, the Chief of Commodity Eligibility and Price Branch in the Office of the Controller.

But before delving into details of such procurement, I would like to describe, in general terms and without specific regard to pharmaceuticals, why we have different types of programs and how they are conducted.

We conduct three basic programs under which commodities are financed with AID funds. Pharmaceutical products may be purchased in two of these programs—technical assistance programs and commercial import programs. The third activity, capital project assistance, is not of concern in our discussion today.

The first type of program mentioned, technical assistance, encompasses educational and training activities. Included are projects in various fields such as health, disease prevention and family planning. Possible programs are developed in the field by our mission specialists working in close collaboration with cooperating country officials and possibly with UN or other international agency experts. Gradually, their ideas gain substance, scope, and specificity and a definite program takes form—goals to be achieved, facilities to be established, technical services to be recruited, material to be assembled, supplies to be procured.

Feasibility studies are made and time frames for performance prepared. Analyses of resource availabilities and needs are of course essential and figure significantly both in regard to project initiation and continuation.

Ultimately, the proposed program is presented by the mission to Washington for consideration. We appraise each proposal in the context of its suitability for AID participation, of its essentiality to the development of the aid-receiving country, and of its priority relative to other project options.

[1] See information beginning at p. 7364.

The Agency seeks to confine approvals to carefully formulated, high priority proposals that promise meaningful achievements. Funds authorized in approved projects thus are earmarked for prescribed technical services and for specific commodities.

In other words, when a technical assistance project is authorized, we have considerable knowledge regarding the commodities to be financed, including knowledge as to what will be bought and what procurement procedures will be employed.

The second type of program is the AID commercial import program. This has two major complementary objectives:

First, it provides foreign exchange to finance private sector imports of commodities needed by industry and agriculture as well as to finance imports of essential consumer goods.

Second, it supplements the revenue of the aid-receiving country and thus enables that government to meet the local currency costs of its development activities.

Senator NELSON. May I interrupt a moment, Governor?

Mr. DWINELL. Yes.

Senator NELSON. That sentence, "First, it provides foreign exchange to finance private sector imports of commodities needed by industry and agriculture as well as to finance imports of essential consumer goods," you are talking about the aided country here?

Mr. DWINELL. The aided country, yes, Mr. Chairman.

Senator NELSON. When you say "foreign exchange," how is foreign exchange involved?

Mr. DWINELL. It provides foreign exchange credits, Mr. Chairman. It provides dollars for the procurement of commodities in this country for import by a lesser developed country, which does not have adequate foreign exchange capability.

Senator NELSON. I do not know the best time to discuss this so that I understand it. Will you discuss it in some detail later on?

Mr. DWINELL. Yes, I do develop this point further, Mr. Chairman.

Senator NELSON. What is meant, then, is that AID, in this case, will pay in American dollars a given amount of money to an American company for a certain amount of product. Then the foreign company—and I note a substantial percentage are subsidiaries of domestic companies—gets the product, so if it is $100,000 worth of American dollars paid to an American company for American products, those products are going to go to the foreign importer, in many cases, the subsidiary. The subsidiary then transfers from its holdings in that foreign country $100,000 worth of that country's domestic currency to that particular country's bank. Is that correct?

Mr. DWINELL. That is correct.

Senator NELSON. Then the American company that received the $100,000 sends the product over to the importing subsidiary (if it is a subsidiary). The subsidiary, then, transfers from its private holdings the equivalent of $100,000 in local currency to its Government, then sells the drugs it receives or the products it receives in the open market in the country in which it is located. Is that a correct analysis of what happens?

Mr. DWINELL. That is correct. But to complete the cycle, the local currency is deposited in the national bank of the aided country and the Government of that country repays the loan to us in dollars, under the terms of the loan.

Senator NELSON. In dollars?

Mr. DWINELL. In dollars. These are all dollar loans, Mr. Chairman.

Senator NELSON. We do not send any dollars over?

Mr. DWINELL. No.

Senator NELSON. The subsidiary in the foreign country transfers local currency which they have to the receiving country's bank. This constitutes a loan and must be paid back in the equivalent of dollars; is that right?

Mr. DWINELL. The country with whom we make the loan agreement, undertakes as a condition of that loan to repay us in dollars at some future time.

Senator NELSON. One hundred percent repayment?

Mr. DWINELL. Yes. We do not make loans which are repayable to us under the commercial import program in local currencies; they are repaid to us in dollars.

Senator NELSON. At what interest rate?

Mr. DWINELL. That depends on the terms of individual loans. Every loan actually is negotiated separately with the different countries and different loans with the same country, and the terms would vary.

Senator NELSON. What is the usual period of time over which the loan extends?

Mr. DWINELL. The typical one at this point might be a loan at 3.5 percent interest for 30 or 40 years. They are long-term, low-interest loans, but they are dollar loans.

Senator NELSON. For 30 or 40 years. Under the terms of the loan, does the receiving country pay back principal and interest annually?

Mr. DWINELL After a grace period.

Senator NELSON. How long is the grace period?

Mr. DWINELL. It is a few years, sometimes as long as 10 years.

Senator NELSON. How long has this particular loan program been in effect? This specific aspect of the program?

Mr. DWINELL. We have had, as I understand it, the commodity import programs going back to Marshall plan days. But I refer to the history of AID in its present form, which goes back to 1961, the Foreign Assistance Act of 1961. Loans made for the commodity import program since then have been dollar repayable.

Senator NELSON. Do I understand that normally interest is paid annually, or is there a grace period on interest, too?

Mr. DWINELL. There is a short grace period on interest and then it is paid annually.

Senator NELSON. And the interest is paid in American dollars?

Mr. DWINELL. In dollars.

Senator NELSON. Are there any countries that default on their interest, or are behind?

Mr. DWINELL. I am informed that the United Arab Republic has been in default on some loans, both as to principal and interest, and there have been possibly a few delinquencies. But the record which we can submit for the record has been exceptionally good.

Senator NELSON. How many countries are involved in this kind of a loan program?

Mr. DWINELL. Of course, the number of countries has varied over the years, but at the present time there are approximately 12 countries.

Senator NELSON. Are any of them in default on principal? Apart from the United Arab Republic?

Mr. DWINELL. No, Mr. Chairman.

Senator NELSON. Please continue.

Mr. DWINELL. Development projects involve substantial local currency expenditures to defray costs such as land purchase, rentals, labor, indigenous materials and services. For many developing countries, these items cost a great deal more money than their financial resources can provide. The commercial import program offers a partial solution. It creates a channel through which imported commodities, purchased with American dollars, can be converted into local currency accruals to the Government of the importing country. This local currency is then available to support joint economic and, where necessary, defense programs. The mechanics of the system explain how this is done.

This addresses itself to the point which we were discussing, Mr. Chairman, but I think this gives the details which may be of interest to the committee.

The commercial import program works through commercial banking channels and is dependent upon the activities of private businessmen. A firm which sees an opportunity for profit in the importation and resale of particular goods eligible for AID financing obtains an import license if it is required, consumates an "exchange contract" with the local bank, arranges for the procurement and transportation of the goods, pays to his local bank the total cost of the goods in local currency, pays customs duty to his government on arrival of the goods, warehouses, and then processes or sells the goods on the open market. The risk inherent in this transaction falls to the importer, the profit or loss also goes to him.

Senator NELSON. May I interrupt a moment?

Mr. DWINELL. Yes.

Senator NELSON. I do not see the risk involved when it is a case of the parent company dealing with its own subsidiary in a foreign country. Can you explain to me where the risk is?

Mr. DWINELL. Yes, Mr. Chairman.

The business risk is on the part of the subsidiary, in this instance in the foreign country, as to whether or not it can sell the product commercially at a profit. There is a normal business risk undertaken here.

This process only finances the importation in the case of pharmaceuticals, the raw materials, if you will; and the drug company takes a normal business risk as to whether or not it can sell the product.

Senator NELSON. That is the part that puzzles me in looking at the prices. I cannot understand where the risk is. The subsidiary is not going to import the drug unless there is a market.

Mr. DWINELL. Well, may I say, Mr. Chairman, that any importer takes a risk in importing something for resale, as to whether or not his market still exists by the time he is ready to make his sale. And may I add, Mr. Chairman, he has competition within the importing country.

Senator NELSON. Do you have a copy of the chart which the staff made up?

(The chart above-referred to, follows:)

COMPARISON OF AID AND EUROPEAN BULK PRICES

Product and AID supplier, 1969	Foreign recipient	AID price 1968–69	European competitive price of same product or therapeutic equivalent	Percent of AID price to European competitive price
Tetracycline HCL (antibiotic):				
American cyanamid	Cyanamid, Pakistan	$270 per kilogram	$24 to $29 per kilogram	1,125
Do	Cyanamid, Colombia	$100 per kilogram	do	416
Bristol	Bristol, Colombia	$250 per kilogram	do	1,041
Do	Bristol, Pakistan	$190 per kilogram	do	792
Chlortetracycline (antibiotic):				
American cyanamid	Cyanamid Colombia	$100 per kilogram	$25 to $30 per kilogram	400
Do	do	$250 per kilogram		1,000
Do	do	$150 per kilogram		600
Do	Blemco Import Co	$17 per kilogram [1]	66 cents to $1.35 per kilogram	2,576
Doxycycline (Vibramycin) (antibiotic):				
Pfizer	Pfizer, Colombia	$1,750 per kilogram	Tetracycline, $24 to $29 per kilogram [2]	7,292
Do	do	$2,250 per kilogram		9,375
Do	Pfizer, Pakistan	$1,750 per kilogram		7,292
Methacycline HCL (Rondomycin) (antibiotic):				
Pfizer	Pfizer, Colombia	$450 per kilogram	Tetracycline, $24 to $29 per kilogram	1,875
Do	Pfizer, Pakistan	$350 per kilogram		1,458
Demethylchlortetracycline (Declomycin) (antibiotic):				
American cyanamid	Cyanamid, Colombia	$400 per kilogram	Tetracycline, $24 to $29 per kilogram	1,667
Do	do	$350 per kilogram		1,458
Do	do	$250 per kilogram		1,042
Do	Cyanamid, Pakistan	$405 per kilogram		1,688
Do	do	$450 per kilogram		1,875
Rolitetracycline (Bristacin) (antibiotic):				
Bristol	Bristol, Colombia	$550 per kilogram	Tetracycline, $24 to $29 per kilogram	2,292
Oxytetracycline HCL (Terramycin):				
Pfizer	Pfizer, Pakistan	$100 per kilogram	$30 per kilogram	333
	Pfizer, Colombia	do		
Ampicillin trihydrate (antibiotic):				
Bristol	Bristol, Colombia	$420 per kilogram	$150 per kilogram	280
Benzathazine penicillin (Bicillin) (antibiotic):				
Wyeth	Wyeth, Colombia	$160 per kilogram	$31 to $32 per kilogram	516
	Wyeth, Chile	$215.75 per kilogram		696
	Wyeth, Pakistan	$44.10 per kilogram		141
Chlordiazepoxide granulate (Libruim) (tranquilizer):				
American Roche	Merck, Pakistan	$245 per kilogram	$21.50 to $25 er kilogram	1,114
Diazepam granulate (Valium) (tranquilizer):				
American Roche	do	$182.90 per kilogram	$49 per kilogram	373

Oxazepam (Serax) (tranquilizer):				
Wyeth	Wyeth, Colombia	$800 per kilogram	Diazepam $49 per kilogram	1,632
	Wyeth, Chile	$187.50 per kilogram		383
Chlorcyclizine (antihistamine):				
Abbott	Abbott, Turkey	$155 per kilogram	$30 per kilogram	
Cyproheptadine HCL (Periactin) (antihistamine):				
Merck	Merck, Colombia	$1,800 per kilogram	Chlorpheniramine, $20.50 per kilogram [3]	8,780
	Merck, Pakistan	$1,600 per kilogram		7,805
Dexchlorpheniramine maleate (Polaramine (anti-maleate) histamine):				
Schering	Laboratories, Undra, Colombia	$650 per kilogram	Chlorpheniramine, $20.50 per kilogram [4]	3,171
Dibenzcycloheptatrien piperdine (antihistamine):				
Merck	Merck, India	$1,060 per kilogram	Not included in USP or NF	5,171
	Merck, Pakistan	do	Chlorphemiramine, $20.50 per kilogram	5,171
Ethoheptazinecitrate (Zactane Citrate) (analgesic):				
Wyeth	Wyeth, Colombia	$150 per kilogram	Aspirin, $1.32 per kilogram	11,364
Triamcinolone (glucocorticoid):				
American Cyanimid	Cyanamid, Brazil	$8,000 per kilogram	Prednisone, $550 to $580 per kilogram [5]	1,454
	Cyanamid, Colombia	$12,000 per kilogram		2,182
	Cyanamid, Pakistan	$13,930 per kilogram		2,533
	Cyanamid, India	$7,960 per kilogram		1,447
Dexamethesone (glucocorticoid):				
Merck	Merck, Colombia	$27.50 per gram	$7.30 per gram	377
	Merck, Pakistan	do	Prednisone sells at 38 cents per gram	4,741
Dexamethasone (Decadron Phosphate) (glucocorticoid):				
Merck	Merck, Pakistan	$31.90 per gram	$7.75 per gram	411
Do	Merck, Colombia	do	do	411
			Price of prednisone, 58 cents per gram.	3,500
Methylprednisolone (glucocorticoid)				
Upjohn	Upjohn, Colombia	$5.10 per gram	Prednisolone, 55 cents per gram	
			Prednisone, 58 cents per gram	879
Trihexyphendyl Hydrochloride (Artane) (antispasmatic:)				
American cyanamid	Cyanamid, Colombia	$1,800 per kilogram	No European competitive price. Note difference in price to Colombia and Brazil.	
Do	Cyanamide, Pakistan	$1,700 per kilogram		
Do	Cyanamid, Brazil	$303 per kilogram		
Nalidixic acid (antibacterial):				
Winthrop	Sydney Ross, Colombia	$94 per kilogram	$70 per kilogram	134
Do	Sydney Ross, Brazil	do		134
Chlormethazone (Fenarol) (tranquilizer):				
Winthrop	Ross, Colombia	$70 per kilogram	$22.50 per kilogram	311
Do	Ross, Brazil			

[1] Feed grade.
[2] Medical Letter, July 25, 1969. No difference among tetracyclines.
[3] See Medical Letter, vol. 9, No. 7, p. 28.
[4] See Burack, p. 89.
[5] See Medical Letter, vol. 9, No. 11, pp. 42–43.

Mr. DWINELL. I have it before me now, Mr. Chairman. I had not seen it before, but I have it now.

Senator NELSON. With regard to the question of risk, the first item on the chart is tetracycline HCL. American Cyanamid is the supplier and Cyanamid, Pakistan, is the foreign recipient. Now, AID pays American Cyanamid $270 for a kilogram of tetracycline HCL. The world price is $24 to $29 a kilogram. AID finances this product at about 11 times the price at which it is available in the world market.

Suppose American Cyanamid buys it at the world price, $24 to $29 a kilogram, and then AID pays them $270, which is over 11 times as much, and then it is shipped to Cyanamid, Pakistan, and Cyanamid, Pakistan, sells it in the market over there.

Where is the risk?

I do not see how in heaven's name any businessman could ever conceivably lose money by selling something at 11 times as much as he can buy it, which is a tremendous profit, and then turn it over to Cyanamid, Pakistan, who would not ask for the importation in the first place unless it had the market.

Where is the risk?

Mr. DWINELL. Well, the risk is on the part of the importer——

Senator NELSON. The importer is owned by the exporter.

Mr. DWINELL. If I understand your question, Mr. Chairman, you are indicating that this pharmaceutical was purchased on the world market.

Senator NELSON. Tetracycline is available in the world market at $24 to $29 a kilogram. AID is paying American Cyanamid $270 a kilogram. So then the company with its subsidiary—after all, the subsidiary is the same outfit—has already made a profit, 1,125 percent markup, and then Pakistan Cyanamid has a market over there and obviously they will sell at a markup from what the American parent company paid. They will not import it unless it is needed, and they can send it back if it is not used.

I wonder where the risk is.

Mr. DWINELL. Mr. Chairman, I think you are assuming that AID is financing pharmaceuticals which are purchased in the world market. AID only finances pharmaceuticals which are purchased in the United States and manufactured in the United States.

Senator NELSON. What is the domestic price for tetracycline manufactured in this country?

Mr. DWINELL. I think, Mr. Chairman, to put this in further perspective, I should indicate that these prices are carefully audited and we make sure that we finance these transactions at a price that does not exceed the prevailing market price in the United States, as we are enjoined to do.

Senator NELSON. However, lots of tetracycline is imported. Do you require some certificate from American Cyanamid saying that they have not imported this tetracycline at $24, that, in fact, they bought it from within the United States and certify the price they paid to the domestic producer?

Mr. DWINELL. Mr. Chairman, we require a certification that the pharmaceutical which we finance is of American origin.

Senator NELSON. Tetracycline is imported by some domestic companies, as are lots of other compounds that are sold in the domestic market. Are you saying that AID requires some certification in writing from the company that the drug for which they are receiving payment from AID and then shipping to a foreign country is, in fact, produced in the United States?

Mr. DWINELL. Yes; that is correct, Mr. Chairman, we do.

Senator NELSON. That certification is required of every company with which AID deals?

Mr. DWINELL. Yes.

Senator NELSON. If you will look at the next row on the chart you will see that American Cyanamid was paid $100 a kilogram on exports to Columbia. That is $170 less than received for shipping to Pakistan. How do you explain that dramatic difference in the amount AID pays to American Cyanamid for shipment to Columbia versus shipment to Pakistan?

Mr. DWINELL. Mr. Chairman, the practice of our agency in its post audit is to take what is considered to be the proper prevailing price, rather than any exceptional price which may show up with respect to individual transactions with a particular country.

Senator NELSON. Well, let me recite the dates for you. On October 8, last year, 1969, AID paid American Cyanamid $100 a kilogram for the shipment of this tetracycline to Cyanamid, Colombia. Then just about 21 or 22 days later, AID paid American Cyanamid $270 a kilogram for the shipment of tetracycline to Cyanamid, Pakistan.

Now, are you saying that the domestic price went up from $100 to $270 a kilogram in 22 days?

Mr. DWINELL. Mr. Chairman, I would like to ask Mr. Eytan, who is more familiar with that point than I, if he might answer that question for you.

Mr. EYTAN. Mr. Chairman, any comparison between two prices taken without looking at the larger picture which consists of all prices for comparable commodities moving during a similar period, tends to be misleading. The Congress has enjoined AID not to finance commodities at prices which exceed in the relevant case——

Senator NELSON. Exceed what?

Mr. EYTAN. Exceed the market price prevailing in the United States for export shipments. That means that we look at the range.

Senator NELSON. The prevailing price for export shipments or the prevailing price for the product in the domestic market?

Mr. EYTAN. The market price prevailing in the United States for export shipments. That means that we are enjoined to look at a broad range of prices to determine what is the prevailing market price for export shipments.

Senator NELSON. Are you saying there are two price structures here; that there may be a domestic price that is charged to any company or anybody buying in the United States and another price if you are a foreign buyer?

Mr. EYTAN. That is possible. I am not saying that a two-price structure does actually exist with respect to any particular commodity, but it may well be that a price structure exists for domestic sales, a sale by a seller to somebody in Pittsburgh; and another price

structure for sales in export. After all, the competitive conditions in export can differ more radically than the competitive conditions in this local market.

But the emphasis which we are putting on this test is that a mere comparison of any two prices tells you nothing about the ranges of prices in other sales which would determine the price that is prevailing. In fact, a prevailing price really connotes a range of prices. It may well be that a price of $100 per kilogram would be below the level of prices prevailing for that particular time.

Senator NELSON. Prevailing where?

Mr. EYTAN. Prevailing in the United States for export shipments.

Senator NELSON. Well, you can see, can you not, that there is certainly a very dramatic difference in 22 days between a price paid by AID at $100 a kilogram, versus $270 a kilogram. What happened to change that price so dramatically?

Mr. EYTAN. Mr. Chairman, we finance each year upward of 50,000 separate transactions covering a wide range of commodities and some years the number is closer to 100,000. We have 43 auditors, full-time auditors, who work through this mountain of paper material to develop a case fully on post audit to determine whether AID has overpaid. It invariably takes longer than 6 months.

One has to survey the market, one has to see whether there were, in fact, special reasons to justify the difference in price. We determine whether the two sales that we are comparing are actually comparable. There are different formulations, different classes of end-use customers. We secure commercial information from all sources available. We put the company upon its metal to explain to us the discrepancy. We hold them to a high standard.

After 6 months or longer, when we have the facts down, we apply the test to which the supplier receiving AID financing is certifying and then we demand a refund payment if we have indeed overpaid.

Senator NELSON. Was there a refund in this particular case?

Mr. EYTAN. I cannot tell you whether this case, this particular case, has been completed in our post audit process.

Senator NELSON. Well, one was October 31, 1969, and the other was October 8, 1969. So that has been post audited, I take it?

Mr. EYTAN. I can assure the committee that if an excessive price was paid under our rules, the AID post audit system will catch it. We post audit nearly every sale of pharmaceutical products.

Now, there is, of course, a time lag between the date of sale—actually, the date of shipment is not the day on which we begin the post audit.

Senator NELSON. Have there been any cases in which you have gone back to the company on drugs and said you charged too much?

Mr. EYTAN. A large number of cases, and Mr. Barondes, on my left, can give you the figures.

Senator NELSON. Can you submit for the record those specific instances?

Mr. BARONDES. Yes, Mr. Chairman.[1] We do spend actually an inordinate amount of time on pharmaceuticals compared to many other products. We have submitted a large tabulation of the prices

[1] See p. 7390.

to you, and in some instances the prices shown exceed the prevailing market prices eligible for financing under our rules. We have collected refunds just within the last year of approximately $1 million.

We have about $2 million in claims outstanding, of which $1.5 million are in the Department of Justice and about half a million are still being worked on. We have issued these claims and we are in the process of discussion with the companies against whom these claims have been issued. We expect that we will get paid on those claims.

Senator NELSON. As I understand it, the American company must assert that this is the domestic price. These two payments were made by AID 22 days apart. There are some more dramatic examples here but this is quite a dramatic change from $100 to $270 a kilogram. What evidence did American Cyanamid submit that the domestic price had changed that dramatically in that 22-day period?

Mr. BARONDES. First, of course, we are talking about the export price, and in looking at these prices we look at it with the same eye that you look at it. Where we see a variation in prices of this nature, we dig further. We do not know at this point whether this price was excessive. As I said, we have issued a large number of claims. We have not issued any claim on this particular item, but I can assure you that if we find this price exceeded prevailing market prices, then we will do the same with American Cyanamid that we have done with a good number of other companies. This information was made available to you rather quickly for the simple reason we had all of these documents available—because they were in the process of review at the time.

These are not closed cases. Most of our claims, by the time they are issued, cover transactions running about 2 years after the day of shipment.

Senator NELSON. Does AID have a listing of domestic prices of the drugs on the marketplace, that is, the wholesale price?

Mr. BARONDES. We do obtain price lists from pharmaceutical companies. We do have, of course, standard publications. Many of these items are intermediate products and might not have a domestic listing. We are concerned with the export price and from my own experience we find that more often than not the export price is lower than the domestic price.

Senator NELSON. Lower than the domestic price?

Mr. BARONDES. Very often, yes. We found that in items sold by the pharmaceutical industry as well. I am talking about the American export price now, as against the American domestic price.

Senator NELSON. It appears to me that this whole arrangement is very beneficial to the United States, and very beneficial to the American company.

In other words, if we are going to be paid back and are paid back in American dollars, 10 to 20 times as much as the value of the drug, we are getting back a tremendous lot of American dollars for a drug that is available to that company for one-tenth or one-twentieth the price any place else in the world.

Isn't there a very serious moral question, in that we are taking back from Pakistan $270 a kilogram in American dollars and are

transferring to them their own soft currency? This seems to be very beneficial to us; it is a good hard Yankee bargain.

Although the American company is getting a very handsome price, the poor consumer over there is paying on a base of $270 a kilogram when, in fact, his Government could be buying it at the world price for $24.

Mr. EYTAN. Mr. Chairman, if I could respond to that.

Senator NELSON. Yes.

Mr. EYTAN. The Congress has pointedly required AID to emphasize procurement from the United States. It is not peculiar to the U.S. drug industry, in that many items from the United States are priced higher than the price which a European competitor might charge for a similar or identical commodity. In the steel business, for example, the U.S. price has notoriously been higher than foreign prices. There are many commodities in which the American price is simply not competitive.

On the moral issue with which you preface your comment, we feel keenly that a foreign aid dollar should not be spent by an AID recipient country to pay a price which is higher than the country would pay for the same item with a non-AID dollar. That is, the price which we finance for the pharmaceutical product under AID financing must not be higher than the price which the same buyer would have to pay if he were using his own funds, free foreign exchange funds of the host AID recipient country, to buy the same product in the United States.

The moral consideration is that AID funds not carry a premium—not carry a higher price on sales from the United States. If the Congress had wished or had felt that it was in the interest of the foreign aid program, notwithstanding the balance-of-payment position of the United States, to open up procurement on a worldwide basis, then American suppliers competing for the AID export dollar would be faced with competition from European and other foreign suppliers.

But as the situation now is, American suppliers are insulated from foreign competition and the only standard that we hold them to is that their prices in AID sales not exceed prices in non-AID export sales.

Senator NELSON. But it is still correct, is it not, that if the United States is able to pay an American company 20 times or 10 times as much as the world price, that that produces money for the American company, it keeps the American dollar in America, it helps the foreign exchange? In many of the countries overseas, there are limitations on the amount of dollars that can be taken out.

So the foreign subsidiaries sit there with a surplus of soft foreign currency, perhaps piasters or the like: they transfer that over to the foreign government, who in turn must pay us back in hard dollars, which helps our foreign exchange. It is a very good deal for us. We get $270 plus interest back for a product that cost $24 on the world market and we pay the domestic company $270.

When the poor consumer goes to buy it, however, after it is processed, he must pay 20 to 30 times as much as he would have to pay if it were coming from another country.

Mr. EYTAN. Mr. Chairman, things rarely work in the marketplace

with that type of wide profit margin being enjoyed by a company for a significant period of time. The importing company, the subsidiary in your hypothetical, competes with other importers. If indeed the product—let us say tetracycline—is available at one-tenth or one-eleventh of the U.S. price in Europe, then the competitor of the importer buying the American product will press his government for permission to buy the tetracycline from the European seller at one-tenth the price, using the free foreign exchange, that is, the non-AID foreign exchange of a country.

When this importer buys from, let us say, Italy at $24 per kilogram, he can then sell the product locally and enjoy a vast profit, which would make it impossible for the overseas subsidiary buying from the American parent to resell at a profit.

The point of this example which I am trying to suggest is that there are powerful forces within each country which make certain that no one is going to enjoy a lock on the market. If there is no competition from Europe at low prices, then goods will be bought from other sources where prices are low.

Of course, Mr. Chairman, as the committee knows, tetracycline is something of a special case, in any event.

Senator NELSON. Special in what way?

Mr. EYTAN. It has had a notorious history in the past decade. Tetracycline has been involved, as you know, in some serious conspiracy charges; the price in the United States may have been maintained, I say *may* have been maintained at artificially high levels; cases affecting tetracycline have been dragging through the courts now for over a decade.

We may also point out—I think we really want to emphasize the point—that especially with respect to tetracycline, the Congress put a provision into the Foreign Assistance Act, section 606(c); that provision had one eye cocked at tetracycline, we believe, since that provision prohibits any government agency from purchasing drug products outside of the United States when a U.S. company holds a valid patent over that product.

In looking at section 606(c) and its legislative history, we note this discrepancy which you have pointed out, namely, that U.S. prices for tetracycline were much higher than prices at which the same product was offered by certain European suppliers. This discrepancy served as a special impetus for insertion of 606(c).

Senator NELSON. I have taken one of the least dramatic examples of the discrepancy. I will give you an 8,000 percent difference between the price charged by the American company and the world market price in a few moments. But let us get back to your one point—that there is tough competition. If there is any competition at all, why would anybody be able to sell 1 kilogram of tetracycline for $270, when it could be purchased by any competitor for $24?

It seems to me that if there were competition, he would not sell any of this drug. I think that sounds ideal in the marketplace where everybody knows what is going on, everybody knows the drug and there is genuine competition. But if there were competition, how would your company outsell any other company in Pakistan, if you are paying $270 and another company is paying $24.

Mr. EYTAN. The availability of the product from a European source is not a constant thing. Moreover, the drug has to be reduced into a finished dosage form. The American companies frequently invest in establishing or acquiring local subsidiaries, who then buy the bulk product from the United States, and then finish off the product into tablets, pills, and other forms.

There is a further processing required and a comparison of a price from the Italian, Portugese source, or whatever source it is, frequently does not tell the whole story. In emphasizing the analysis of competition within the local market I call the attention of the Committee to the fact that there are pressures in the local economy and that if it is not profitable to purchase the bulk product from the United States, using AID dollars, it will not be done.

Senator NELSON. I still do not quite follow it. If there is competition over there and there are other companies with the capacity to make a finished product out of a kilogram of bulk tetracycline, how does American Cyanamid compete at $270 a kilogram versus $24. Can you name any companies that compete with American Cyanamid over there producing finished products out of tetracycline bulk?

Mr. EYTAN. I can say in most of these countries the privilege of securing an import license is extended to many importers. We do not have a situation in a country which I am familiar with in which licenses are issued to a very small and selective group. Therefore, the subsidiary abroad must always take into account that any other drug importer can compete with it by securing free foreign exchange to buy from Europe.

It is because of this open licensing that we feel it is proper to say that the American price can make economic sense in the local market, because otherwise the AID funds would not be spent for this product.

Senator NELSON. Let me ask another question.

In the purchasing of drugs by AID, do Europeans make any evaluation of therapeutic equivalency? For example, the Medical Letter takes the position that the drug of choice is tetracycline HCL. Prices vary dramatically. There are many kinds of tetracyclines and the very distinguished Medical Letter said that the different tetracyclines have similar clinical effectiveness. It also states that the oral tetracycline of choice is tetracycline hydrochloride capsules. And for parental administration, the tetracycline of choice is tetracycline hydrochloride.

In the tetracycline family we have Pfizer's doxycycline (Vibramycin) at $2,250 a kilogram; American Cyanamid's demethylchlortetracycline (Declomycin) at $400 a kilogram. And yet the best medical experts say that tetracycline HCL is the drug of choice.

Why do you buy a major brand name "me-too" drug that costs several times as much as just plain tetracycline, when the Medical Letter says they are therapeutically equivalent?

Mr. DWINELL. Mr. Chairman, I would like to have Mr. Salant answer that question, if I might. But first, may I say with regard to AID purchasing these pharmaceuticals under the commodity import program, AID does not purchase, AID finances.

Senator NELSON. I am sorry——

Mr. DWINELL. Such purchases, such imports of a lesser developed country as that country desires by its own policy.

I think it is clear, probably, to the committee, but I would like to emphasize this.

Senator NELSON. I do not see that Uncle Sam is losing anything. I think he is coming out very well. I think the American manufacturers of drugs are coming out very well. I think, on the other hand, the poor consumer and poor undeveloped countries that we claim we are helping are coming out very poorly.

Mr. DWINELL. May I only say this, Mr. Chairman, that AID does not, in any sense, dictate to its client country what it shall buy. In other words, under a program loan, it is the choice of the host country or the lesser developed country, to whom we make this loan, to use the foreign exchange which is made available by this loan for a wide range of commodities.

So if the country, by its own policy, decided that it did not want pharmaceuticals imported from the United States, if it felt that the interest of the country would be better served by using those dollars for some other product or commodity, it has a choice to do so.

Senator NELSON. But are we not dealing with a situation in which there is no sophisticated pharmaceutical expertise in any developing country in the world? Most of these countries rely upon our standards, FDA, or European, so you are dealing with a developing country in which the local subsidiary decides the particular drug to be purchased.

Who is going to make the judgment over there as to whether or not it is wise for them to buy an expensive, duplicative type of tetracycline for several times as much as plain tetracycline HCL would cost, while the Medical Letter claims they are all therapeutically equivalent.

So we are dealing with a country that has no qualifications to make a judgment, simply because they do not have a sophisticated pharmaceutical industry comparable to ours, or pharmaceutical expertise. Do we not have some obligation to say to them, don't pay $2,200 a kilogram, pay $100, because the Medical Letter says they are all therapeutically equivalent and, in fact, tetracycline is the drug of choice among all of these? Why don't we so inform them?

Mr. EYTAN. Mr. Chairman, when a foreign government receiving AID funds buys drugs for public purposes, we require that government to advertise its needs in terms of a generic description of the drug, not in terms of brand name. When a private importer advertises for offers from American suppliers, we also require him to state his needs in generic terms.

A further category of cases exists, however, in which importers are not required to buy under formal competitive bid procedures, or to advertise, but can buy directly from American suppliers. Now, in such a situation, the importer is left to his own private negotiating standards, and he may choose.

Senator NELSON. Private importer—whom is he negotiating with?

Mr. EYTAN. Well, if he is not related with the American supplier, he advertises his requirements by generic name in the AID Financed Export Opportunities circular, he chooses the supplier he wishes, he bargains over the price, he decides whether to buy by brand name or some other basis. Of course, if you are talking about a subsidiary of

an American firm, that subsidiary will quite naturally buy the product of its parent.

Senator NELSON. In the list which AID submitted, it appears that most are American companies dealing with their own subsidiaries.

Mr. EYTAN. Well, in such cases the subsidiaries naturally will deal with the parent; and the question you further touched upon then arises—where does the demand for a particular brand item arise in the local country? Well, the demand for product X, for brand name X, will arise in the foreign country the same way that it arises here. Sums of money are spent to promote certain brand names and doctors write prescriptions for certain brand-named items. A demand thus arises for brand X as opposed to brand Y.

Senator NELSON. It puzzles me a little bit. In our AID program, we send over a group of experts. They work with the foreign government on a development plan. That government accepts the judgment and advice of our experts and we do not give them money unless we approve their development plan. We must be satisfied there is a development plan which is beneficial to that particular country.

We are there advising them as to what the development plan ought to be. Why then don't we advise them—since they do not have the commerce, the engineers, the business managerial expertise—why should we not advise them on what they ought to pay for drugs?

Mr. EYTAN. We do more than that. We actually direct them by means of our regulations and loan agreements, that when they purchase for public purposes, for their municipal and state-run hospitals, for their own public facilities, that they not get trapped by the brand-name hangup. But one of the things we impress when they buy for——

Senator NELSON. With their own money?

Mr. EYTAN. No; with our money. We say you must buy by generic description. We advertise by generics.

Senator NELSON. Could you give me any examples where they get any particular drug dramatically cheaper by that process than by this one?

Mr. EYTAN. I cannot give you specific instances in which a country has purchased drugs by formal competitive bidding describing the broad generic term and what the price was. If you would like, we will prepare something for you for a subsequent submission to indicate our experience with financing drugs for public purposes in foreign countries under competitive bidding where the product is described generically.

But the second point to be made here is that we emphasize in each country the importance of the private sector of the economy. We resist having the AID program routed entirely into the public sector of the economy. We try to emphasize the importance of private importers dealing privately, both with American suppliers and with end-use suppliers.

This aspect, this emphasis on commercial aspects of the program, the commercial import program, really forces us in large measure to accept the private sector of the economy as it really is. And it is the same way in the United States. Doctors do write prescriptions on certain brand-named items, and it would be extremely difficult for

AID to tell private buyers in Pakistan that they should not buy brand X, they should buy brand Y because brand Y is equivalent and much cheaper. It would be impossible for us to tell the importer you should buy the product generically and then resell it locally on a generic basis when that importer knows there is a particular demand for brand X.

Senator NELSON. I do not quite follow the difficulty. The difficulty is easily resolved by AID saying we won't pay that price. It is American dollars and we are paying it directly to an American company, with a foreign subsidiary, so they just do not have to pay the price.

Mr. EYTAN. The importer will only purchase an item which he believes he can resell at a profit. If AID tells a private importer he may not buy brand X, which he believes he can resell, but we insist he buy only brand Y, the importer who has no faith in his ability to resell brand Y, will simply not purchase brand Y. AID could very well tell countries—we will not make our funds available to finance drug products in the private sector.

Countries are very insistent on spending a portion of AID funds for drugs. The desire of countries to promote the health of their citizens leads them to press for AID financing for drugs, and that is quite understandable.

Senator NELSON. Well, take a look at the prices paid on competitive bids for the same drugs by New York City and the Defense Supply Agency. I think you will find quite a dramatic difference. I do not quite follow the reasoning that we should not insist that the country we are trying to help get a high-quality drug at a reasonable price. This puzzles me very much. Part of the program, as you explain, is to get private foreign money in the importing country into the hands of its government, so that government can carry on certain developmental programs. Right?

Mr. DWINELL. Correct.

Senator NELSON. Then, on the other hand, we are paying American companies dramatically excessive prices for all kinds of drugs which are going to be sold overseas, extracting from those poor people, their piasters or other local currency, far in excess of what they would have to pay if it were being bought at the world price or at least a somewhat more competitive price.

Mr. EYTAN. I believe that it is fair for me to say AID as a whole would—and certainly this is my personal view—that AID would welcome the impact of foreign competition, that is, non-U.S. competition on AID-financed sales from the United States. We do not believe that AID overpays for drug products or other products, because inevitably at a certain period of time after a sale takes place, AID carefully reviews the transaction under the standards handed to us by the Congress, and if there has been overpricing as measured against U.S. pricing in both AID and non-AID sales, we secure a refund.

The chairman is returning to the issue that American prices tend to be higher for some items than prices charged by foreign competitors. To bring American prices down it would certainly be imperative that foreign suppliers become eligible to compete with American suppliers.

Senator NELSON. The point I want to make is that you have a special case here where competition is for all practical purposes limited. Cyproheptadine, on page 3 of the chart, is an antihistamine, sold by Merck to Colombia, at $1,800 a kilogram, while the price for chlorpheniramine is $20.50 and the Medical Letter is unable to find any record of well-controlled trials showing cyproheptadine is superior to other antihistamines, including chlorpheniramine, for such use.

Most Medical Letter consultants believe the antihistamine * * * effects are due mainly to their sedative properties.

I get back to the question of allowing a developing country and its consumers in the open marketplace to pay dramatically high prices while our own Government would not buy it on any bid at all. New York City would not pay such prices—any well-controlled purchasing system in this country would not pay them—and yet we are, in fact, subsidizing at an exorbitant price a drug for which there is an equivalent at a fraction of the cost.

Mr. DWINELL. Mr. Chairman, the particular case you are citing has been reviewed and Mr. Barondes has comments on it.

Mr. BARONDES. We have reviewed, as I indicated, a good number of transactions that we have submitted to you. We have gone through many transactions of the Merck Co. Again, keep in mind that we look at the prevailing export price. And it happens that this item has been reviewed and we find that this company in its sales, worldwide, generally sells at this price.

We do not feel we can develop a refund claim on this particular item.

If you had picked some other items on this list, we might be able to tell you a substantially different story.

Senator NELSON. No, this is a monopoly price. A well-informed pharmacologist or physician is not going to use it because the Medical Letter concludes that it does not do anything that another antihistamine would not do.

All I am saying is, we are not dealing with a sophisticated medical and pharmaceutical community; we are dealing with a developing country which does not have any sophistication to speak of—in industry, business, management, finance, medicine, pharmacy, or anything else. It seems to me we have an obligation to protect that poor buying public from a fantastically high price.

Mr. BARONDES. I could say to that, in looking at most of these items, it is quite true that a substantial portion, the great majority of the sales are to affiliates. However, almost invariably we will find that these companies are selling not only to affiliates in less developed nations, they are also selling to affiliates in Great Britain, West Germany, or France, where they have to compete with affiliates of German companies, and so forth.

Senator NELSON. If that is the case, how can they compete, especially if these products are available to everyone at world prices, which are dramatically lower than the price the subsidiary is paying?

Mr. BARONDES. That is what I am getting to. They make a substantial number of sales in many instances to third parties—arms length sales. We had one case where—you will not find it in your

tabulation because these are non-AID cases—a substantial amount of sales was made to a third party in Japan. Japan was the biggest customer. We look at all of those sales and take all of these other factors into account. We find that these companies are selling to West Europe, they are selling to third parties, they are selling to subsidiaries who often have substantial minority interests—subsidiaries who are very much concerned that they do not overpay. We think we get a reasonably fair price.

That is why we have obtained substantial price reductions in many of these cases, and if you wish to go down this list, we could indicate where we have gotten them.

Senator NELSON. You mean we will find a buyer in an industrially developed country willing to buy tetracycline at $270 a kilogram when it is available in England at $24?

Mr. BARONDES. I doubt whether you will find that.

Senator NELSON. I doubt it, too, and if you do, that buyer is not going to be in business very long.

Mr. BARONDES. And if we find it happened after our review is completed and if our doubts are confirmed, we will take the necessary action, as we have done in many of the cases you have before you, as I said before.

Senator NELSON. At the bottom of page 3 of your prepared statement on this same issue, I understand your response, even though I do not think I agree with it——

Mr. BARONDES. May I interrupt for a moment. I just received some information on that one item. We have, for example, a sale by the Merck Co., truly arms' length sales, to an independent buyer in Europe—Spain—at $2,990 a kilo.

Senator NELSON. For what?

Mr. BARONDES. For the item you mentioned, cyproheptadine—also a sale to Uruguay and another to Yugoslavia at $3,550.

Senator NELSON. Yugoslavia?

Mr. BARONDES. Not under an AID program. These are non-AID sales.

Senator NELSON. It is nice to get the best of the Iron Curtain once in a while.

Mr. BARONDES. We have to live with what they are getting. In other words, we do not control their prices. If that is what they get, we have to live with it.

Senator NELSON. I am concerned about what these developing countries are paying in sales that just are not arms' length.

Look at the glucocorticoids at the bottom of page 3 of the chart. Merck sells dexamethesone to Merck Colombia at $27.50 a gram. It is available at the world price of $7.30 a gram. But more importantly, prednisone is available at 58 cents a gram. The Medical Letter says it knows of no disorder requiring the use of a glucocorticoid for its pharmacological effect, in which prednisone cannot be used as successfully as any other glucocorticoid, especially for long-term therapy.

Therefore, there seems to be no reason not to prescribe a low-priced prednisone. This is the price they are giving to all of the doctors in the country, and yet we are paying Merck $27.50 a gram while prednisone can be purchased in this country at 58 cents a gram.

It seems to me that we have some obligations because we have all the necessary information on drugs to protect the buyer on the private market in the developing country against this kind of exploitation. I am not raising the question about how well we do. I repeat, I think the United States does great under this system, better than the country we are trying to help, and I think the American companies do great under it. I just think the poor consumer is taking an awful licking when he ought to be buying prednisone at 58 cents a gram instead of a duplicative drug like dexamethesone at $27.50 a gram.

Mr. EYTAN. Mr. Chairman, I would like to comment on that, if I might, for just one minute.

There is a category of drugs where the effectiveness of the drugs is called into question. There is a second category where different drugs carrying different prices are thought to be of special effectiveness, or one among them might be slightly better than the others, but none of them are really harmful or deleterious to health.

In the first category of cases, where new information comes out in the United States through the FDA especially, where a certain drug that has been on the market is ineffective, not efficacious or harmful, we move very quickly to make certain that from that date no AID funds are expended for the importation of that product.

Senator NELSON. That is what the law is. If the FDA says it is ineffective, it is supposed to go off the market, because under the law, as you know, you have to prove efficacy as well as safety. I am glad to know that you act expeditiously in such a situation.

Mr. EYTAN. I believe the FDA administers an act which refers to sales in interstate commerce. The FDA does not by itself ban sales for export. AID moves under its own authority and piggybacks immediately and very frequently even predates final FDA action domestically in withdrawing a product from export financing by AID.

Senator NELSON. May I ask a question at this point.

Are you aware of any drugs that have been declared to be unsafe or not efficacious and prohibited for sale in the American marketplace which are manufactured by American companies and sold to foreign countries?

Mr. EYTAN. I cannot answer yes to that. What happens, though, is that certain drugs are on the market and they are withdrawn from interstate sales by the FDA, and the question then arises whether those commodities which henceforth cannot be sold domestically can be sold in export, and it is AID's action, action which it takes, which makes certain that drugs already manufactured and available somewhere in the United States, being stored or even on the druggist's shelves, do not move under AID financing in export.

The second issue, the one you raise with respect to this Medical Letter, is a far more difficult issue for us. This involves drugs not harmful in and of themselves, but all performing the same function. They are equivalent, yet one product costs more than the other. AID attempts to meet this issue by minimizing sales of finished dosage form. We rarely finance——

Senator NELSON. By minimizing?

Mr. EYTAN. Financing of drugs in finished form.

Senator NELSON. How do you control that at all, when a kilogram of some compound goes to a foreign subsidiary of an American company? You have no control over what they charge on the domestic market for the finished product, do you?

Mr. EYTAN. Their resale is a sale for local currency which is not the sale AID finances. AID finances the dollar export sale.

Senator NELSON. I understand.

Mr. EYTAN. The second level is purely a local, internal currency sale.

Senator NELSON. You say you tried to minimize the possibility of exploited prices by not financing finished products, just the compound. My query is, how do you minimize it when you are paying the local domestic producer for the compound and the domestic American producer is going to get the compound produced in finished product and charge whatever price he desires in the foreign market? How could you minimize that?

Mr. EYTAN. In the days when AID was financing finished dosage forms, the types of variation, pricing, manipulation, exploitation, brand-name preferences, the particular abuses that were then possible were far greater than those which are now possible. We admit that even financing bulk items lends itself to a situation in which some bulk products can be preferred over others. But it is simply not within AID's ability to transmit the latest information emerging in the United States concerning the relative merit of certain pricing patterns and thus affect the demand for products immediately.

The demand by the consumer in the foreign countries is shaped over a period of time, in part through promotional activities. This demand expresses itself in requests for import licenses or in import requirements. It takes some time for a feedback to develop from the foreign doctor, who ultimately creates the demand for a particular product, as a result of something like a Medical Letter issued in the United States.

Senator NELSON. This is a very small percentage of AID's operation. I suppose it would not be very practical for you to have a group of pharmacologists assay the drugs. Would it make more sense if it were done centrally by the Government?

In addition, shouldn't drugs be purchased by competitive bids on a generic basis in accordance with the best practices of some of our Federal and municipal government agencies? Why can't the drugs be bought from the lowest qualified bidder and then shipped to the country which is to receive American assistance?

Mr. EYTAN. We completely agree with you that it would be desirable to maximize purchases by generic name, and we do emphasize this form of ordering. It is only in those areas where private buyers purchase under less strict marketplace considerations that we have had difficulty in encouraging and insisting upon competitive generic procurement. The answers and reasons for that have been developed—they go back to demand for certain products.

Senator NELSON. As I look over a list of some of these foreign countries we are dealing with, you would not have to convince but one or two, or half a dozen of the people in one of those countries where their best interests lie.

Mr. EYTAN. We agree, and the officials of all countries agree—for public purposes, procurement should be by generic name and, when feasible, under competitive bidding procedures; that is the way the item should be procured.

Senator NELSON. Could you submit for the committee the lowest domestic price for each of the drugs listed on the summary of four sheets that we gave you, recognizing, of course, when you are dealing with a brand name that there is no competitor with that same brand name? But I would like to know what is the lowest domestic price of tetracycline, as well as the rest of them, for the record.

Mr. BARONDES. Are you referring to the price of items sold domestically or the domestic price for exports?

Senator NELSON. I would like to have them both. I do not understand why it ought to cost more for export.

Mr. BARONDES. I think it does not, but this is just an off-the-cuff reaction. We do not have too much information. It is hard for us to get information on domestic prices for unfinished forms—and also, we do not really need those prices for finished products. We are primarily concerned with the export price of unfinished products. But we could attempt to get the domestic prices.[1]

Senator NELSON. Are you saying again there is a difference between the domestic price, wholesale price, and the overseas price?

Mr. BARONDES. We do not know. In the few instances I know about, I find the export price very often has been lower. I know it has been lower in some cases for the finished dosage form we have financed in the previous years. I do not really know.

Senator NELSON. It is dramatically lower in the finished product. We have loads of testimony showing that domestic price charges for finished products in this country may be four or five times as high as in foreign countries, even though it is manufactured, finished, packaged, shipped to countries in Europe, where they have to compete on a more competitive basis.

We have had considerable testimony to that effect. Prednisone is an example which at the time it was being sold by trade name here at $17.90 a 100, in Bern, Switzerland, it was $4.25, even though it was manufactured here and shipped over there. So that does not tell us anything. It just tells us the prices here are exorbitant.

Mr. BARONDES. The problem in talking about bulk pharmaceuticals—this, again, I am not too expert on—is that in many cases there is no domestic price. This is because the integrated concerns who produce the bulk material also produce the finished dosage. We may only be able to obtain a smattering of domestic prices; I do not know.

Senator NELSON. If an American company has a patent or an exclusive license for a drug developed in Europe, the domestic price is a monopoly price but we can compare it with the foreign prices of the same drug if the drug is being made in the foreign country.

Mr. GORDON. Governor, in section 8 of the Small Business Act of 1958, there is the following passage:

> It shall be the duty of the Secretary of Commerce, and he is hereby empowered, to obtain notice of all proposed . . . actions of $10,000 or above, and

[1] See p. 7399.

all civilian procurement actions of $5,000 and above, from any Federal Department, establishment, or agency engaged in procurement of supplies and services of the United States; and to publicize such notices in the daily publication, U.S. Department of Commerce . . . and the United States Government proposal, ...

This is designed to give small business an opportunity to bid and participate in procurement programs of the U.S. Government. Is there anything in the AID law or regulations which prevents you from doing this, that is, notifying the Secretary of Commerce? Or is it just the practice of buying from the parent company that prevents you from doing it?

Mr. DWINELL. In the Foreign Assistance Act, there is a provision that participation opportunities under AID financing shall be brought to the attention of small business. We do have in our agency, in the Office of Procurement, a Special Assistant for Small Business, and we take every step that is possible, we believe, to see that the interests of small business are protected and that opportunities are given to small business to participate.

Senator NELSON. Do you have a set-aside provision which applies to domestic small business in competitive bidding to the Federal Government? Is there such a provision?

Mr. DWINELL. There is not a set-aside program for AID-financed procurement by the private foreign importer. I would indicate, Mr. Chairman, that because of congressional interest in increased participation by small business in procurement financed by AID, we have at the present time a study underway in which the Department of Commerce and the Small Business Administration are collaborating with us in trying to determine the feasibility of a set-aside program for AID-financed procurement. That study is now underway.

Senator NELSON. Do you have any examples of small business winning any bids for these programs we are talking about here, supplying drugs to foreign countries?

Mr. DWINELL. Yes, we do; both in pharmaceuticals and in other commodities. I think Mr. Barondes can explain.

Mr. BARONDES. When we get away from the broad spectrum antibiotics, we find a number of small businesses who are successfully getting bids. In the last year, between three-quarters and a million dollars of sales went to what we think are small business.

We find it difficult to get a definition of what small business is. But I think we knocked out all of the big ones we knew about.

Senator NELSON. Could you submit that information for the record?

Mr. BARONDES. Yes.[1]

Mr. GORDON. Incidentally, Mr. Chairman, I have gone through the data given to us by AID on AID-financed drugs in 1968 and 1969. I find it very difficult to find the names of more than a couple of small businesses. Is it not true, though, that given the present system of purchasing by subsidiaries from parent companies, that small businesses really do not have much of an opportunity?

How can small businesses participate in this type of program?

Mr. DWINELL. It is fair to say, Mr. Chairman, that the pharma-

[1] See p. 7399.

ceutical industry does not lend itself to substantial participation by small business. That is true in certain other fields as well. That is true particularly, of course, since we gave up financing pharmaceuticals in finished dosage form.

Mr. GORDON. Why did you stop doing that?

Mr. DWINELL. My colleagues who have been with the Agency longer and have had experience with the financing in finished dosage form, I think, can speak to that better than I. Mr. Salant?

Mr. SALANT. I think Mr. Eytan has already mentioned some of the problems with respect to the financing of the finished-dosage-form pharmaceuticals that were encountered by the Agency.

Mr. GORDON. I do not recall any of the explanations.

Mr. SALANT. I am sorry, I will repeat some of them and perhaps add a few others.

First, there was a problem of identification of pharmaceuticals: trade names given to finished dosage products made it extremely difficult to identify precisely what each product was. The second thing was the virtual impossibility——

Senator NELSON. I do not follow that first answer. What is so difficult about identifying what the finished dosage form is?

Mr. SALANT. At the time we financed private sector purchases of finished-dosage-form pharmaceuticals, we could not identify many of the generic designations from non-U.S. suppliers who were then eligible sources of supply.

Senator NELSON. That would make it very difficult.

Mr. SALANT. So it was difficult to compare one pharmaceutical with another. It was also extremely difficult to evaluate prices as between pharmaceuticals, as between one product and another.

Senator NELSON. What is so difficult about that?

Mr. SALANT. I beg pardon?

Senator NELSON. What is difficult about that?

Mr. SALANT. We can, of course, see the prices, but whether the prices are or are not justified constituted a real problem for our price review people.

Senator NELSON. Just so I have it clear in my mind, if you are going to take the bid on prednisone—everyone knows what it is—and you set the specifications on its contents and characteristics in accordance with USP or NF standards. You would then get bids from perhaps 10 or 15 companies, some of which sell it by brand names. But I do not understand the difficulty.

Mr. SALANT. I fully agree with you—in connection with any formal bid procurement, it is possible to do that. I was addressing myself to the private sector, to which I thought Mr. Gordon was posing his question. And in private sector procurement under the commercial import program, our rules now state that we do not finance pharmaceuticals in finished dosage form.

So if I may amend the statement and bring it down to that particular aspect, agreeing with you that for the public procurement we can, we do, currently and effectively, purchase financed dosage form pursuant to formal bid procedures.

Senator NELSON. When you say "private sector," you are referring to the programs we are talking about now——

Mr. SALANT. Exactly, sir.

Senator NELSON (Continuing). That is not exclusively private sector, really.

Mr. SALANT. The commercial import program is the sale of commodities by a private seller to a private importer.

Senator NELSON. There is a very dramatic addition, however, and that is that AID is furnishing American dollars from our Treasury to pay the supplying company.

Mr. SALANT. Yes; we are providing the foreign exchange through loans to finance these particular transactions. That is quite true.

Senator NELSON. Two questions occur to me. One, what is so difficult about requiring competitive bidding; and two, how do you know you are really assisting the developing country by financing bulk purchases when you do not have any knowledge as to what the foreign subsidiary is charging for its finished product?

You may be much worse off than you were before.

Mr. SALANT. Let us take the first question—can it be done? What is so difficult about doing it in the private sector? It can theoretically be done in the private sector. It is not a common method of doing business in the private sector, and the Foreign Assistance Act does enjoin us to use commercial channels of trade and also to follow commercial practices. So we do not deny an importer the privilege of purchasing by formal bids, but we do not require it.

We attempt, to the extent that we possibly can, to follow the standard commercial practices of international trade. Formal bids are not customary. Therefore, we do not require it. It can be done in theory. We question its practicality.

Now, the second question, sir, if you would repeat it.

Senator NELSON. I had understood in the testimony earlier that there was some problem controlling exorbitant prices being charged when the AID program financed shipments of finished products. How do you know the situation is not even much worse now since you have no way of knowing what the subsidiary who gets the bulk charges for the product when it is in finished form?

Mr. SALANT. We were concerned about this very aspect at the time that we decided not to finance finished dosage pharmaceuticals for the commercial import program. Our initial thought was not to finance any pharmaceuticals at all. Various countries beseeched us not to make them ineligible. They felt that they needed to import such pharmaceuticals, at least in raw form, for further processing. And since it is possible to avoid some of the pitfalls of negotiated procurement when we finance raw drugs, we decided to continue to authorize such purchases in those countries wishing to expend their loans for that purpose.

We do have rules, though, in connection with these. Certain commodities are ineligible, pursuant to the FDA's findings as soon as a determination is made and frequently a year or more in advance of its actual application to the U.S. industry in interstate commerce.

We also have certain pharmaceuticals which are prior review pharmaceuticals. Here we are concerned very much with the manner in which they will be used—the formulations that will be made from the unfinished product, the instructions that will go with the product.

Only if we are completely satisfied, pursuant to advice from medical experts here in the United States, that the end use is, in fact, something that will achieve a beneficial result without adverse side effects and that there is a complete understanding of any dangers that may be connected with the finished product, only in those instances will we authorize the financing of these bulk pharmaceuticals and combination drugs.

Senator NELSON. What followup do you have to insure that the drug is promoted for the limited purposes that the FDA authorizes and that the finished product is provided with the same package insert as it has here, describing the indications for use, side effects, and contraindications?

Mr. SALANT. Part of our agreement with the importing government is that they will monitor and follow through on our recommendations.

Senator NELSON. What recommendations do you actually give? Suppose that you finance purchases of tetracycline or one of its numerous brand named duplicates. Do you supply the foreign government with the FDA's package insert that must go to every pharmacist who buys it, and do you also advise the foreign government as to the limited purposes for which that drug may be used in this country?

Mr. SALANT. Yes, that information is provided. Agreement is reached with the individual governments as to the types of information that will affect the proposed finished product and also the uses to which the final dosage will be employed.

Senator NELSON. I would appreciate having in the record the instructions that you send, to whom you send them, the Government as well as the foreign subsidiary.[1]

Mr. SALANT. The information is submitted by our agency to our missions in the country concerned. Our mission transmits that information to the health department of the cooperating country and to the importer of the drug product.

Senator NELSON. What information, specifically, do you submit? All of the FDA requirements?

Mr. SALANT. The basic FDA requirements, not necessarily all of the requirements, but we follow closely the FDA requirements as published in the Federal Register.

Senator NELSON. The package insert which lists all of the indications and contraindications, does that go with it?

Mr. SALANT. The package insert would be inserted if required by the government of the importing country. We finance, of course, the bulk material; we provide the information with respect to it. If the country wishes to have that information inserted, it will so stipulate.

I might indicate in this connection that in financing these raw drugs, the ingredients for further processing, we are helping to establish industries in these countries, thus providing to them the ability to gain the technical skills in the field of pharmaceuticals. We are likewise offering them a possibility to conserve foreign exchange to the extent there may be savings between cost of ingredients

[1] See p. 7392.

and the cost of the finished dosage pharmaceuticals resulting from such ingredients.

Senator NELSON. Do you have proof of any such savings? It appears to me there is no savings at all. They are paying many times more than they ought to pay.

Mr. SALANT. I am not discussing whether they are paying more than they ought to pay, based upon comparison with non-U.S. prices. I say they are paying less for ingredients than they would pay for the finished form made from those ingredients, assuming both were procured in the United States as required under our present rule.

Senator NELSON. Could you do this for the Committee. A year or two ago, when we were comparing domestic prices of finished products manufactured in this country and sold overseas, we made up a list of drugs and asked the State Department to check with our Embassies in the foreign countries. For example, we checked London; Bern, Switzerland; Berlin; Rome; Paris; Mexico City; Australia; Canada; and a couple of South American countries.

We compared the finished product prices to the pharmacist and to the consumer in foreign countries with those prices charged here. Would you mind checking these through your agency to determine what the finished product price in the marketplace is, what the name of the drug is, its dosage form, and submit it for the record, so we would see what those foreign subsidiaries are charging the pharmacist or whoever dispenses the finished product? Would you do that?

Mr. DWINELL. We will, Mr. Chairman.

Senator NELSON. Then can you also ask for the markup price to the consumer, so that we can compare what happens in this country with the situation in these foreign countries.

Mr. EYTAN. Mr. Chairman, these, of course, would be local currency prices. Would you want us to convert them at the official rate of exchange?

Senator NELSON. Just give them both to us, the local currency and its conversion into American terms. A U.S. company is paid $100,000 for X amount of compound, then the foreign subsidiary transfers the equivalent in exchange money of the local domestic currency with the government there, don't they?

Mr. EYTAN. Yes, they do. But your question relates to the next stage when the importer sells the product to a druggist or to some further wholesaler, or perhaps even a retailer. When you received information from the State Department, you were talking about European countries where no exchange problem exists. And here it may require some adjustment in a price for an item in New Delhi expressed in rupees, and before you reduce that to a dollar equivalent, you might have to keep in mind this is a rupee price and there might be a half dozen different exchange rates, depending upon the purpose of the manipulation, the purpose for which you want the information.

Senator NELSON. What method do you use for determining how much the foreign subsidiary should turn over to the foreign government after AID has paid dollars to the U.S. supplier?

Mr. EYTAN. There is an exchange rate agreed upon between AID and the country.

Senator NELSON. There is?

Mr. EYTAN. There is an exchange rate which AID agrees upon with the country, the Foreign Assistance Act provides us some guidance here. It speaks about proceeds concept but we note that there may be multiple exchange rates in many countries.

Senator NELSON. Yes. Give us the best you can. I realize there are some problems with it, but I think it might be helpful for the record to try to find out just what the subsidiaries are charging in the retail market for certain formulations so they can be compared with prices here.[1]

Mr. SALANT. I did want to indicate, Senator, that while in our commercial import programs we generally are not too much concerned with the elements that you have raised at the session this morning——

Senator NELSON. Who is not too much concerned?

Mr. SALANT. The Agency is not too much concerned in the case of commercial import programs as to what most imported products might be sold for on the domestic market, since the basic purpose for having a commercial import program is not directly related to the consumption of the end item. In the case of pharmaceuticals, we do express this concern. We are concerned that there be quality products imported, we are concerned that they meet the highest standards in the United States. We are concerned that they comply with the FDA requirements throughout.

We are concerned that the product be used to manufacture finished dosage items that are efficacious, nondangerous, useful. This does not apply to other commodities to the degree that we apply it here in the case of pharmaceuticals.

Senator NELSON. I realize it is a complicated question, but I would just point out that a lot of tetracycline is imported into this country and made into the finished product by American companies. Now Cyanamid, I think, is paid $270 a kilogram and you and I agree that Cyanamid does not have a base cost anywhere near that if they are going to sell any tetracycline in this country in the face of competition from a domestic firm which imports the bulk at $24 to $29 a kilogram.

Please proceed. You may wish to skip the testimony we have already covered.

At the appropriate place in the record, I would place this four-page sheet entitled, "Comparison of AID and European Bulk Prices."

Let me say, in looking at the prices paid by AID under technical assistance programs, AID does a superb job. With respect to the price of oral contraceptives for fiscal year 1970, I note that AID is paying 17¼ to 17¾ cents per cycle, which is about one-tenth of what the pharmacist has to pay and perhaps one-fifteenth to one-twentieth of what the American consumer pays.

So with regard to your technical program, where you have total control because you purchase directly from the manufacturer, I think the AID is to be commended for getting an excellent price. I

[1] See p. 7399.

would just hope somehow or other we could do that well by these foreign countries in furnishing them reasonably priced drugs for their own retail market.

Mr. DWINELL. Thank you for that comment, Mr. Chairman.

Senator NELSON. I ask that that be printed in the record.

(The information above-referred to, follows:)

[U.S. Government memorandum]

JULY 23, 1970.

From: TA/POP/PGD, Irene B. Walker.

Subject: Response to Your Request for Information from the Nelson Committee.

A.I.D.-financed oral contraceptives purchase orders under projects funded from Title X of the FAA were as follows including freight:

[In thousands]

	Cost including transportation	Monthly cycles
Fiscal year:		
1968	$562	2,845
1969	756	3,823
1970	$2,252	11,394
Total	$3,570	18,062

COMMODITY COST PER CYCLE

	Cents per cycle		
	21's	28/P	28/FE
Fiscal year:			
1968		.18 .197	
1969	.1625	.1675	.1675
1970	.1725	.1775	.1775

Note: All project procurement was made through GSA; in FY 1969 and FY 1970 under GSA term contracts.

CONTRACEPTIVE PURCHASE ORDERS

July 1, 1967, to June 30, 1968

Contraceptive type	Quantity	Commodity costs	Estimated transport cost	Total cost
Orals	2,845,000 mc	$499,000	$63,000	$562,000
Condoms	20,003,616 ea	319,618	24,578	344,196
IUD's				
Aerosol foam	1,150,000 ct	97,750	7,516	105,266
Total		916,368	95,094	1,011,462

July 1, 1968, to June 30, 1969

Orals	3,823,000 mc	$671,000	$85,000	$756,000
Condoms	102,195,648 ea	1,771,941	598,384	2,370,325
IUD's	412,000	12,360	247	12,607
Aerosol foam	1,266,819 ct	256,972	19,761	276,733
Other [1]	various	26,957	3,087	30,044
Total		2,739,230	706,479	3,445,709

[1] Diaphragms, foaming tablets, vaginal creams and jellies.

Mr. DWINELL. Of course, the point you just made illustrates probably better than I can illustrate or have tried to in my statement, the difference between our technical assistance program and the commodity import program. In other words, in the technical assistance program, purchases are made by the GSA or the Defense Supply Agency, or by ourselves, in extreme cases of emergency, such as earthquakes or floods, where we need a quick action for relief purposes, not only of pharmaceuticals, but of other commodities as well, by competitive bidding according to Government purchasing regulations.

Senator NELSON. These transactions are not purely commercial, because we are paying all of the dollars at this end. So we do have some influence over what happens. We do not have to pay it at all. And I would just go on to say that I think that the foreign countries are paying a tremendously exorbitant price because in those countries they do not have the expertise to make a judgment of their own. I think we ought to be much more vigorous in advising those countries as to what are the best drugs at the most reasonable prices.

Mr. DWINELL. Mr. Chairman, to continue with my statement, I think I might resume at that point where I was putting our procurement activities into perspective with respect to the volume of transactions.

During fiscal year 1969, AID-financed commodity expenditures totaled $1.02 billion. Pharmaceutical products accounted for $20.6 million, or about 2 percent of that total. The figures for fiscal year 1968 showed a higher ratio for pharmaceuticals with expenditures of $31.7 million or 2.7 percent of the $1.06 billion expended for commodities. Detailing these figures further, commodity expenditures for specific technical assistance projects totaled $5 million in fiscal year 1969 and $13 million in fiscal year 1968. These were respectively, 24 and 41 percent of total expenditures for pharmaceuticals.

I have already referred to the fact, as I point out on the top of page 5 of my statement, that the purchases financed under technical assistance for project use, for the most part, were purchased by other U.S. Government agencies, such as GSA or Defense Supply Agency of the Department of Defense.

The procurement practices and procedures followed by GSA are those set forth in the Federal procurement regulations, supplemented by "Additional Program Bidding Terms and Contract Provisions" developed expressly by GSA for its procurement on behalf of AID. These additional terms and provisions cover such items as eligible source, bidding terms, taxes and duties, shipping, labeling, and other requirements peculiar to AID. The Defense Supply Agency in its procurement for AID follows rules of the armed services procurement regulation. Purchases made directly by AID conform to requirements of the AID procurement regulations. Those by a borrower-grantee or its private sector agent, must comply with the rules in AID Regulation 1, usually with an added requirement that the formal invitation for bid procedure be used.

We spent most of our time this morning on the commercial transactions. The amount involved with respect to pharmaceuticals was valued at $15.6 million in fiscal year 1969 and $18.7 million in fiscal year 1968. And it has been already pointed out that under these

commercial import programs, only unfinished pharmaceuticals may be purchased, except that contraceptives in finished dosage form are authorized.

Transactions involving commercial imports must comply with the provisions of AID Regulation 1 as supplemented by special requirements that the Agency applies to pharmaceutical products. AID Regulation 1 prescribes the basic rules that govern AID-financed transactions. It covers conditions of eligibility of commodities and services, the responsibilities of importers and suppliers, the payment and reimbursement requisites, and the price rules for commodities and commodity-related services. These provisions apply uniformly to all commodities financed by AID under a commercial import program.

There are, however, special requirements that apply only to pharmaceutical products. These relate to commodity eligibility, commodity quality, and commodity certification. As already indicated, pharmaceuticals in finished dosage form are not eligible for financing under our commercial import programs. In addition, drug substances and drug products must meet all requirements prescribed by the Federal Food, Drug, and Cosmetic Act for interstate shipments.

Biologics for human use must have been manufactured at an establishment holding a product license issued under the Biological Control Provisions of the Public Health Service Act for such products; veterinary biologics must meet requirements of the Veterinary Biologics Division of the U.S. Department of Agriculture; oral contraceptives must comply with the Food and Drug Administration requirements relating to their marketing in the United States.

Antibiotics, biologics, contraceptives and several other drugs must be approved in advance by AID on an individual transaction basis. This prior approval requirement was established for several reasons: first, to assure that AID-financed purchases reflect Food and Drug Administration actions pursuant to studies by the Drug Efficacy Study Group of the National Research Council of the National Academy of Sciences; second, to assure that importers have adequate storage and distribution facilities to handle perishable products such as vaccines; and, third, to assure that significant findings pertaining to proposed end products are transmitted to the importing government. These prior approval requirements were instituted for biologics several years ago, for antibiotics on June 6, 1969, and for oral contraceptives on May 4, 1967, when they first became eligible for AID financing. Ingredients for contraceptives were made subject to prior approval on January 1, 1970.

We now have an extensive list of medicinal chemicals that are eligible for AID financing if they are included in the list of commodities authorized under a given agreement and if they meet the special provision requirements established by AID. We have published and released to the trade, through our small business memos, listings of both eligible and ineligible pharmaceuticals as well as other information regarding pharmaceutical requirements.

We also have a series of internal manual order issuances dealing with pharmaceutical policies and procedures. Copies of pertinent releases were supplied to the subcommittee.[1]

[1] See information beginning at p. 7368.

Most commercial import program purchases are made by negotiation and not by formal bid procedures. This is standard commercial practice—in fact, procurement by formal bid procedures would be the exception rather than the rule. However, we still expect importers to canvass the market whenever possible and to place orders so as to obtain optimum economic advantage.

Mr. GORDON. May I ask a question at this point?

You say you require importers to canvass the market whenever possible and to place orders. I would think it is impossible to do this in the case of drugs, since subsidiaries buy from parent companies. Is that not correct?

Mr. DWINELL. I was referring, of course, to commercial import program purchases in general. When it comes to pharmaceuticals, that would be the case in some instances. This is indicated by the fact not all of our AID-financed pharmaceutical purchases are by subsidiaries.

Mr. GORDON. But most of them are.

Mr. DWINELL. It is true that a large percentage is.

Senator NELSON. Just for clarification, a question I should have asked earlier. If you took one of the tetracyclines like Bristol's Rolitetracycline, it is at the bottom of page 1 of the chart, or any one of those above it, how does it come about that Rolitetracycline or any one of those above ends up in being the drug that is imported? Is it because the foreign subsidiary asks for this particular drug by brand name?

Mr. EYTAN. There is, of course, a competition among importers to secure import licenses.

Senator NELSON. You mean import license for each import shipment?

Mr. EYTAN. Yes. It is shipment-by-shipment, generally.

Senator NELSON. Explain to me how that works, would you?

Mr. EYTAN. AID begins the process by making a loan to country X, with which eligible commodities may be purchased.

Senator NELSON. The loan is the payment they make to the country?

Mr. EYTAN. The loan does not result in any dollar funds actually changing hands between AID and the foreign government. AID negotiates and concludes a loan agreement with country X for $10 million——

Senator NELSON. For drugs?

Mr. EYTAN. Product items will be mentioned in the loan or in the supplement to the loan and, let us say, drugs are eligible. At that point, the country under its own internal procedures will apportion the $10 million of AID loan funds among importers. It will require applicants for import licenses to describe the commodity which they seek to import with great specificity. It will require them to provide detailed commercial information concerning the product; then the relevant ministry in the foreign government will allocate the $10 million, and some of that money in this hypothetical will go for the purchase of drugs.

The overseas subsidiary of the American firm will attempt to secure a portion of this $10 million, with which it may then issue a

purchase order or even enter into some other agreement with its parent, to accomplish the importation. The transaction itself on the commercial side begins after the importer has his license from his government, by having the importer go to a commercial bank.

He goes to a commercial bank with respect to a proposed AID-financed import in exactly the same way that he would go to the same bank in his country in a non-AID sale. He goes to the bank with a request that that bank open a letter of credit to pay for goods to be purchased from a foreign country—in our case, from the United States—a letter of credit to be issued in the name of the designated supplier.

In our case, let us say, the parent company——

Senator NELSON. Let me ask a question at this stage. There is a purchasing agent, of course, for the foreign country and they decide that of their $10 million of loan, they need to buy $1 million of drugs, let us say. Right?

Mr. EYTAN. With respect to the commercial sector——

Senator NELSON. No, I am just talking about getting an import license—

Mr. EYTAN. If you are talking about a $10 million loan with the commercial sector, there really is no——

Senator NELSON. Let us say, some part of it is allocated for import licenses for drugs; right?

Mr. EYTAN. Right.

Senator NELSON. How is it decided that some particular type of tetracycline gets the import license? How do they decide that? Do they have a bid on different tetracyclines or negotiate, or what do they do?

Mr. EYTAN. The Government determines how to apportion the money for drugs.

Senator NELSON. We have already passed that. They apportioned some money for drugs.

Mr. EYTAN. At that point, the various applicants come in, each one seeking a license to import a particular bulk product.

It is going to be a very rare situation where the total dollar sum involved in the application does not vastly exceed the amount of money available. The country then will require under its own procedures, its applicants for import licenses to make out the best case that they can—why they should be granted the import license in the amount they seek or a portion of that amount, as opposed to others competing for licenses for similar or different drugs.

Senator NELSON. Who would be the other competitors? Other American subsidiaries?

Mr. EYTAN. Not necessarily. Any importer.

Senator NELSON. Do you have a list of drug importers of the various countries which have been getting drugs under this program?

Mr. EYTAN. Our mission abroad, that is, the AID mission in a particular country, would have or could secure the names of importers in any area. And if you would like us to do so, to solicit our overseas missions for names of importers of drugs, both AID and non-AID, we could do so.

Senator NELSON. Who are the competitors for AID imports?

Mr. EYTAN. There are importers in nearly every country who are not subsidiaries of American firms.

Senator NELSON. There do not seem to be any of them who have succeeded under this program except American subsidiaries.

Mr. EYTAN. Just a few minutes ago, we mentioned that over three-quarters of a million dollars was financed by AID for drugs in fiscal 1969 for small business on sales by small business concerns from the United States. We have a list here of some 30 or 40 small business concerns and we doubt that any of these have overseas subsidiaries. So we do not believe it is correct to say that all AID sales in the drug area take place between parents and subsidiaries.

At least with respect to this three-quarters of a million dollars—those were sales between private importers and private U.S. companies having no relationship to each other at all.

Senator NELSON. All of these duplicative brand name tetracyclines have no competitors except tetracycline hydrochloride which is the drug of choice. It would be considered irrational prescribing and purchasing by medical experts to take anything other than tetracycline hydrochloride at the lowest price according to the Medical Letter. I wonder how a company that has a brand name is charging a price many times more, some 1,000 or 2,000 percent more than the world price and much more than the cheapest of the available tetracyclines.

How do they get the foreign government to give them an importer's license, even though it is going to cost 2,000 percent of the world price, and it is no better than tetracycline hydrochloride and you have no competitor because you are the only one who makes this brand name drug? I am puzzled about how this works.

Mr. EYTAN. You have, of course, described the situation quite accurately when you say that an American company who controls the product by brand name X, or otherwise, or who has an overseas subsidiary in that particular country, is really going to try to maximize its sales to that country through its subsidiary. And when that subsidiary competes with other importers in that country, it could point out to the license-issuing authority that it is the subsidiary of the American producer of the product.

And if it makes out a case with the licensing authority that there is a strong need or demand, which may be the same thing, in the country for this particular item, the country will usually issue licenses to it.

Senator NELSON. Please proceed.

Mr. GORDON. Could you give us for our record the percentage of sales moving from parent to subsidiary under the commercial import program for drugs?

Mr. EYTAN. Percentage of sales of all pharmaceutical products?

Mr. DWINELL. Just pharmaceuticals?

Mr. GORDON. That is right. Percentage of sales going from parents to subsidiaries.

Mr. EYTAN. It will be a considerable job but we can do it, of course.

Mr. GORDON. And the number of small businesses.

Mr. EYTAN. Yes, we have the list prepared on small businesses.[1]

[1] See p. 7393.

Mr. BARONDES. I would like to add one point on the question of sales to subsidiaries. I am sure you realize that it is not unique in the drug industry that a substantial proportion of all American exports moves from parent corporations to overseas affiliates. To mention a few: much of our oil exports, petroleum exports, are going to subsidiaries; synthetic rubber and tire cord are moving from U.S. corporations to their overseas tire plants; many of the large automobile companies have assembly plants overseas. So to that degree, pharmaceutical producers are not entirely unique.

Senator NELSON. Go ahead.

Mr. DWINELL. I was at this point in my statement indicating commercial import program purchases are made by negotiation and not by formal bid procedure. This is the standard commercial practice. And I referred to the canvassing of the market which was affected.

Under the regulation 1 notification requirement, importers must, unless exempted for reasons stated in the regulation, advertise proposed purchases in the "AID-Financed Export Opportunities" bulletin, published by our Office of Small Business. We require importers to identify proposed purchases of pharmaceuticals by generic terms rather than by trade name, as we have already indicated.

This widens the range of potential competitive offers and alerts interested U.S. firms to possible trade opportunities, both for the immediate purchase and for future market explorations. Advertising by generic name enables importers to learn of competitive product availabilities. For AID, in addition to its impact on price, generic designation permits routine determination of commodity eligibility or ineligibility when notice is first received regarding a proposed pharmaceutical purchase.

But whether or not an intended pharmaceutical purchase is advertised in the "AID-Financed Export Opportunities" bulletin, we are alerted to all proposed shipments made under regulation 1 rules, by the "Application for Approval of Commodity Eligibility"—form AID–11—that every commodity supplier must submit to AID/Washington for approval. This prior approval procedure, which was developed in response to Section 604(f) of the Foreign Assistance Act of 1961, enables us to reject in advance shipments of any pharmaceuticals on our ineligible list or of pharmaceuticals not authorized in the specific commercial import program concerned.

We also require suppliers to list in their invoices, opposite each item billed, the established generic name and the quantities of active ingredients in each item supplied. This offers an opportunity at the post-audit stage for a final check on commodity eligibility and for more effective determination of compliance with the Agency's price rules.

I have already indicated that notification of proposed procurement is not always required, and may be modified or waived under certain conditions.

For example, publication of individual purchase intentions is not required under the so-called "Colombia Plan", of notification. Instead, our Office of Small Business publishes general information regarding the commodities authorized under each program, together with the names and addresses of importers of such commodities. U.S.

suppliers can then determine whether to explore the market for their specific products.

The Colombia system is considered for countries whose import and foreign exchange controls preclude individual importer notifications or for countries where the standard system of advertising is disadvantageous to program objectives. It is now authorized for Brazil, Chile, Colombia, Dominican Republic, Uruguay, and Indonesia.

As a second example, the Small Business notification requirement may be waived on an individual company basis when special contractual relationships exist between importer and supplier which render advertising meaningless. In such cases, the supplier may apply for an "Agency Waiver" on behalf of his importing distributor or manufacturing licensee. That type of waiver is granted only when our analysis indicates that the importer has a contractual obligation to refrain from handling competitive products. The validity period of an Agency waiver is determined by the conditions of the controlling agreements, with a maximum of 3 years.

As of now waivers of small business notification requirements for pharmaceuticals are effective for 27 importers located in Ghana, India, Morocco, Pakistan, and Turkey.

I wish to stress that transactions conducted under "Agency Waivers" of the small business notification requirements are subject to careful post-audit examinations. Prices are tested against those charged in comparable export sales that are financed by AID and those sales that are not financed by AID. Briefly, our rules provide that a supplier's price may not exceed the prevailing export market price for comparable sales of all exporters nor may it exceed the price generally charged by the seller in his comparable sales.

Posting of the generic nomenclature for each item invoiced facilitates that comparison. Audits made under these rules provide reasonable assurance that cases of excessive pricing will be uncovered when goods are sold under agency arrangements. As a result of these examinations, significant refunds have been obtained from suppliers whose prices were found to exceed those permitted under AID regulations.

I think it well to emphasize a point I already made—namely, that purchases under the commercial import program are made by private firms. These firms buy foreign exchange credits made available by our loans or grants. They buy these credits with their own local currency—the only form of currency that is generally available to them. Barring peculiar situations that may give rise to currency manipulations or other irregularities, an importer stands to profit when he buys properly at a fair price; he will inevitably fail if he buys imprudently without regard to price.

I would like to summarize my statement in this way: we administer our commercial import program for pharmaceuticals in a manner designed to reduce the potential for irregularities. We do this by excluding from financing commodities for which irregularities are most difficult to detect—the dosage form pharmaceuticals—and by monitoring the requirement that pharmaceuticals be identified by

generic name. This strips away the brand name cloak under which product similarity may be concealed and price escalation practiced without restraint.

Senator NELSON. I do not quite follow how it works. What do you mean that you are monitoring the requirements that pharmaceuticals be identified by generic name? Where do you do that? In what part of the process?

Mr. DWINELL. On the invoices which are subject to our audit.

Senator NELSON. I don't see that that reveals anything.

Mr. DWINELL. And any advertising for procurement by the importer.

Senator NELSON. As I pointed out before, we have a whole series of brand name products here. Our list does not include all of them.

They end up ordering a brand name duplicative product that is very expensive. Does carrying the generic name on the invoice do anything about stripping away the brand name cloak?

Mr. EYTAN. What we are saying in the statement is that we always know precisely what it is that we are financing. It is not possible for a company to give a mumbo-jumbo description on its invoice. After all, the American seller deals privately with the foreign firm so that by insisting that alongside any special nomenclature the generic description of the drug appears on the invoice, and alongside any mumbo-jumbo description of the drug in its advertised solicitation, which the importer engages in before concluding his contract, a generic description of the drug also would appear.

We assure to ourselves that on post audit we will know exactly what the item is so that no one can push on us an argument that this drug is really different, it is an exotic something.

We know exactly how to proceed in our post audit efforts.

Mr. BARONDES. May I elaborate on that?

Senator NELSON. All I would say is that they do not fool you in that way, but they do foist off on you some rather exotic prices.

That is the problem, and that is as clear as a bell all the way through.

Mr. BARONDES. Senator, this is in a difficult area. There are apparently generic names and generic names. There are certain generic drugs which are apparently pretty widely recognized—I am not an expert on drugs—let us say penicillin, or some other product which most of the companies will be selling. We will then, in these cases, compare the prices, regardless of brand names, with the sale of other products of the same generic nature. But then you get into other areas where each company has its own generic cubicle. These types of products are more difficult to compare.

Senator NELSON. They each have a trade or brand name, but all of these products are different tetracyclines and the price ranges from $100 to $2,200, yet the Medical Letter, which has great prestige in this country, evaluates tetracycline hydrochloride as the drug of choice. They consulted with expert physicians around the country and concluded that all the tetracyclines are therapeutically equivalent. If the purchaser knew this, he would buy the cheapest one of the tetracyclines.

He would be buying it at $24 a kilogram instead of $2,200. Ac-

tually, you do no favor to the developing country. All I can see is that you have a program where we get some hard dollars back and a whole lot more than we ought to get back where a domestic company gets a chance to sell drugs at an exorbitant price. And instead of doing a favor to the country, we are damaging the consumer and the country. We would be better off if we just bought tetracycline hydrochloride for $24 to $29 per kilogram in the foreign marketplace. It may cost you a million instead of $15 million, and you would help the developing country a lot more.

We are hurting the country with this drug and I think it is obvious. You are stuck with the law, I guess, but I would hate to have anybody do any favors like this for me. I think it is an outrage.

The law is contrived in such a way that justice could not conceivably be done to those people in those countries—neither the government nor the consumer.

I would think at least we ought to just give them every month the bid prices of New York City, Defense Supply Agency, telling them what they are paying for the finished product. We are bringing them all kinds of expertise on how to get businesses going. Let's give them some expertise on how to keep from being cheated. They ought at least to look at and say—"we are paying 10, 20, 50, a hundred times as much as we ought to be paying."

Give them the facts. If they are foolish enough to do it after that, you might have some suspicion as to how the money is being used over there.

Mr. DWINELL. Mr. Chairman, I am glad you recognize the fact that we are complying with the statute——

Senator NELSON. I think you are.

Mr. DWINELL (Continuing). Or we are attempting to do so, and trying to monitor these transactions to the best of our ability.

Senator NELSON. It is a case of Uncle Sam exploiting a foreign country on the pretense we are doing them some good. I am not blaming you for that. I say when you have an opportunity to operate the program the way it should be operated, you have handled the program very well.

Mr. DWINELL. We encourage also the use of quality raw and intermediate ingredients and bulk compounds of demonstrated efficacy that are produced in the United States to recognized standards and that are available under the programs at competitive prices and at savings in the foreign exchange positions of the importing countries .

Pharmaceutical purchases are relatively small as compared to overall expenditures of AID funds for commodities, to repeat.

They represented 2 percent of total commodity expenditures in fiscal year 1969 and 2.7 percent in fiscal year 1968.

However, those pharmaceuticals that are purchased with AID funds must conform to strict eligibility requirements, to rigid quality standards, and to permitted price schedules.

I am grateful to the subcommittee for allowing me to present this broad view of our commodity financing programs, particularly as they relate to pharmaceuticals. I will be glad to elaborate on any other areas which the subcommittee may wish to examine.

Thank you very much, Mr. Chairman.

Senator NELSON. You are operating under the law, and as I stated, Uncle Sam is doing very well under it, and so are the private companies.

I do think it is worthwhile taking a look at giving the foreign countries a little more information. At least the government over there could understand the difference in the pricing structure, and it might be very helpful to them.

Mr. DWINELL. Mr. Chairman, the only point I would make there, even though our client countries are lesser developed and undeveloped countries, my own experience in visiting some of them is that they are not completely unsophisticated countries. Communications today, interchange of information, the accessibility of information on a worldwide basis is available at least to the officials of governments of lesser developed countries.

Senator NELSON. We have a hard time getting our own medical community to prescribe rationally and they cannot do it over here.

The testimony here from the experts continually is that all of these countries around the world are relying upon the United States and its expertise. They are very limited. You can be a fine doctor practicing in a developing country and if you are, I might say you are probably ten times as busy as it is conceivable to be here.

No one can keep up on drugs. We have trouble with our own physicians keeping up on drugs. I think these exotic prices are so exotic that the foreign countries ought to be informed. And we are buying them all of the time.

I think we might find they would be amazed. They might even think of going back to the finished product and letting them see what they can buy.

Take prednisone running from $17.90 per hundred to the pharmacist at the time of our hearing, to 59 cents a hundred, with the Medical Letter saying they are all equivalent.

So I do not know how you expect those poor souls over there to make a better judgment than was being made in this country.

I guess the minority counsel has a question.

Mr. JONES. One brief question. Could you give me the total sales volume of the drug sales financed by AID in the last 2 years?

Mr. DWINELL. That was in the statement, but I may have skipped it—in the commodity import program, pharmaceuticals were valued at $15.6 million in fiscal year 1969, a reduction from $18.7 million in fiscal year 1968.

Mr. JONES. I understand each year these sales amount to less than 3 percent of the total commodity import loan program.

Mr. DWINELL. Yes; that would be even less than 2 percent, because our total pharmaceutical procurement, including the technical assistance portion, was 2 percent in 1969 and 2.7 percent in 1968.

So that the CIP, as we call it, would have been less than 2 percent in 1969, last year.

Mr. JONES. Mr. Chairman, with your permission, I would simply like to state it is my understanding that the questions raised today imply no criticism whatsoever of the commodity import loan program in general, and pertain only to the small fraction of that program which relates to pharmaceutical sales.

Senator NELSON. There has been no testimony today on any matter other than pharmaceuticals, has there?

Mr. JONES. No, sir.

Senator NELSON. Thank you very much. We appreciate your coming.

(The complete prepared statement and supplemental information submitted by Mr. Dwinell follows:)

STATEMENT BY LANE DWINELL, ASSISTANT ADMINISTRATOR FOR ADMINISTRATION, AGENCY FOR INTERNATIONAL DEVELOPMENT, DEPARTMENT OF STATE

I appreciate this opportunity to discuss the AID programs which involve the procurement of pharmaceutical products. But before delving into details of such procurement, I would like to describe, in general terms and without specific regard to pharmaceuticals, why we have different types of programs and how they are conducted.

We conduct three basic programs under which commodities are financed with AID funds. Pharmaceutical products may be purchased in two of these programs—technical assistance programs and commercial import programs. The third activity, capital project assistance, is not of concern in our discussion today.

The first type of program mentioned, Technical Assistance, encompasses educational and training activities. Included are projects in various fields such as health, disease prevention and family planning. Possible programs are developed in the field by our Mission specialists working in close collaboration with cooperating country officials and possibly with UN or other international agency experts. Gradually, their ideas gain substance, scope, and specificity and a definite program takes form—goals to be achieved, facilities to be established, technical services to be recruited, material to be assembled, supplies to be procured.

Feasibility studies are made and time frames for performance prepared. Analyses of resource availabilities and needs are of course essential and figure significantly both in regard to project initiation and continuation. Ultimately, the proposed program is presented by the Mission to Washington for consideration. We appraise each proposal in the context of its suitability for AID participation, of its essentiality to the development of the aid-receiving country, and of its priority relative to other project options. The Agency seeks to confine approvals to carefully formulated, high priority proposals that promise meaningful achievements. Funds authorized in approved projects thus are earmarked for prescribed technical services and for specific commodities. In other words, when a Technical Assistance project is authorized, we have considerable knowledge regarding the commodities to be financed, including knowledge as to what will be bought and what procurement procedures will be employed.

The second type of program is the AID commercial import program. This has two major complementary objectives:

First, it provides foreign exchange to finance private sector imports of commodities needed by industry and agriculture as well as to finance imports of essential consumer goods.

Second, it supplements the revenue of the aid-receiving country and thus enables that government to meet the local currency costs of its development activities.

Development projects involve substantial local currency expenditures to defray costs such as land purchase, rentals, labor, indigenous materials and services. For many developing countries, these items cost a great deal more money than their financial resources can provide. The commercial import program offers a partial solution. It creates a channel through which imported commodities, purchased with American dollars, can be converted into local currency accruals to the government of the importing country. This local currency is then available to support joint economic and, where necessary, defense programs. The mechanics of the system explain how this is done:

The commercial import program works through commercial banking channels and is dependent upon the activities of private businessmen. A firm which sees an opportunity for profit in the importation and resale of particular goods eligible for AID financing obtains an import license if it is required, consummates an "exchange contract" with the local bank, arranges for the procurement and transportation of the goods, pays to his local bank the total cost of the goods in local currency, pays customs duty to his government on arrival of the goods, warehouses, and then processes or sells the goods on the open

market. The risk inherent in this transaction falls to the importer, the profit or loss also goes to him.

The dollar cost of the commodities and of transportation, if on U.S. flag vessel, is paid to the supplier against documents he submits to a U.S. bank, out of funds ear-marked for the program.

The importer's bank pays the local currency equivalent into a special account at the National bank. Through this mechanism, local currency is in effect transferred from the private sector to the government for uses jointly agreed to by the U.S. and the aid receiving country.

All this is by way of prologue to pharmaceutical procurement with AID funds. It explains to a degree why we authorize the expenditure of dollars to buy commodities, including pharmaceuticals, that are at times directly related and at other times indirectly related to approved economic development programs.

But perhaps it would be well to bring the pharmaceutical segment of our procurement activities into perspective. During fiscal year 1969, AID-financed commodity expenditures totaled $1.02 billion. Pharmaceutical products accounted for $20.6 million or about 2.0 percent of that total. The figures for fiscal year 1968 showed a higher ratio for pharmaceuticals with expenditures of $31.7 million or 2.7 percent of the $1.06 billion expended for commodities. Detailing these figures further, commodity expenditures for specific Technical Assistance projects totaled $5 million in fiscal year 1969 and $13 million in fiscal year 1968. These were respectively, 24 percent and 41 percent of total expenditures for pharmaceuticals.

In the case of Technical Assistance, pharmaceutical requirements are developed by the technical experts assigned to the respective projects, stated in generic terms, and procured in accordance with government regulations.

This procedure was followed in buying project pharmaceuticals valued at $5 million in FY 1969 and $13 million in FY 1968.

Purchases financed under Technical Assistance for project use are for the most part purchased on behalf of AID by other U.S. government agencies, specifically the General Services Administration or the Defense Supply Agency of the Department of Defense. In rare instances—notably of emergency nature, such as earthquakes, epidemics and other disasters—AID may itself undertake to purchase pharmaceuticals. In still less frequent cases, where there is demonstrated ability to handle transactions effectively, the borrower-grantee is permitted to buy directly or through a purchasing agency that it selects.

The procurement practices and procedures followed by GSA are those set forth in the Federal Procurement Regulations, supplemented by "Additional Program Bidding Terms and Contract Provisions" developed expressly by GSA for its procurement on behalf of AID. These additional terms and provisions cover such items as eligible source, bidding terms, taxes and duties, shipping, labeling, and other requirements peculiar to AID. The Defense Supply Agency in its procurement for AID follows rules of the Armed Services Procurement Regulation. Purchases made directly by AID conform to requirements of the AID Procurement Regulations. Those by a borrower-grantee or its private sector agent, must comply with the rules in AID Regulation 1, usually with an added requirement that the formal invitation for bid procedure be used.

I turn now to activities where AID finances commercial transactions—programs under which we financed pharmaceuticals valued at $15.6 million in FY 1969 and $18.7 million in FY 1968. In these Commercial Import Programs only unfinished pharmaceuticals may be purchased, except that contraceptives in finished dosage form are authorized.

Transactions involving commercial imports must comply with the provisions of AID Regulation 1 as supplemented by special requirements that the Agency applies to pharmaceutical products. AID Regulation 1 prescribes the basic rules that govern AID financed transactions. It covers conditions of eligibility of commodities and services, the responsibilities of importers and suppliers, the payment and reimbursement requisites, and the price rules for commodities and commodity related services. These provisions apply uniformly to all commodities financed by AID under a commercial import program.

There are, however, special requirements that apply only to pharmaceutical products. These relate to commodity eligibility, commodity quality, and commodity certification. As already indicated, pharmaceuticals in finished dosage form are not eligible for financing under our Commercial Import Programs. In addition, drug substances and drug products must meet all requirements

prescribed by the Federal Food, Drug, and Cosmetic Act for interstate shipments.

Biologics for human use must have been manufactured at an establishment holding a product license issued under the Biological Control Provisions of the Public Health Service Act for such products; Veterinary Biologics must meet requirements of the Veterinary Biologics Division of the U.S. Department of Agriculture; Oral Contraceptives must comply with the Food and Drug Administration requirements relating to their marketing in the U.S.

Antibiotics, biologics, contraceptives and several other drugs must be approved in advance by AID on an individual transaction basis. This prior approval requirement was established for several reasons: First, to assure that AID financed purchases reflect Food and Drug Administration actions pursuant to studies by the Drug Efficacy Study Group of the National Research Council of the National Academy of Sciences; second, to assure that importers have adequate storage and distribution facilities to handle perishable products such as vaccines; and third, to assure that significant findings pertaining to proposed end products are transmitted to the importing government.

We now have an extensive list of medicinal chemicals that are eligible for AID financing if they are included in the list of commodities authorized under a given agreement and if they meet the special provision requirements established by AID. We have published and released to the trade, through our Small Business Memos, listings of both eligible and ineligible pharmaceuticals as well as other information regarding pharmaceutical requirements.

We also have a series of internal manual order issuances dealing with pharmaceutical policies and procedures. Copies of pertinent releases were supplied to the Subcommittee.

Most Commercial Import Program purchases are made by negotiation and not by formal bid procedures. This is standard commercial practice—in fact; procurement by formal bid procedures would be the exception rather than the rule. However, we still expect importers to canvass the market whenever possible and to place orders so as to obtain optimum economic advantage. Our system of notification prescribed in AID Regulation 1 was devised to keep U.S. small business informed of sales opportunities arising out of our Commercial Import Programs. Concurrently, however, it makes it possible for importers to solicit competition.

Under the Regulation 1 notification requirement, importers must, unless exempted for reasons stated in the regulation, advertise proposed purchases in the "AID Financed Export Opportunities" bulletin, published by our Office of Small Business. We require importers to identify proposed purchases of pharmaceuticals by generic terms rather than by trade name. This widens the range of potential competitive offers and alerts interested U.S. firms to possible trade opportunities, both for the immediate purchase and for future market explorations. Advertising by generic name enables importers to learn of competitive product availabilities. For AID in addition to its impact on price, generic designation permits routine determination of commodity eligibility or ineligibility when notice is first received regarding a proposed pharmaceutical purchase.

But whether or not an intended pharmaceutical purchase is advertised in the "AID Financed Export Opportunities" bulletin, we are alerted to all proposed shipments made under Regulation 1 rules, by the "Application for Approval of Commodity Eligibility" (Form AID–11) that every commodity supplier must submit to AID/Washington for approval. This prior approval procedure, which was developed in response to Section 604 (f) of the Foreign Assistance Act of 1961, enables us to reject in advance shipments of any pharmaceuticals on our ineligible list or of pharmaceuticals not authorized in the specific commercial import program concerned.

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I have already indicated that notification of proposed procurement is not always required, and may be modified or waived under certain conditions.

For example, publication of *individual* purchase intentions is not required under the so-called "Colombia Plan", of notification. Instead, our Office of Small Business publishes general information regarding the commodities authorized under each program, together with the names and addresses of im-

porters of such commodities. U.S. suppliers can then determine whether to explore the market for their specific products.

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As a second example, the Small Business notification requirement may be waived on a individual company basis when special contractual relationships exist between importer and supplier which render advertising meaningless. In such cases, the supplier may apply for an "Agency Waiver" on behalf of his importing distributor or manufacturing licensee. That type of waiver is granted only when our analysis indicates that the importer has a contractual obligation to refrain from handling competitive products. The validity period of an Agency Waiver is determined by the conditions of the controlling agreements, with a maximum of three years.

As of now waivers of small business notification requirements for pharmaceuticals are effective for 27 importers located in Ghana, India, Morocco, Pakistan, and Turkey.

I wish to stress that transactions conducted under "agency waivers" of the small business notification requirements are subject to careful post-audit examinations. Prices are tested against those charged in comparable export sales that are financed by AID and those sales that are not financed by AID. Briefly, our rules provide that a supplier's price may not exceed the prevailing export market price for comparable sales of all exporters nor may it exceed the price generally charged by the seller in his comparable sales. Posting of the generic nomenclature for each item invoiced facilitates that comparison. Audits made under these rules provide reasonable assurance that cases of excessive pricing will be uncovered when goods are sold under agency arrangements. As a result of these examinations, significant refunds have been obtained from suppliers whose prices were found to exceed those permitted under AID regulations.

I think it well to emphasize a point I already made—namely, that purchases under the commercial import program are made by private firms. These firms buy foreign exchange credits made available by our loans or grants. They buy these credits with their own local currency—the only form of currency that is generally available to them. Barring peculiar situations that may give rise to currency manipulations or other irregularities, an importer stands to profit when he buys properly at a fair price; he will inevitably fail if he buys imprudently without regard to price.

I would like to summarize my statement in this way: We administer our commercial import program for pharmaceuticals in a manner designed to reduce the potential for irregularities. We do this by excluding from financing commodities for which irregularities are most difficult to detect—the dosage form pharmaceuticals—and by monitoring the requirements that pharmaceuticals be identified by generic name. This strips away the brand name cloak under which product similarity may be concealed and price escalation practiced without restraint. As a concurrent consequence of these administrative policies and actions, we encourage participating countries to develop their own pharmaceutical laboratories to formulate dosage drugs.

We encourage also the use of quality raw and intermediate ingredients and bulk compounds of demonstrated efficacy that are produced in the U.S. to recognized standards and that are available under our programs at competitive prices and at savings in the foreign exchange positions of the importing countries.

Pharmaceutical purchases are relatively small as compared to over-all expenditures of AID funds for commodities. They represented 2.0 percent of total commodity expenditure in FY 1969 and 2.7 percent in FY 1968. However, those pharmaceuticals that are purchased with AID funds must conform to strict eligibility requirements, to rigid quality standards, and to permitted price schedules.

I am grateful to the Subcommittee for allowing me to present this broad view of our commodity financing programs, particularly as they relate to pharmaceuticals. I will be glad to elaborate on any areas which the Subcommittee may wish to examine.

A.I.D. Small Business Memo

Trade Information for American Suppliers

Issued By
DEPARTMENT OF STATE
Agency for International Development, Office of Small Business
Washington, D. C. 20523 Area Code 202 383-6664

SBM No. 68-24
(SUPERSEDES SBM No. 68-8)
November 27, 1968
(M/L: Entire OSB List)

FINANCING OF PHARMACEUTICALS UNDER PROGRAM ASSISTANCE

I. Pharmaceuticals in finished dosage form have been excluded from A.I.D. financing under commodity import program agreements entered into since March 14, 1967, except:

i. When A.I.D. determines that such financing is necessary for the attainment of program objectives, e.g., where A.I.D. financing is needed and sufficient facilities for "finishing" do not exist in the importing country; or

ii. When the procurement is to be made on a competitive basis by a government agency of the cooperating country or its designated purchasing agent (including any agency of the United States Government so designated).

II. Finished dosage form is the finished pharmaceutical, such as tablet, capsule, ointment, elixir, syrup, injectable, or other such form, which requires no further processing before packaging and labeling to be suitable for administration. Packaging, bottling, sterilizing, and/or labeling do not constitute processing operations which produce finished dosage forms. However, antibiotics for injection are eligible for A.I.D. financing when shipped in bulk for sterilizing and/or bottling in the importing country.

This definition supersedes the one given in Small Business Memo 68-8 dated April 17, 1968.

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A.I.D. Small Business Memo

Trade Information for American Suppliers

Issued By
DEPARTMENT OF STATE
Agency for International Development, Office of Small Business
Washington, D. C. 20523 Area Code 202 63-20237

SBM No. 70-6
April 3, 1970
(M/L: Entire OSB List)

REPUBLICATION OF A.I.D. COMMODITY PROCUREMENT SOURCE-ORIGIN POLICY AND AMENDMENTS

This Small Business Memo supersedes the SBM 69-4 series in its entirety. It contains the Agency source-origin policy and individual commodity componentry rulings issued to date in the SBM 69-4 series. Future rulings will be issued in the SBM 70-6 series.

A.I.D. COMMODITY PROCUREMENT SOURCE-ORIGIN POLICY

A commodity, even though produced through manufacturing, processing or assembly in, and shipped to the cooperating country from, an authorized source country, will not be eligible for A.I.D. financing if: (i) it contains any component from countries other than free world countries, as listed in A.I.D. geographic code 899*; or (ii) it contains components which were imported into the country of production from such free world countries other than authorized source countries and (a) such components were acquired by the producer in the form in which they were imported and (b) the total cost of such components (delivered at the point of production) amounts to more than 10 percent, or such other percentage as A.I.D. may prescribe, of the lowest price (excluding the cost of ocean transportation and marine insurance) at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).

A.I.D. may from time to time waive or modify this 10 percent limitation if in its view such action is necessary to achieve A.I.D.'s objective of conformity with normal industry practices. Requests for waivers or modification should be addressed to Industrial Resources Division, Agency for International Development, Washington, D. C. 20523.

Listed herein are the commodity source rulings, modifying or waiving the 10 percent componentry limitation, which are currently in effect.

Separate rulings applicable to Latin America are contained in SBM 70-7.

*A.I.D. Geographic Code 899 includes any area or country in the world except the U.S.S.R., Eastern Europe, Poland, North Vietnam, North Korea, China (Mainland) and other Chinese Communist controlled areas, Outer Mongolia, and Cuba.

SOURCE RULINGS

SR-1 TEXTILE FABRICS

Schedule B Numbers - 652.1100 - 652.2976(P); 653.2110 - 653.2200(P); 653.5110 - 653.6400(P); 653.8010 - 653.8021(P); 654.0110 - 654.0120(P); 654.0130(P); 655.4110 - 655.4127(P); 655.4210 - 655.4620(P)

Textile fabrics must be manufactured and processed within the area of source specified in the authorization document. Manufacturing and processing of textile fabrics is interpreted as being all steps required in the manufacture of the finished product, including spinning, weaving, felting, knitting, and finishing as applicable. The foreign componentry percentage limitation is waived as long as the above requirement is met. (Note: This ruling is not applicable to yarns, thread, and man-made textile fibers).

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SR-2 MOTOR VEHICLES

Schedule B Numbers - 732.0120 - 732.0150; 732.0204 -732.0256; 732.0310 - 732.0346; 732.0420 - 732.0430

If authorized by A.I.D./Washington on a case-by-case basis, knocked-down units of automotive equipment, to be assembled in the recipient country, may include up to 10 percent of foreign manufactured components from Free World countries other than the United States; this applies even though the knocked-down unit is not complete and needs the addition of indigenously manufactured units to make a complete vehicle. The foreign components so included must, however, be shipped from the United States on a single Bill of Lading with the other components.

A.I.D./Washington will consider authorizing componentry modifications of this type only on the basis of individual supplier applications supported by adequate justification. (See also SR-28, SR-53 and SR-55)

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SR-3 AUTOMOTIVE EQUIPMENT

Superseded by SR-28.

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SR-4 IRON AND STEEL MILL PRODUCTS

Schedule B Numbers - 671.1000 - 674.4445; 674.4460 - 674.7010; 674.7030; 674.7060 - 676.1020; 676.2010 - 678.4000; 678.5010 - 679.3030; 691.1015; 691.1030; 691.1035; 691.1045; 691.1060; 691.1080; 692.1110(P); 692.1120; 693.1100; 693.2010 - 693.3120; 694.1110 - 694.1120; 694.2110 - 694.2130; 698.8710 - 698.8720; 698.9110; 698.9130; 731.7010 - 731.7020

Foreign ores from Free World countries, used in the production of iron and steel by United States producers, need not be included when computing the 10 percent componentry limitation.

****

SR-5 DIAMOND DRILL BITS, WHEELS, AND TOOLS

Schedule B Numbers - 663.1110; 663.1200(P); 695.2350(P); 695.2450; 695.2470(P); 695.2490(P); 695.2495(P); 718.5118(P); 718.5125(P); 718.5138(P); 718.5145(P); 861.7125(P)

Drill bits, wheels, and tools which normally contain industrial diamonds or bortz cutting edges must be wholly manufactured within the area specified in the A.I.D. authorizing document as an eligible source of supply. The term "manufactured" means all processes necessary to produce the basic bit, wheel, or tool, including the setting of industrial diamonds or bortz cutting edges. The foreign componentry percentage limitation is waived as long as the above requirement is met.

****

SR-6 TIRES AND TUBES

Cancelled.

****

SR-7 TEXTILE FABRICS

SEE SR-1.

****

SOURCE RULINGS

SR-8 APPLICABILITY OF COMPONENTRY RULE TO COMPLETE INSTALLATIONS

The question of whether the 10 percent componentry rule applies to a complete installation rather than to the elements making up the installation is decided on the basis of the circumstances involved in each case.

Factors involved include such things as the particular elements of the installation to be imported and whether the source of financing would restrict the competition to U.S. firms or allow foreign competition as well.
****

SR-9 ASBESTOS CEMENT PIPE

Schedule B Number - 661.8320(P)

Asbestos cement pipe produced in the United States may include asbestos fibers imported from Free World countries provided the total cost of such asbestos fibers (delivered at the point of production) does not exceed 20 percent of the lowest price (excluding the cost of ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).
****

SR-10 DIESEL ELECTRIC GENERATORS

Schedule B Numbers - 722.1052 - 722.1054(P)

Diesel engine driven electric generators manufactured in the United States, up to and including 15 KW (18.75 KVA) capacity, may contain diesel engines of foreign manufacture from Free World countries, provided the total cost of such engines (delivered at the point of production) does not exceed 50 percent of the lowest price (excluding the cost of ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).
****

SR-11 ELECTROLYTIC MANGANESE DIOXIDE

Schedule B Number - 513.5220

Electrolytic Manganese Dioxide, produced in the United States, may contain Manganese ore imported from Free World countries, provided the total cost of such ore (delivered at the point of production) does not exceed 20 percent of the lowest price (excluding the cost of ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).
****

SR-12 MOTORCYCLES

Schedule B Number - 732.9100(P)

If authorized by A.I.D. /Washington on a case-by-case basis, lightweight motorcycles manufactured in the United States may contain engines and other miscellaneous components from Free World countries provided that (1) the total cost of such components (delivered at the point of production) does not exceed 50 percent of the lowest price (excluding the ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.) and (2) provided further that such components are shipped from the United States on the same Bill of Lading with the finished product. This ruling does not extend to parts or components intended for use as spare or replacement parts. (See SR-55)

A.I.D./ Washington will consider authorizing componentry modifications of this type only on the basis of individual supplier applications supported by adequate justification.
****

SOURCE RULINGS

SR-13 TITANIUM DIOXIDE

Superseded by SR-47.
****

SR-14 REFINED COPPER

Schedule B Number - 682.1200

Foreign copper ores, copper concentrates, black copper, and blister copper from Free World countries, used in the production of refined copper by United States producers need not be included when computing the 10 percent componentry limitation.
****

SR-15 ELECTROLYTIC MANGANESE METAL

Schedule B Number - 689.5045(P)

Electrolytic Manganese metal produced in the United States may contain manganese ore imported from Free World countries, provided the total cost of such ore (delivered at the point of production) does not exceed 15 percent of the lowest price (excluding the cost of ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).
****

SR-16 AGRICULTURAL TRACTORS AND IMPLEMENTS

Cancelled.
****

SR-17 BASIS FOR COMPUTING COST OF COMPONENTS

The cost of imported foreign components is computed on the basis of cost as of the time of delivery to the point of production. The cost should not be calculated on a net basis to reflect an anticipated rebate or drawback of import duty.
****

SR-18 ANTHROSOL BLUE, IBC

Schedule B Number - 531.0100(P)

Anthrosol Blue, IBC, produced in the United States, may contain 2 Acetyl Amino, 3 Chloro Anthraquinone imported from Free World countries, provided the total cost of such raw material (delivered at the point of production) does not exceed 33 percent of the lowest price (excluding the cost of ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).
****

SR-19 NATURAL CRYOLITE

Schedule B Number - 276.5500(P)

Processed Natural Cryolite produced in the United States may contain raw material imported from Free World countries, provided that the total cost of such raw material (delivered at the point of production) does not exceed 25 percent of the lowest price (excluding the cost of ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).
****

SOURCE RULINGS

SR-20 SPARE PARTS

Superseded by SR-55.
********** **********

SR-21 SILVER NITRATE

Schedule B Number - 514.7050(P)

Any silver metal obtained from the U.S. Treasury Department and used in the production of Silver Nitrate by the United States producers is exempt from the 10 percent componentry rule.
********** **********

SR-22 FULLY REFINED PETROLEUM WAXES

Superseded by SR-25.
********** **********

SR-23 GALVANIZED IRON AND STEEL PRODUCTS FOR VIETNAM

Obsolete
********** **********

SR-24 HYDROUS TRIBASIC LEAD SULFATE

Schedule B Number - 514.7050(P)

Lead imported from Free World countries and used in the production of Hydrous Tribasic Lead Sulfate by U.S. manufacturers need not be included when computing the 10 percent componentry rule.
********** **********

SR-25 FULLY REFINED PETROLEUM WAXES

Superseded by SR-42.
********** **********

SR-26 GALVANIZED IRON AND STEEL PRODUCTS FOR VIETNAM

Obsolete.
********** **********

SR-27 HYDRAULIC TURBINES

Schedule B Number - 711.8120

Non-U.S. product engineering services associated with the design, testing, fabrication, and installation of hydraulic turbines are relevant computable items within the 10 percent componentry limitation.

As used below, the following terms have meanings indicated:

1. "Non-U.S. product engineering" means product engineering services which are performed by other than a U.S. firm.

2. "U.S. firm" means an entity which:

   a. Is incorporated or legally domiciled in the United States;

   b. Has its principal place of business in the United States; and

   c. Is more than 50 percent beneficially owned by a U.S. firm or firms and/or U.S. citizens.

(SR-27 continued on page 6)

SOURCE RULINGS

SR-27 HYDRAULIC TURBINES (Continued):

In cases involving the procurement of hydraulic turbines the following procedures apply:

1. Bids for one or more turbines shall be taken separately from all other equipment. Turbines shall not be bid with generators as one package. (A request for a waiver of this requirement may be submitted to A.I.D./Washington by the borrower/grantee. Requests shall be in writing and shall include a detailed justification for the combined procurement).

2. The bidder shall submit (preferably with his bid documents), for review and approval by the borrower/grantee or his agent, evidence of all non-U.S. product engineering associated with the hydraulic turbine being offered. Such evidence shall be in the form of a binding subcontract, or other equivalent documentation, and shall include:

a. A clear description and a detailed account of all non-U.S. product engineering which was (or will be) performed as part of the turbine sale; and

b. An estimate based on the total bid price for the hydraulic turbine, reflecting:

(1) The percentage of price attributable to expenditures relating to the non-U.S. product engineering, and

(2) The total percentage of price for all non-U.S. component cost (including the non-U.S. product-engineering element).

********** **********

SR-28 MOTOR VEHICLES, TRUCKS AND BUSES

(Supersedes SR-3)

Schedule B Numbers - 732.0204 - 732.0234; 732.0236 - 732.0256; 732.0310 - 732.0346; 732.0420; 732.0430; 732.9100(P)

If authorized by A.I.D. on a case-by-case basis, trucks manufactured in the United States may contain diesel engines or gasoline engines of foreign manufacture from Free World countries provided that (1) the total cost of all foreign components (delivered at the point of production) does not exceed 30 percent or 15 percent respectively of the lowest price (excluding the cost of ocean transportation and marine insurance) at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.) and (2) provided further that any vehicle equipped with tires and/or tubes from other than authorized sources shall be eligible for A.I.D. financing only if the vehicles conform to the componentry limitation of 10 percent as stated in A.I.D. Regulation 1, Section 201.11(b)(2)(ii)(b).

The ruling applies whether the trucks are shipped assembled or completely knocked down, provided the shipment is from the United States on a single Bill of Lading. The ruling does not extend to parts or components shipped separately for use as spare or replace parts. (See also SR-53 and SR-55.)

A.I.D./Washington will consider authorizing componentry modifications of this type only on the basis of individual supplier applications supported by adequate justification.

********** **********

SR-29 NICKEL CADMIUM BATTERIES (INDUSTRIAL TYPE)

Superseded by SR-36.

********** **********

SOURCE RULINGS

SR-30 MANGANESE DIOXIDE, MANGANESE HYDRATE 25x

Schedule B Numbers - 513.5220; 513.6932(P)

Manganese Dioxide, Manganese Hydrate 25x, produced in the United States, may contain precipitated Manganese Dioxide and Manganese ore imported from Free World countries, provided the total cost of such material (delivered at the point of production) does not exceed 28 percent of the lowest price (excluding the cost of ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).

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SR-31 GALVANIZED IRON AND STEEL PRODUCTS FOR VIETNAM

Obsolete.

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SR-32 CHLORTETRACYCLINE HYDROCHLORIDE

See SR-34.

****

SR-33 GALVANIZED IRON AND STEEL SHEETS FOR VIETNAM

Obsolete.

****

SR-34 MEDICINAL AND PHARMACEUTICAL PREPARATIONS

Schedule B Numbers - 512.0310 - 512.0325; 512.0730; 514.8000; 541.1010 - 541.9932

Medicinal and pharmaceutical preparations produced in the United States may contain components imported from Free-World countries provided the total cost of such components (delivered at the point of production) does not exceed 25 percent of the lowest price (excluding the cost of ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).

****

SR-35 NICKEL CHEMICALS

Superseded by SR-38.

****

SR-36 NICKEL CADMIUM BATTERIES (INDUSTRIAL TYPE)

Superseded by SR-39

****

SR-37 ALUMINUM PRODUCTS

Schedule B Numbers - 684.0130 - 684.2600

Aluminum ingots imported from Free World countries and used by U.S. producers in the production of aluminum products may be considered as of U.S. source when the manufacturer of such products agrees to purchase at least an equivalent quantity of aluminum ingots from the U.S. Government stockpile.

****

SOURCE RULINGS

SR-38 NICKEL CHEMICALS

(Supersedes SR-35)

Schedule B Numbers - 512.0999(P); 514.7050(P): 599.9910(P)

Nickel imported from Free World countries may be considered as of indigenous source when used by U.S. producers in the manufacture of nickel sulfate, nickel carbonate, nickel acetate, nickel chloride, nickel formate, nickel nitrate, and nickel catalysts.

********** **********

SR-39 NICKEL CADMIUM BATTERIES (INDUSTRIAL TYPE)

Superseded by SR-50.

********** **********

SR-40 CONTRACEPTIVES

Schedule B Numbers - 541.5040(P); 541.7010(P); 629.3000(P); 861.7150(P)

Contraceptives in finished-dosage form produced in the United States may contain components from Free World countries provided the total cost of such components (delivered at the point of production) does not exceed 25 percent of the lowest price (excluding the cost of ocean transportation and marine insurance) at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).

********** **********

SR-41 ALUMINA AND ALUMINUM INGOTS

Schedule B Numbers - 513.6510 - 513.6600

Alumina, produced in the United States, may contain bauxite imported from Free World countries, provided the total cost of such bauxite (delivered at the point of production) does not exceed 20 percent of the lowest price (excluding the cost of ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).

Schedule B Numbers - 684.0110 - 684.0120

Aluminum ingots, produced in the United States, may contain alumina imported from Free World countries, provided the total cost of such alumina (delivered at the point of production) does not exceed 25 percent of the lowest price (excluding the cost of ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).

********** **********

SR-42 PARAFFIN WAXES, FULLY REFINED AND SEMI-REFINED

(Supersedes SR-25)

Schedule B Numbers - 332.6220 - 332.6230

Crude oils imported from Free World countries may be considered as of indigenous source when used by U.S. producers in the production of fully refined or semi-refined paraffin waxes.

********** **********

SOURCE RULINGS

SR-43 MAGNESITE-CHROME REFRACTORIES

Schedule B Number -662.3260

Magnesite-chrome refractories, produced in the United States may contain magnesite and chrome ore imported from Free World countries provided the total cost of such materials (delivered at the point of production) does not exceed 25 percent of the lowest price (excluding the cost of ocean transportation and marine insurance) at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).
****
****

SR-44 PHOTOGRAPHIC AND CINEMATOGRAPHIC SUPPLIES

Schedule B Numbers - 862.3000 - 862.4670

Photographic and cinematographic supplies must be manufactured within the United States (A.I.D. Geographic Code 000). This is interpreted as requiring that all steps in the manufacture of the finished product must have been performed within the United States. The foreign componentry percentage limitation is waived as long as the above requirement is met.
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SR-45 ACETATE CIGARETTE TOW AND ACETATE YARNS AND FIBERS

Cancelled.
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SR-46 ALUMINUM FLUORIDE

Schedule B Number - 514.5020(P)

Aluminum Fluoride produced in the United States may contain acid grade fluoride (calcium fluoride) and alumina derived from bauxite imported from Free World countries, provided the total cost of such materials (delivered at the point of production) does not exceed 36 percent of the lowest price (excluding the cost of ocean transportation and marine insurance), at which the supplier makes such aluminum fluoride available for export sale (whether or not financed by A.I.D.).
****
****

SR-47 TITANIUM DIOXIDE

(Supersedes SR-13)

Schedule B Number 513.5520

Titanium Dioxide produced in the United States, may contain raw material imported from Free World countries, provided the total cost of such materials (delivered at the point of production) does not exceed 35 percent of the lowest price (excluding the cost of ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).
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SOURCE RULINGS

SR-48 COLOR INDEX DYES

Schedule B Number - 531.0100

Time Limited Source Ruling

A. Reactive Yellow 13

Color Index Dye Reactive Yellow 13, produced in the United States, may contain CA Acid (chlor-3-amino-4-sulfo-benzoic acid) imported from Free World countries, provided the total cost of such raw material (delivered at the point of production) does not exceed 25 percent of the lowest price(excluding the cost of ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).

B. Reactive Blue 19

Color Index Dye Reactive Blue 19, produced in the United States, may contain Bromoaminic Acid, imported from Free World countries, provided the total cost of such raw material (delivered at the point of production) does not exceed 51 percent of the lowest price (excluding the cost of ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).

C. Reactive Yellow 15

Color Index Dye Reactive Yellow 15, produced in the United States, may contain Amino Sulfone K imported from Free World countries, provided the total cost of such imported material (delivered at the point of production) does not exceed 31 percent of the lowest price (excluding the cost of ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).

D. Reactive Yellow 17

Color Index Dye Reactive Yellow 17, produced in the United States, may contain Amino Sulfone D imported from Free World countries, provided the total cost of such imported material (delivered at the point of production) does not exceed 38 percent of the lowest price (excluding the cost of ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).

F. Solubilized Vat Black 1

Color Index Dye Solubilized Vat Black 1, produced in the United States, may contain Vat Printing Black BL for Sol 100%, imported from Free World countries, provided the total cost of such raw material (delivered at the point of production) does not exceed 33 percent of the lowest price (excluding the cost of ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).

The above rulings apply to deliveries of dyestuffs supported by Bills of Lading dated not earlier than October 1, 1968, and not later than September 30, 1970.

********** **********

SR-49 HIGH ALUMINA REFRACTORIES

Schedule B Number - 662.3210

Bauxite imported from Free World Countries may be considered as of indigenous source when used by United States producers in the production of High Alumina Refractories.

********** **********

SOURCE RULINGS

SR-50 NICKEL CADMIUM BATTERIES (INDUSTRIAL TYPE)

Superseded by SR-50.1

********** **********

SR-50.1 NICKEL CADMIUM BATTERIES (INDUSTRIAL TYPE)

(Supersedes SR-50)

Schedule B Number - 729.1230(P)

Time Limited Source Ruling

The following ruling applies to deliveries supported by Bills of Lading dated not earlier than November 1, 1969, and not later than October 31, 1970:

Industrial type nickel-cadmium batteries (i.e., railroad signaling and locomotive starting) manufactured in the United States, may contain foreign components from Free World countries provided the total cost (delivered at the point of production) does not exceed 42 percent of the lowest price (excluding the cost of ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).

Any deliveries supported by Bills of Lading dated later than October 31, 1970, must comply with the standard 10 percent rule or such other percentage limitation as A.I.D. may prescribe.
********** **********

SR-51 NICKEL OR NICKEL-BASE ALLOY ELECTRODES

Schedule B Numbers - 698.8730 - 698.8740(P)

Nickel imported form Free World countries may be considered as of indigenous source when used by U.S. producers in the manufacture of nickel or nickel-base alloy electrodes.
********** **********

SR-52 COMPACTORS AND TOWED TYPE ROAD ROLLERS (DIESEL POWERED)

Schedule B Number - 718.4228

Towed type, diesel engine-equipped vibratory compactors including pneumatic-tired, sheepsfoot and steel-wheeled rollers designed for 30 or more brake horsepower (continuous duty rating in accordance with the air-cooled diesel manufacturer's standard commercial published horsepower curves), when manufactured in the United States, may contain air-cooled diesel engines produced in Free World countries provided the total cost of foreign components (delivered at the point of production) does not exceed 20 percent of the lowest price (excluding the cost of ocean transportation and marine insurance) at which the supplier makes the finished compactor or roller available for export sale (whether or not financed by A.I.D.).
********** **********

SR-53 MOTOR VEHICLE PARTS

Sch. B 612.1000; 621.0510 - 621.0520; 629.4005; 633.0010;642.9885; 633.8105; 663.8225; 664.7020 - 664.8015; 698.1115; 698.1204; 698.1245; 698.3010; 698.6110 - 698.8110; 711.5062 - 711.5064; 719.2105 - 719.2145; 719.2257;719.2260; 719.7010 - 719.7075; 719.9212; 719.9310 - 719.9320; 719.9340 - 719.9900; 722.1023; 722.1066; 722.2054; 723.1030; 723.1080; 729.1210; 729.1240 - 729.1255; 729.2025; 729.4110 - 729.4120; 729.4135 - 729.4230; 729.5288 - 729.5290; 729.5295; 729.9555 - 729.9610; 732.8100 - 732.8910; 732.8932 - 732.8948; 812.4125; 812.4145; 812.4210; 861.8220; 861.9742 - 861.9748; 861.9950 and such additional Schedule B numbers specifically requested by individual suppliers and authorized by A.I.D. (PROC/IRD).

Basic materials (copper, tin, steel, cork, asbestos, etc.) imported from Free World countries may be considered as of indigenous source when used by U.S. producers in the manufacture of motor vehicle parts.

********** **********

SOURCE RULING

SR-54 NICKEL AND NICKEL ALLOY PRODUCTS

Schedule B Numbers - 683.2110 - 683.2400

Nickel imported from Free World countries may be considered as of indigenous source when used by U.S. producers in the manufacture of nickel and nickel alloy products.
********** **********

SR-55 SPARE AND REPLACEMENT PARTS

The foreign-componentry limitation is applied to spare and replacement parts as follows:

1. In the case of parts shipped separately from the equipment to which they are applicable, the 10 percent foreign-componentry limitation is applied to the shipment as a whole and not to each individual spare or replacement part.

2. In the case of parts ordered to accompany a product (machine or piece of equipment) to which they are applicable, and the product is subject to a maximum foreign-componentry limitation (either 10 percent or another percentage specifically determined), A.I.D. will allow the supplier to include foreign parts to the following extent: the cost of imported parts (delivered to the supplier), plus the cost of the other foreign components of the product, may not exceed the allowable foreign componentry percentage of the lowest export price of the product, (excluding the cost of ocean transportation and marine insurance), at which the supplier makes the product available for export sale (whether or not financed by A.I.D.).

********** **********

SR-56 MULTISPEED BICYCLES

Schedule B Number - 733.1100

Bicycles with multispeed gearing devices of three or more speeds manufactured in the United States may contain components from Free World countries provided that the total cost of such components from other than authorized sources (delivered at the point of production) does not exceed 45 percent of the lowest price (excluding the cost of ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.) and, in the case of shipments of knocked-down units, provided also that components from other than authorized sources are shipped from the United States on the same Bill of Lading with the other components. This ruling does not extend to parts or components intended for use as spare or replacement parts. (See also SR-55.)
********** **********

SR-57 FERROCHROME

Schedule B Number - 671.5010

Ferrochrome produced in the United States may contain chrome ore imported from Free World countries, provided the total cost of such materials (delivered at the point of production) does not exceed 20 percent of the lowest price (excluding the cost of ocean transportation and marine insurance) at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).
********** **********

SR-58 MIMEOGRAPH STENCIL TISSUE

Schedule B Number - 641.5055(P)

Mimeograph stencil tissue, produced in the United States, may contain abaca fiber from Free World countries, provided the total cost of such raw material (delivered at the point of production) does not exceed 15 percent of the lowest price (excluding the cost of ocean transportation and marine insurance), at which the supplier makes the commodity available for export sale (whether or not financed by A.I.D.).

********** **********

SOURCE RULINGS -- SR 70-6 Series INDEX

* Cancelled

SOURCE RULINGS -- SR 70-6 Series INDEX

SOURCE RULINGS -- SR 70-6 Series INDEX

* Cancelled

SOURCE RULINGS -- SR 70-6 SERIES INDEX

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A.I.D. 11-104 (4-69)

AGENCY WAIVER APPLICATION
under
Section 201.24(c)(1) of A.I.D. Regulation 1

BUDGET BUREAU NO. 24-R0050
APPROVAL EXPIRES JUNE 30, 1971

PLEASE COMPLETE AND RETURN IN DUPLICATE (INCLUDING ATTACHMENTS)

1. To:
Office of Small Business
Agency for International Development
Department of State
Washington, D. C. 20523

2. From: Supplier (Name and Address)

3. On behalf of Importer (Name and address)

4. Who is Supplier's (Check One):

☐ a. Distributor
☐ b. Dealer
☐ c. Agent
☐ d. Licensed Manufacturer

e. Other Relationship:
☐ (1) Subsidiary, wholly owned _____
☐ (2) Subsidiary, partially owned _____
☐ (3) Other Affiliation _____
(attach statement describing)

5. For products: (Identify - or attach list - or continue on reverse side) Include USDC Schedule B Nos.

6. Which products are (Check One):

☐ a. Manufactured by supplier _____
☐ b. Manufactured under supplier's U.S.-registered trade mark or U.S.-registered brand name of _____
☐ c. Distributed by supplier as the manufacturer's duly authorized exporter for: _____ (country)

7. And imported by above-named importer for (Check One):

a. Resale in _____ (country)

b. ☐ Manufacturing, or ☐ Processing, or ☐ Assembly, and sale of end-product for which importer is supplier's duly authorized distributor in _____ (country)

8. Should A.I.D. grant a waiver based on the documents submitted herewith, the supplier undertakes to provide promptly to the A.I.D. Office of Small Business a record of any changes thereto which might affect the waiver. Two copies of the waiver instrument will be furnished the supplier, one for his records and one to be forwarded to the importer.

(Signature - Authorized Official) (Title) (Date)

Attachments, per subsections (c) and (d) of Section 201.24(c)(1)ii (check applicable documents)

☐ 1. Contractual Agreement between Supplier and Importer (4, a - d above)

☐ 2. Agreement between Manufacturer and Supplier (6-b or 6-c above)

☐ 3. Statement of Other Affiliation between Supplier and Importer (4-e above)

PLEASE COMPLETE AND RETURN IN DUPLICATE (INCLUDING ATTACHMENTS)

AID Small Business Memo

Trade Information for American Suppliers

Issued By
DEPARTMENT OF STATE
Agency for International Development, Office of Small Business
Washington, D. C. 20523 DUdley 3-7091

SBM No. 65-3
March 1, 1965
(M/L: Entire OSB List)

WAIVERS OF PUBLICATION REQUIREMENTS FOR PROCUREMENT UNDER CERTAIN SPECIAL SUPPLIER IMPORTER RELATIONSHIPS

(SBM No. 65-3 supersedes in their entirety SBM No. 59-3 dated April 22, 1959; Supplement No. 1 to SBM No. 59-3 dated March 30, 1961, and Supplement No. 2 to SBM No. 59-3 dated August 11, 1961.)

Section 602 of the Foreign Assistance Act of 1961 provides that the Office of Small Business, A.I.D., shall make available to suppliers in the United States, and particularly to small independent enterprises, information as far in advance as possible with respect to purchases proposed to be financed by A.I.D. funds.

To notify U.S. suppliers of opportunities to furnish commodities financed under the Foreign Assistance Program, A.I.D. requires that the foreign government or private importers, before placing any order or agreeing to place any order covered by a subauthorization of more than $5,000, shall give the A.I.D. Office of Small Business a description of the commodities desired, stated in terms of United States standards. This description is published in the Small Business Circular, requesting formal competitive bids, (usually in the case of procurement by a government agency) or informal quotations, (usually in the case of procurement by a private importer). The Circular is distributed, without charge, to all interested subscribers.

A.I.D. recognizes that certain conditions can exist where publication of proposed purchases in the Small Business Circular would serve no useful purpose, such as where the existence of contractually binding commercial relationships would vitiate competition. Such conditions are recognized in the commercial relationships described in A.I.D. Regulation 1, Section 201.24(c)(1)(i), subsections (a), (b), (c), and (d). Briefly they comprise those situations when procurement concerns commodities imported under the following conditions:

1. A registered brand name commodity for resale by a regularly authorized dealer of the sole distributor of the brand item;

2. A commodity for resale by a regularly authorized distributor of the manufacturer, or of the manufacturer's regularly authorized exporter for the destination involved; and

3. A commodity for assembly, manufacture or conversion, and resale of the end-product, by a regularly authorized importing distributor of the manufacturing supplier or the manufacturer's regularly authorized exporter for the destination involved.

Section 201.24(c)(1)(ii) explains how to apply for a waiver when such conditions exist.

For the convenience of applying suppliers, the enclosed form has been designed to facilitate submission of the information required to permit ready evaluation of qualifying relationships, and to accelerate processing of all applications.

Unless otherwise indicated on the Agency Waiver when issued, the waiver will remain valid for three years and will apply to all repetitive sales of the commodities to the importer indicated thereon. Renewal, when required, should be requested from the Office of Small Business sufficiently in advance of the expiration date to avoid possible lapse in continuous validity of the waiver.

Pertinent changes in the controlling supplier/importer relationship for which an Agency Waiver is issued, however, will automatically nullify its validity, and the supplier is responsible for notifying the Office of Small Business of all such changes.

Agency Waivers are issued to the supplier in duplicate, one copy for his records and one to be forwarded to his importing distributor.

The status of waivers issued prior to November 1, 1964, will remain unchanged until/unless notified to the contrary.

Additional copies of Agency Waiver Application form AID 11-1C4 may be obtained upon request from the Office of Small Business.

AGENCY WAIVERS OF SMALL BUSINESS NOTIFICATION REQUIREMENT ISSUED TO SUPPLIERS ON BEHALF OF IMPORTERS OF MEDICINALS AND PHARMACEUTICALS
(AS OF July 28, 1970)

Country (5)	U.S. Suppliers (27)	Agents (27)
Ghana (1)	Norwich Pharmaceuticals	Ghana Drug House Ltd.
India (7)	Abbott Laboratories (Universal Enterprises	*Abbott Laboratories (India)
	Merck, Sharp & Dohme Intl.	*Merck, Sharp & Dohme of India Ltd.
	Park, Davis & Co.	*Park, Davis (India) Ltd.
	Richardson-Merrell, Inc.	*Richardson Hindustan Ltd.
	A. H. Robins Co. Inc.	Khandelwal Laboratories Pvt. Ltd.
	E. R. Squibb & Sons, Inc.	*Karamchand Premchand Pvt. Ltd.
	Wyeth Intl. Ltd.	*Wyeth Laboratories Ltd.
Morocco (1)	Merck, Sharp & Dohme Intl.	Etablissements Pierre My SA
Pakistan (12)	Abbott Laboratories (Universal Enterprises)	*Abbott Laboratories (Pakistan)
	American Roche Intl. Inc.	Merck, Sharp & Dohme of Pakistan
	Burroughs Wellcome & Co.	*Burroughs Wellcome (Pakistan)
	CIBA Pharmaceuticals Co.	*CIBA (Pakistan) Ltd.
	Park, Davis & Co.	*Park, Davis & Co. Ltd.
	Pfizer Corp.	*Pfizer Laboratories Ltd.
	Pfizer Overseas	*Pfizer Laboratories Ltd.
	G. D. Searle & Co.	*Searle (Pakistan) Ltd.
	E. R. Squibb & Sons, Inc.	*Squibb of Pakistan Ltd.
	Upjohn Intl. Inc.	The Schazoo Laboratories Ltd.
	Whitehall Intl. Inc.	*Wyeth Laboratories (Pakistan) Ltd.
	Wyeth Intl. Ltd.	*Wyeth Laboratories (Pakistan) Ltd.
Turkey (6)	Abbott Lab. (Universal Enter.)	*Abbott Laboratories CA
	American Hospital Supply Corp. (Don Baxter) Intl. Div.	Eczacibasi Ilac Sanayi ve Ticaret
	Lakeside Laboratories	D.E.V.A. Sanayi ve Ticaret A.S.
	Norwich Pharmacal Co.	Eczacibasi Ilac Sanayi ve Ticaret Anonim Sirketi
	Pfizer (Corp. & Overseas)	*Pfizer Ilaclari A.S.
	E.R. Squibb & Sons, Inc.	*E.R. Squibb & Sons Ilaclar A.S.

*Affiliated with U.S. Supplier listed.

A.I.D. Expenditures: Total Commodities and Pharmaceuticals
Fiscal Years 1968 and 1969
(Values in Millions of Dollars)

	1968	1969
Total Commodities	1,161	1,025
Total Pharmaceuticals		
Value	31.7	20.6
Percent of total commodities	2.7	2.0%
Project Pharmaceuticals		
Value	13.0	5.0
Percent of totals pharmaceuticals	41%	24%
Non-Project Pharmaceuticals		
Value	18.7	15.6
Percent of total pharmaceuticals	59%	76%

REFUND CLAIMS ASSERTED BY A.I.D. AGAINST PHARMACEUTICAL SUPPLIERS

TABLE I.—CLAIMS ON WHICH REFUNDS HAVE BEEN RECEIVED

Supplier	Date of claim	Nature of violation	
		Overpricing	Other [1]
Abbott Laboratories	Dec. 22, 1961		$5,996.23
Do	Feb. 5, 1962		1,857.00
Do	Sept. 29, 1969	$209,277.69	
Do	June 4, 1970	162,626.55	
Allied Biochemical Labs	Dec. 7, 1961	3,065.00	
American Chemical & Drug	Sept. 20, 1957		1,844.70
Do	Sept. 21, 1965		9,449.00
American Cyanamid	Mar. 2, 1962		263,383.00
Do	July 28, 1967		17,429.29
Do	July 28, 1967		32,570.71
Do	May 24, 1968	3,306.25	
Do	Aug. 22, 1968	3,255.12	
Do	Sept. 4, 1961	3,000.00	
Arco Espanola, S.A	Aug. 22, 1962	37,624.00	
Labs Atral, Ltd	Apr. 10, 1962	3,599.72	
Don Baxter	Feb. 12, 1968		3,842.00
Bristol Labs	Aug. 30, 1961	41,800.00	
Burroughs Wellcome	June 26, 1970	3,755.00	
Byron Chemical Co	Jan. 2, 1967	9,000.00	
Ciba of India	Sept. 13, 1962	17,545.50	
Labs Diamant	Oct. 30, 1962		1,010.25
Bank Negara Indonesia	May 2, 1968	1,515.96	
Farmaceutici Biagini	Dec. 13, 1961		1,101.94
Do	Dec. 13, 1961		684.50
Jensen-McLean Co	Mar. 21, 1956	6,270.00	
Lakeside Labs, Inc	May 16, 1969	16,107.50	
Do	May 16, 1969	516.04	
Do	May 16, 1969	616.00	
Do	May 16, 1969	13,699.00	
Eli Lilly, S.A	July 6, 1967	13,294.20	
Do	May 1, 1970	3,620.00	
S. E. Massengil Co	May 22, 1969	916.58	
Do	Sept. 25, 1969	118.62	
Do	Nov. 3, 1969	165.63	
Do	May 1, 1970	5,161.92	
Do	May 1, 1970	15,040.00	
E. Merck	June 15, 1960		1,426.79
Merck Sharp & Dohme	Jan. 22, 1965		905.54
Do	Jan. 8, 1968		144,970.00
Do	Mar. 14, 1969	13,460.00	
Do	June 23, 1970	28,540.00	
B. Niadas & Fils	Feb. 16, 1962	3,445.00	
Nisco Labs, Inc	May 17, 1966	5,000.00	
Olin Mathieson-P. Bauer	Apr. 22, 1965		263,000.00
Organon	Nov. 13, 1961		9,485.58
Pacific California Pharm	Mar. 24, 1966	4,000.00	
Pacific States Labs	Apr. 3, 1962	8,393.00	
Panmed Pharm	Jan. 12, 1962	690.00	
Do	July 23, 1963	9,602.80	
Parke, Davis & Co	Dec. 13, 1961	32,459.62	
Do	May 15, 1963		469.50
Do	Sept. 9, 1963	2,328.10	
Do	Nov. 12, 1968	1,300.88	
Do	Dec. 17, 1962		50,744.77
Do	Feb. 24, 1965	66.95	
Pfizer Corp	July 31, 1961		8,799.15
Do	July 31, 1961		20,760.00
Do	June 27, 1961		26,286.10
Do	Aug. 6, 1963	1,022.05	
Do	Aug. 20, 1963	2,900.91	
Do	Sept. 30, 1964	599.50	
Do	Oct. 7, 1964	434.94	
Do	Oct. 27, 1964	905.12	
Do	Dec. 30, 1964	1,824.00	
Do	June 13, 1961	4,160.00	
Do	Mar. 30, 1965	500.72	
Do	Apr. 29, 1965	52.80	
Do	Dec. 30, 1964	1,238.45	
Do	Dec. 30, 1964	864.00	
Do	July 28, 1967		24,686.12
Do	June 4, 1964		279.92
Do	July 29, 1967		220.00
Do	July 28, 1967		32,171.00
Richardson-Merrell	May 17, 1966		3,687.33
Roussel Corp	Sept. 27, 1963	3,003.01	
Do	Apr. 12, 1966	167,970.00	
Sandoz, Ltd	Aug. 14, 1962	1,082.40	
Scherer	Apr. 13, 1964		4,292.44

See footnote at end of table.

REFUND CLAIMS ASSERTED BY A.I.D. AGAINST PHARMACEUTICAL SUPPLIERS—Continued

TABLE I.—CLAIMS ON WHICH REFUNDS HAVE BEEN RECEIVED—Continued

Supplier	Date of claim	Nature of violation: Overpricing	Nature of violation: Other [1]
Schering Corp. Pan Am	Sept. 29, 1961		$16,729.45
Do	Mar. 7, 1967		75,525.02
Do	Mar. 31, 1967	$16,500.00	
Schering Trans Am	Mar. 31, 1967	997.50	
Schering Corp	Jan. 14, 1969	841.20	
Searle International	Sept. 15, 1960	3,600.00	
E. R. Squibb & Zons	July 24, 1967		7,717.44
Sterling Products	Sept. 26, 1961		26,692.05
Sterling Drug International	May 31, 1962		2,733.30
Do	May 31, 1962	1,078.00	
Supramar Chemicals	Nov. 15, 1967	3,063.80	
Do	Aug. 22, 1968	5,578.81	
Swan Chemical	Sept. 10, 1969	5,280.00	
Upjohn International	Mar. 22, 1962		14,621.45
Do	Mar. 22, 1962		5,516.38
Upjohn Overseas	June 16, 1959	3,865.00	
Warner Lambert	Jan. 27, 1965	7,646.21	
Total Refunds Received		919,191.05	1,080,868.51
Total claims (44 companies)		61	34

[1] Includes claims for recovery of ineligible payments made for benefit of the importer or other ineligible commissions and from suppliers who shipped ineligible commodities.

TABLE II.—CLAIMS REFERRED TO THE DEPARTMENT OF JUSTICE

Supplier	Date of claim	Nature of violation: Overpricing	Nature of violation: Other
Archifar Pharm	Jan. 27, 1964	$49,066.67	
Gedeon-Richter Ph	Mar. 8, 1968	802,617.44	
Malcolm-Gregg Co	Oct. 17, 1961	47,792.26	
Timothy Chew & Co	Jan. 31, 1961	31,364.00	
Roussel Corp	July 31, 1967	24,548.00	
Do	Feb. 23, 1967	208,680.00	
Do	June 30, 1967	56,000.00	
Do	Aug. 21, 1969	32,000.00	
Do	Aug. 21, 1969	180,613.75	
Do	Aug. 21, 1969	49,000.00	
Total referred to the Department of Justice		1,481,682.12	
Total claims (5 companies)		10	

TABLE III.—CURRENT CLAIMS UNPAID AS OF JULY 31, 1970

Supplier	Date of claim	Nature of violation: Overpricing	Nature of violation: Other
Alcon Labs	June 9, 1970	$2,217.60	
F & S International Ltd	Apr. 21, 1970	63,610.05	
Merck, Sharp & Dohme	May 20, 1970	239,189.00	
Wyeth Labs	July 1, 1970	218,572.87	
Total current claims		523,589.52	
Total claims (4 companies)		4	

SUMMARY

Grand total of pharmaceutical refund claims:
Dollars: $4,005,331.20.
Number of claims: 109.
Number of companies: 53.

EXAMPLES OF GUIDANCE AND INSTRUCTIONS REGARDING SELECTED PHARMACEUTICALS

1. Items requisitioned for use in a Technical Assistance project under which finished dosage form pharmaceuticals are eligible:

Trisulfapyrimidines and "Combiotic"

a. Advice regarding the triple sulfa item:

"Based on evaluation of these (sulfa) drugs by the National Academy of Science, National Research Council, the Food and Drug Administration is restricting the label claims of nine short-acting sulfonamides to a narrow range of conditions, such as uncomplicated urinary tract infections, trachoma, malaria resistant to antibiotics, and chanchroid. The sulfonamides affected include combinations of sulfadiazine and sulfamerazine, either with or without sulfamethazine. While the product is available and may be purchased from several U.S. sources, the information from FDA is offered in order that the proposed purchase may be reconsidered and evaluated in the light of the very recent information concerning its recommended use."

The product was procured following assurance to AID/W that the intended use included treatment of the conditions for which it was recommended by FDA.

b. Advice regarding the "Combiotic" item:

Mission was told that this pharmaceutical was dropped from the AID eligibility because of findings published by FDA and instructed to select a safer and more effective drug. This was done.

2. A commercial importer in Pakistan requested AID/W approval to purchase: dihydrostreptomycin for proposed production of "Entox" tablets which would be made by combining dihydrostreptomycin with iodochlorohydroxyquinoline.

We instructed our mission to inform the importer and the appropriate agency of the Government of Pakistan that dihydrostreptomycin is a potent antibiotic with potential for causing irreversible diminished hearing and that it is not usually approved for combination with other potent ingredients such as the one proposed. We also advised that the product the importer proposed to make would not be legal for sale in the U.S. under the FDA regulations and that a combination of the two ingredients is consequently ineligible for AID financing. Despite this advice, the Government of Pakistan confirmed its authorization to finance dihydrostreptomycin for the production of "Entox". 3. A commercial importer in Colombia requested AID/W approval to purchase, as separate items: streptomycin and potassium penicillin for combination in the production of veterinary injectables.

We instructed our Mission to inform the importer and appropriate agency of the Government of Colombia of the following labeling requirements for streptomycin and potassium penicillin G for veterinary injectables:

"Warning: The use of this drug must be discontinued 30 days before treated animals are slaughtered for food."

AID/W approval was withheld pending receipt of a statement from the Government of Colombia confirming its desire for AID financing for these two ingredients to produce the veterinary injectables. The proposed purchase was then approved for AID financing.

4. A commercial importer in Colombia requested AID/W approval to purchase: streptomycin for production of a fixed-combination consisting of streptomycin and "Leocillin".

We instructed our mission to inform the importer and the appropriate agency of the government that streptomycin is a potent antibiotic with potential for causing diminished hearing and that it is not usually approved for combination with other potent ingredients. "Leocillin", the other active ingredient with which the importer proposed to combine streptomycin, is a brand name for penicillin. Because fixed combinations of streptomycin with penicillin for injection needlessly subject patients to hazards of both drugs, FDA recommended their withdrawal from U.S. markets. Such combinations are therefore ineligible for AID financing. The Government of Colombia nevertheless advised that AID financing of streptomycin was desired.

5. A commercial importer in Chile requested AID/W approval to purchase: dihydrostreptomycin sulfate for processing into finished dosage form.

We requested our mission to obtain information as to the proposed finished products and the strengths, forms and other active ingredients which would

be combined with the dihydrostreptomycin in the finished product. Our mission learned that the dihydrostreptomycin was to be combined in 75 percent strength with chloramphenicol in 100 percent strength base to produce "Chlorostrep" capsules and liquid forms described as an antimicrobian in the treatment of intestinal disorders and also in post-operative treatment of the gastro-intestinal duct.

We then informed our mission that:

(a) penicillin in combination with dihydrostreptomycin was added to our ineligible list because of dihydrostreptomycin's potential for causing delayed but irreversible deafness.

(b) although chloramphenicol is a valuable drug for intestinal infections, such as typhoid and paratyphoid, it is recommended as a last resort rather than as a first line treatment for lesser gastrointestinal disorders, since chloramphenicol not uncommonly produces a reaction which induces serious and fatal blood dyscrasias.

(c) dihydrostreptomycin and chloramphenicol as a fixed-combination compound would not be eligible under AID financing and would be illegal for sale in the U.S.

Upon receipt of this information, the importer cancelled his request for AID financing of the dihydrostreptomycin.

6. A commercial importer in India requested AID/W approval to purchase: tyrothricin which he proposed to combine with benzocaine to troches (lozenges).

We instructed our mission to inform the importer and the appropriate agency of the Government of India that such combinations were outlawed for shipment in U.S. inter-state commerce in 1966, because of health hazards resulting from the combination of these ingredients in lozenges.

Continued failure of the Government of India to provide our mission with a statement either confirming or cancelling its approval for importation of the tyrothricin for the intended production resulted in a recommendation from our mission that the request for prior approval be denied.

Sometime later, another importer requested the same ingredient for production of the same finished product. Our mission was again instructed to provide the importer and the appropriate agency of the Indian Government with the identical information provided in the first instance. This time the additional information was provided that the only products approved containing tyrothricin are topical ointments and solutions and bandages. The Indian Government promptly advised that in view of the U.S. Food and Drug Administration views concerning the finished products, the importer's request should be disapproved.

SALES MOVING FROM PARENT TO SUBSIDIARY AND NUMBER OF SMALL BUSINESSES

A review of all applications for commodity eligibility for AID financing filed with the Agency during FY 1969 indicates that approximately 83 percent of the dollar value of drug sales under program loans in that year were made by U.S. parents selling to their foreign subsidiaries.

U.S. suppliers selling to non-affiliated importers include at least forty-five small businesses.

[Press release, June 20, 1969]

FORMER NEW HAMPSHIRE GOVERNOR JOINS AID AGENCY

Lane Dwinell, New Hampshire businessman and banker, and a former Governor of the State, was sworn in today (June 19, 1969) as Assistant Administrator of the Agency for International Development in charge of administration.

Dr. John A. Hannah, AID Administrator, officiated as the oath of office was administered. The ceremony was attended by Administration and Congressional officials.

A former Assistant Secretary of State for Administration during the Eisenhower administration, Dwinell was president of the Carter Churchill Company in Lebanon, N.H. for many years, and president and director of the National Bank of Lebanon from 1961 to 1968.

During his two terms as Governor of New Hampshire (1955–59), Dwinell served for two years as chairman of the Federal-State Relations Committee of the National Governors Conference.

Before his election as Governor, he had served as a member of the New Hampshire Board of Education and was successively elected to the State House of Representatives, where he served as Speaker for two years, and to the State Senate, where he was elected President.

Born in Newport, Vermont in 1906, Dwinell received a bachelor's degree from Dartmouth College in 1928 and a master's degree from Dartmouth's Amos Tuck School of Business Administration in 1929. He was employed by General Motors Corporation as a financial analyst from 1929 to 1935.

Dwinell has served as a trustee of the University of New Hampshire and of Dartmouth College. He was president of the New Hampshire Manufacturers Association in 1946-47 and a director of the National Association of Manufacturers from 1963 to 1966.

He is married to the former Elizabeth Cushman of New Bedford, Massachusetts.

DEPARTMENT OF STATE,
AGENCY FOR INTERNATIONAL DEVELOPMENT,
Washington, D.C., June 18, 1970.

HON. GAYLORD NELSON,
Chairman, Subcommittee on Monopoly,
Select Committee on Small Business,
U.S. Senate,
Washington, D.C.

DEAR MR. CHAIRMAN: Thank you for your letter of June 5 in which you request certain information concerning pharmaceutical purchases financed by AID.

Part of the information you ask for relates to total expenditures for drugs financed by AID in 1968 and 1969. We attach summary tabulations showing the dollar value of AID expenditures for bulk pharmaceuticals during each of the three successive six month periods commencing on July 1, 1968. The data are broken down into the geographic and product categories provided in our computer runs. We do not have available comparable data for the first six months of 1968. For your information, however, the total value of pharmaceuticals paid for out of AID funds in the latter period, including finished dosage items, was $8,740,309.00.

We are also preparing data which you require in connection with specific shipments of the items you list in your attachment as well as a number of other items purchased in large quantities with AID financing. For each designated item, the listings will show the U.S. supplier, the foreign importer and the FAS price paid. This information must, however, be developed for you from individual transaction records. We expect to complete our compilation and forward it to you before July 3.

We hope you will find this satisfactory.

Sincerely yours,

MATTHEW J. HARVEY,
Director, Congressional Liaison.

(Attachments (3).)

PROGRAM ASSISTANCE—AID COMMODITY EXPENDITURE ANALYSIS—WORLDWIDE SUMMARY

July 1, 1968, to Dec. 31, 1968

Schedule B commodity Code	Description	East Asia	Vietnam	Africa	NESA [1]	Latin America	Total
5120310	Sulfonamide drugs, in bulk	$36,270	—$177,540		$45,413	$21,636	—$74,220
5120315	Acetylsalicylic acid, bulk				6,667		6,667
5120325	Syn. org. med. chems., bulk, necessary	248,301	—17,429		697,679	1,875,342	2,803,893
5120730	Enzymes				21,252	301,222	322,474
5148000	Inorg. mdcnl. chems., necessary, bulk	1,614	49,002	756	6,941	40,513	98,828
5411010	Vitamin A, bulk	4,927			25,885	651	31,464
5411020	Vitamin B1, bulk				19,521	31	19,553
5411030	Vitamin B12, bulk				1,340	25,467	26,807
5411040	Vitamin B, Ex. B1 and B12, bulk	12,568			86,767	12,166	111,501
5411050	Vitamin C, bulk	26,772			64,226	8,031	99,030
5411060	Vitamins, bulk, necessary	3,547			79,359	6,303	89,209
5413010	Penicillin, bulk				149,755	180,190	329,945
5413025	Streptomycin, etc., bulk				622,280	9,957	632,237
5413035	Tetracycline, etc., bulk				242,878	234,670	477,549
5413040	Antibiotics, necessary, bulk		—23,434		34,174	217,518	228,259
5413045	do	117,237			163,442	939,710	1,220,390
5414000	Vegetable alkaloids and derivatives, bulk	138,764			574	27,973	167,312
5415010	Prednisolone, bulk				13,547	133,347	146,894
5415020	Hydrocortisone, bulk					6,686	6,686
5415040	Hormones, necessary, bulk	1,327			73,906	105,976	181,211
5416100	Glyosides and derivatives, bulk				1,590	2,968	4,558
5416230	Other animal products, medicinal				42,110	36,483	78,593
5416320	Vaccines, for human use					12,895	12,895
5416340	Bacterial products, veterinarian use					16,792	16,792
5417002	Medicinal chems., bulk, necessary				227,475	174,250	401,725
5419930	Pharmaceutical goods, necessary	7,867			4,935	27,776	40,579
	Total	599,194	—169,401	756	2,631,716	4,418,553	7,480,831

[1] Near East and South Asia.

PROGRAM ASSISTANCE—AID COMMODITY EXPENDITURE ANALYSIS—WORLDWIDE SUMMARY—Continued

Jan. 1, 1969, to June 30, 1969

Schedule B Commodity Code	Description	East Asia	Vietnam	Africa	NESA [1]	Latin America	Total
5120310	Sulfonamide drugs, in bulk	$19,298			$144,176	$25,671	$189,147
5120315	Acetylsalicylic acid, bulk				16,438		16,438
5120325	Sun. org. med. chems., bulk, necessary	46,302	$11,565		887,415	807,049	1,752,333
5120730	Enzymes				24,045	274,326	298,281
5148000	Inorg. mdcnl. chems., necessary, bulk		11,149		58,572	8,817	78,539
5411010	Vitamin A, bulk		−40,882		24,230	−16,174	−32,826
5411020	Vitamin B1, bulk				89,998		89,998
5411030	Vitamin B12, bulk				57,355	5,132	62,487
5411040	Vitamin B, ex. B1 and B12, bulk				150,832	31,254	182,087
5411050	Vitamin C, bulk				86,911	4,717	91,628
5411060	Vitamins, bulk, necessary		−67		41,261	1,267	42,462
5413010	Penicillin, bulk				383,588	249,312	632,901
5413025	Streptomycin, etc., bulk				775,096	49,141	824,238
5413035	Tetracycline, etc., bulk				432,196	215,760	647,957
5413040	Antibiotics, necessary, bulk				27	2,941	2,968
5413045	⊕	14,945			437,913	1,245,586	1,698,445
5414000	Vegetable alkaloids and derivatives, bulk	73,775			9,922	6,726	90,425
5415010	Prednisolone, bulk				196,749	126,214	322,963
5415020	Hydrocortisone, bulk				2,325	9,866	12,191
5415040	Hormones, necessary, bulk	14,213	−2,070		90,149	50,964	153,256
5416100	Glyosides and derivatives, bulk				6,767		6,767
5416230	Other animal products, medicinal				9,289	19,920	29,209
5416320	Vaccines, for human use	980	−2,663			2,062	379
5416330	Ferments, excl. yeasts					−24,555	−24,555
5416340	Bacterial products, veterinary use					18,598	18,598
5417002	Medicinal chems., blk, necessary				687,706	210,438	898,144
5419930	Pharmaceutical goods, necessary	12,018			48,984	2,467	63,470
	Total	181,531	−22,968	0	4,661,944	3,327,409	8,147,930

PROGRAM ASSISTANCE—AID COMMODITY EXPENDITURE ANALYSIS—WORLDWIDE SUMMARY—Continued

July 1, 1969, to Dec. 31, 1969

5120310	Sulfonamide drugs, in bulk	—$5,280	—$16,500		$34,334	$9,853	$22,408
5120315	Acetylsalicylic acid, bulk				42,625		42,625
5120325	Syn. org. med. chems., bulk, necessary		26,635		1,212,239	1,490,912	2,729,786
5120730	Enzymes				23,926	229,324	253,251
5148000	Inorg. mdcnl. chems., necessary, bulk				11,030	5,033	16,063
5411010	Vitamin A, bulk				30,161	7,246	37,407
5411020	Vitamin B_1, bulk				51,085	2,874	53,960
5411030	Vitamin B_{12}, bulk				28,487	11,104	39,592
5411040	Vitamin B, ex. B^1 and B_{12}, bulk				119,153	9,338	128,491
5411050	Vitamin C, bulk				27,397	7,339	34,736
5411060	Vitamins, bulk, necessary				6,990	1,260	8,250
5413010	Penicillin, bulk				125,031	180,478	305,510
5413025	Streptomycin, etc., bulk				165,642	12,627	178,270
5413030	Dihydrostreptomycin, bulk					20,325	20,325
5413035	Tetracycline, etc., bulk				291,334	123,998	415,333
5413040	Antibiotics, necessary, bulk				16,158		16,158
5413045	do				422,615	572,264	994,880
5414000	Vegetable alkaloids and derivatives, bulk				648	3,305	3,953
5415010	Prednisolone, bulk				130,323	125,866	256,190
5415020	Hydrocortisone, bulk				10,211	2,820	13,031
5415030	Cortisone, and ACTH, bulk				—153		—153
5415040	Hormones, necessary, bulk				117,449	73,594	191,043
5416230	Other animal products, medicinal				22,589	7,429	30,018
5416320	Vaccines, for human use	234				4,907	5,141
5416330	Ferments, excl. yeasts					4,396	4,396
5416340	Bacterial prods. veterinary use					7,909	7,909
5417002	Medicinal chems., bulk, necessary				439,437	235,639	675,076
5419930	Pharmaceutical goods, necessary	51,111				304,405	309,517
	Total	65	10,135	0	3,328,711	3,454,245	6,793,166

[1] Near East and South Asia.

U.S. SENATE,
SELECT COMMITTEE ON SMALL BUSINESS,
Washington, D.C., September 24, 1970.

HON. LANE DWINELL,
Assistant Administrator,
AID, Department of State,
Washington, D.C.

DEAR GOVERNOR DWINELL: During the course of the hearing on AID's financing of drugs to foreign countries under the Commercial Import Program, you stated that your agency can finance transactions only at the prevailing market price in the United States.

It was pointed out, however, that there were large differences in prices of the same drugs sold to different countries. For example, American Cyanamid charged its Pakistan subsidiary $270/kg. for tetracycline at about the same time it was charging its Colombia subsidiary $100/kg. Wyeth was charging its Colombia subsidiary $800/kg. for oxazepam while charging its Chilean subsidiary $186.50 for the same thing. American Cyanamid charged its Pakistan subsidiary almost $14,000/kg. for triamcinolone, while charging its Indian subsidiary less than $8,000/kg. for the same drug.

It would be greatly appreciated if you would let me know which of these prices you consider the prevailing market price, on what basis you make this determination, and also the method of securing a market price if the drug is under patent and the product can be secured from only one firm.

An early reply will be appreciated.

Sincerely yours,

GAYLORD NELSON,
Chairman.

DEPARTMENT OF STATE,
AGENCY FOR INTERNATIONAL DEVELOPMENT,
Washington, D.C., October 13, 1970.

HON. GAYLORD NELSON,
Chairman, Subcommittee on Monopoly,
Select Committee on Small Business,
U.S. Senate,
Washington, D.C.

DEAR MR. CHAIRMAN: Thank you for your letter of September 24, 1970 concerning the prices charged for pharmaceutical ingredients under the AID commercial import program. You ask that we answer some further questions which relate to our explanation in the August 6 hearing of AID's maximum price requirements.

You list the following different prices which were charged under AID financing in sales of three products by U.S. pharmaceutical suppliers to their importing affiliates:

Product and U.S. supplier	Importing country	Price per kilo
Tetracycline:		
American Cyanamid	Pakistan	$270.00
Do	Colombia	100.00
Oxazepam:		
Wyeth	do	800.00
Do	Chile	187.50
Triamcinolone:		
American Cyanamid	Pakistan	14,000.00
Do	India	8,000.00

You specifically ask that we let you know which of these prices we consider the prevailing market price, the basis upon which we make this determination, and the method of securing a market price if the drug is under patent and the product can be secured from only one firm. We stated at the hearing that our pricing rules, in brief, provide "that a supplier's price may not exceed the prevailing export market price for comparable sales of all exporters nor may it exceed the price generally charged by the seller in his comparable sales". The

transactions listed above either have been or are being reviewed on a post audit basis for conformance with these pricing rules.

In the case of Oxazepam our post audit has been completed. Laboratorios Wyeth, Inc. were requested under AID Bill for Collection No. 40–514–36828 dated June 30, 1970 to refund to AID overcharges on this product of $31,680.00 plus interest from the date of overpayment. AID informed Wyeth, in connection with the Bill that the maximum price eligible for AID financing was $320.00 per kilo and that this price constituted the prevailing export market price. Our examination included all export sales of Oxazepam by Wyeth. The prevailing export market price was determined based on review of information for all Oxazepam export transactions as to the FAS prices charged and quantities sold in the years 1967 and 1968. The data include 2,386 kilos purchased by affiliated and non-affiliated importers in eleven countries. We consider that the AID-financed price exceeds the prevailing export market price if a preponderance of comparable AID and non-AID sales are at prices lower than the price charged in the AID-financed transaction. In this case, we found that $320.00, the prevailing market price, was also the price to a non-affiliated buyer in a developed nation, not receiving AID assistance. You will also note that this is a patented, sole source product which can be secured only from Wyeth and we have, accordingly, reviewed and made our determination based upon information obtained for this product only.

While the Agency post audits all AID financed pharmaceutical transactions, the process is time consuming and in the case of tetracycline and Triamcinolone shipments by American Cyanamid, we do not as yet have data which permit us to know the prevailing market price. These data are being collected and when our information is complete we shall apply the standards described above for Wyeth's Oxazepam to these products. At this point, we can only observe that a discrepancy between prices in AID sales does not necessarily establish the actual existence of a price violation. We must examine not only all the sales of the product but the factors which relate to comparability of sales. In the case of tetracycline we will be dealing with a product sold by a number of U.S. exporters. Our examination and determination will include all export sales and will apply to AID financed prices charged by all companies. Our Triamcinolone review, on the other hand, will be limited to the patent holder and his licensees.

We hope you will find this information satisfactory. When we have completed our review of the Triamcinolone and tetracycline transactions we will notify you of the results.

Sincerely,

LANE DWINELL.

DEPARTMENT OF STATE,
AGENCY FOR INTERNATIONAL DEVELOPMENT,
Washington, D.C., November 13, 1970.

HON. GAYLORD NELSON,
Chairman, Monopoly Subcommittee,
Select Committee on Small Business,
U.S. Senate,
Washington, D.C.

DEAR MR. CHAIRMAN: In accordance with my letter of September 8, 1970, I am pleased to transmit the balance of the information prepared in response to the request of the Subcommittee on Monopoly of the Select Committee on Small Business during the hearings on August 6, 1970. Specifically, the information transmitted herewith in duplicate covers the following:

Pages 7346–7347

"Lowest domestic price and lowest export price from the U.S. at which drugs listed on the 4-sheet summary are sold."

Data provided cover prices on selected pharmaceuticals as reported to AID by U.S. manufacturers named on the attached listing.

Page 7351

"Price comparisons in importing countries of raw drugs and of finished products."

The Subcommittee requested information relating to the prices in importing countries of bulk raw drugs financed by AID and of finished products manu-

factured from such bulk raw drugs. The attached table lists both the unit price to the pharmacists and to the consumer for finished dosage forms manufactured from 23 selected AID financed ingredients. I have also attached for your ready comparison, a copy of a table summarizing information previously given to the Subcommittee indicating prices for the bulk ingredients financed by AID.

With respect to page 7347, I had transmitted on September 8 a list of small business companies that supplied pharmaceuticals under AID financing during fiscal years 1968 and 1969. I now find that three of the companies included in that list do not qualify under our definition of "small business" firms, i.e., that (a) it is not dominant in its field of operations and, with its affiliates, employs fewer than 500 employees, or (b) is certified as a small business concern by the Small Business Administration. The firms to be deleted are:

1. Carter Wallace N.S. Inc.
2. International Chemical Corporation.
3. A. H. Robbins Inter-American Corporation.

Please let me know if I can be of further assistance.

Sincerely yours,

LANE DWINELL.

(Enclosures.)

AID FINANCED PRICES FOR CERTAIN PHARMACEUTICAL INGREDIENTS (1968-69)

Product	Country	Unit price per kilo
		Kilogram
Ampicillin trihydrate	Colombia	$420.00
Benzathazine	Chile	215.75
Benzathazine penicillin	Pakistan	45.60
Benzathazine bicillin	Colombia	160.00
Penicillin-G	Chile	294.50
Chlorcyclizine hydrochloride	Turkey	155.00
Chlormethazone	Brazil	70.00
Do	Colombia	70.00
Chlordiazepoxide granulate	Pakistan	245.00
Cyproheptadine hydrochloride	do	1,600.00
Do	Colombia	1,800.00
Do	India	1,060.00
Dexamethesone glucocorticoid	Pakistan	27.50
Do	Colombia	27.50
Dexchlorpheniramine maleate	do	650.00
Diazepam granulate	Pakistan	99.20
Doxycycline	Pakistan	1,750.00
Do	Colombia	2,250.00
Ethoheptazine citrate	do	150.00
Mothylcycline hydrochloride	Pakistan	350.00
Do	Colombia	450.00
Nalidixic acid	Brazil	94.00
Do	Colombia	94.00
Oxazepam	Chile	187.50
Do	Colombia	800.00
Chlortetracycline	do	100.00
Demethylchlortetracycline	Pakistan	405.00
Do	Colombia	250.00
Oxytetracycline	Pakistan	100.00
Do	Colombia	100.00
Rolitetracycline	do	550.00
Tetracycline hydrochloride	Pakistan	270.00
Do	Colombia	150.00
		Gram
Methylprednisolone	do	5.10
Triamcinolone (glucocorticoid)	Brazil	8.00
Do	Pakistan	13.93
Do	Colombia	12.00
Do	India	7.96
Triamcinolone acetate	Pakistan	32.92
Do	Colombia	36.00
Do	India	7.96
Trihexyphendyl hydrochloride	Brazil	.30
Do	Pakistan	1.70
Do	Colombia	1.80

FINISHED DOSAGE PRICES—PHARMACEUTICALS MANUFACTURED FROM SELECTED AID FINANCED INGREDIENTS

Importer and country	Finished product: Generic name	Finished product: Trade name	Dosage form	Strength	Unit packaging to pharmacist	Current unit price to pharmacist	Unit packaging to consumer	Current unit price to consumer
Bristol, Colombia	Ampicillin	Pentraxyl	Capsules	250 mg	12 per bottle	$2.992	12 per bottle	$3.990.
Do	do	do	Vial	do	250 mg. vial	$0.538	250 mg. vial	$0.718.
Do	do	do	Bottle per 60 cc	do	60 cc bottle	$1.69	60 cc bottle	$2.254.
Wyeth, Chile	Benzathazine		Vial	1,200,000 units	Vial	$0.59 vial	Vial	$0.71.
Do	do		do	2,400,000 vial	do	$0.96 vial	do	$1.17 vial.
Wyeth, Pakistan	Benzathazine pencillin	Penidure, LA	Injections	600,000 units	1 cc vial	$0.79 vial	1 cc vial	$0.94 vial.
Do	do	do	do	1,200,000 units	do	$1.01 vial	do	$1.18 vial.
Wyeth, Colombia	Benzathazine bicillin	Benzetacil, LA	Bottle	600,000 units	Bottle	$0.361 bottle	Bottle	$0.536 bottle.
Do	do	Benzetacil fortified	do	300,000 units	do	$0.342 bottle	do	$0.493 vial.
Do	do	Benzetacil, LA	do	2,400,000 units	do	$0.999 bottle	do	$1 440 bottle.
Do	do	Benzetacil 6–3–3	do	600,000 units	do	$0.566 bottle	do	$0.816.
Do	do	Benzetacil, LA	do	1,200,000 units	do	do	do	do.
Wyeth, Chile	Penicillin, G	Bicillin	Vial	600,000 units	Vial	$0.29 vial	Vial	$0.34 vial.
Abbott, Turkey	Chlorcyclizine HCL	Diparalene	Tablet	50 mg	25 per tube	$0.40	25 per tube	$0.55.
Do (Winthrop)	do	do	Cream	6 percent	30 gr. tube	$0.3033	30 gr. tube	$0.4166.
Sydney Ross, Brazil	Chlormethazone	Fenarol	Tablet	200 mg	12 tabs per box	$0.33 box	12 tabs per box	$0.48 box.
Do	do	do	do	do	48 tabs per box	$1.54 box	48 tabs per box	$2.06 box.
Do	do	Beserol	do	100 mg	20 tabs per box	$0.89 box	20 tabs per box	$1.20 box.
Do	do	do	do	do	100 tabs per box	$4.43 box	100 tabs per box	$5.69 box.
Sydney Ross, Colombia	do	Fenarol	do	200 mg	48 tabs per box	$0.998 box	48 tabs per box	$1.536 box.
Do	do	Beserol	do	100 mg	100 tabs per box	$3.12 box	2 tab. strip	$0.096 strip.
Merck, Pakistan	Chlorodiazepoxide granulate.	Librium	Tablet	5 mg	3 per bottle	$ .83 bottle	3 per bottle	$1.04 bottle.
Do	do	do	do	10 mg	25 per bottle	$1.08 bottle	25 per bottle	$1.35 bottle.
Do	Cyproheptadine HCL	Periactin	do	4 mg	20 per bottle	$0.71 bottle	20 per bottle	$0.83 bottle.
Do	do	do	do	do	100 per bottle	$2.74 bottle	100 per bottle	$3.23 bottle.
Do	do	do	Sirup	2 mg in 5 ml	114 ml. bottle	$0.86 bottle	114 ml. bottle	$1.02 bottle.
Do	do	do	do	do	456 ml. bottle	$2.95 bottle	456 ml. bottle	$3.47 bottle.
Merck, India	Cyproheptadine HCL	do	Tablet	4 mg	10 x 10's 100 per bottle.	$2.34 bottle	10 x 10's	$2.66 bottle.
Do	do	do	Sirup	2 mg. in 5 ml	114 ml. bottle	$0.73 bottle	114 ml. bottle	$0.83 bottle.
Do	do	do	do	do	228 ml. bottle	$1.31 bottle	228 ml. bottle	$1.57 bottle.
Do	Cyproheptadine HCL and Dexamethasone.	Peridecadexa+Cypro	Tablet	4 mg.–.25 mg.–4 mg.	10 x 10's 100 per bottle.	$4.10 bottle	10 x 10's	$4.66 bottle.
Do	do	do	Elixir (sirup)	2 mg. in 5 ml. .25 mg.–2 mg.	57 ml. bottle	$0.41 bottle	57 ml. bottle	$0.46 bottle.

FINISHED DOSAGE PRICES—PHARMACEUTICALS MANUFACTURED FROM SELECTED AID FINANCED INGREDIENTS—Continued

Importer and country	Finished product: Generic name	Finished product: Trade name	Dosage form	Strength	Unit packaging to pharmacist	Current unit price to pharmacist	Unit packaging to consumer	Current unit price to consumer
Merck, Columbia	Cyproheptadine HCL	Periactin	Tablet	4 mg	20 per bottle	$0.822 bottle	20 per bottle	$1.174 bottle.
Do	do	do	Sirup	0.4 mg. cc	118 cc. bottle	$0.642 bottle	118 cc. bottle	$0.918 bottle.
Do	do	Periactin, Vit. B and C	Tablet	0.4 mg	24 per box	$1.112 box	24 per box	$1.60 box.
Do	do	do	Sirup	0.8 mg x c3	118 cc. bottle	$1.456 bottle	118 cc. bottle	$2.081 bottle.
Do	do	Peridex Elixir	do	0.4 mg. x c3	do	$1.83 bottle	do	$2.614 bottle.
Do	do	do	Tablet	0.4 mg	20 per bottle	$1.419 bottle	20 per bottle	$2.027 bottle.
Merck, Pakistan	Dexamethasone Gluco-carticoid.	Decadron	do	0.5 mg	10 per bottle	$0.58 bottle	10 per bottle	$0.69 bottle.
Do	do	do	do	do	30 per bottle	$1.59 bottle	30 per bottle	$1.87 bottle.
Do	do	do	do	do	100 per bottle	$4.76 bottle	100 per bottle	$5.62 bottle.
Do	Dexamethasone gluco-carticoid sodium phos-phate.	do	Injection	4 mg. per ml	2 ml. vial	$1.99 vial	2 ml. vial	$2.34 vial.
Do	do	do	Solution	1 mg. per ml	2.5 ml. vial	$.705 vial	2.5 ml. vial	$0.88 vial.
Do	do	do	Cream	1 mg. per gm	5 mg. tube	$0..75 tube	5 mg. tube	$0.88 tube.
Merck, Columbia	Dexamethasone, not steril	do	Sirup	0.1 mg. x cc	118 cc. bottle	$1.71 bottle	118 cc. bottle	$2.443 bottle.
Do	do	Decagesic	Tablet	0.25 mg	25 per bottle	$1.083 bottle	25 per bottle	$1.547 bottle.
Do	do	Peridex	Sirup	0.05 mg. x cc	118 cc. bottle	do	118 cc. bottle	$2.614 bottle.
Do	do	do	Tablet	0.25 mg	20 per bottle	$1.419 bottle	20 per bottle	$2.027 bottle.
Do	Dexamethasone phosphate	Decadron	Injection	4 mg	2 cc. ampule	$1.718 ampule	2 cc. ampule	$2.454 ampule.
Do	do	do	Drops	1 mg. x cc	2.5 cc. bottle	$0.829 bottle	2.5 cc. bottle	$1.184 bottle.
(Schering) Undra, Columbia	Dexchlorpheniramine	Polasarmine	Sirup-Expect	48 mg	120 cc bottle	$0.576 bottle	120 cc bottle	$0.857 bottle.
Do	do	do	Ampule	5 mg	1 cc ampule	$0.216 ampule	1 cc ampule	$0.320 ampule.
Do	do	Polaronil	Tablet	2 mg	20 per bottle	$0.828 bottle	20 per bottle	$1.227 bottle.
Do	do	Coricidine	Capsule	do	10 per bottle	$0.396 bottle	10 per bottle	$0.587 bottle.
Do	do	do	Sirup	24 mg	120 cc bottle	$0.468 bottle	120 cc bottle	$0.693 bottle.
Do	do	Celestaune F	do	48 mg	do	$1.404 bottle	do	$2.08 bottle.
Merck, Pakistan	Diazepam granulate	Valium	Tablet	2 mg	30 per bottle	$0.81 bottle	30 per bottle	$1.02 bottle.
Do	do	do	do	5 mg	25 per bottle	$1.23 bottle	25 per bottle	$1.54 bottle.
Pfizer, Pakistan	Doxycycline	Vibramycio	Capsule	100 mg	3 per bottle	$2.07 bottle	3 per bottle	$2.45 bottle.
Do	do	do	do	do	5 per bottle	$3.15 bottle	5 per bottle	$3.72 bottle.
Do	do	do	Sirup	50 mg. per 5 ml	20 ml. bottle	$1.53 bottle	20 ml. bottle	$1.81 bottle.
Pfizer, Colombia	do	do	do	100 mg	5 per bottle	$2.336 bottle	5 per bottle	$3.201 bottle.
Do	do	do	do	300 cc per 300 mg	30 cc bottle	$1.713 bottle	30 cc bottle	$2.347 bottle.
Wyeth, Colombia	Ethoheptazine citrate	Equagesic Zacticin	Tablet	75 mg	20 per box	$0.622 box	20 per box	$0.896 box.
Do	do	Zacticin	do	do	do	$0.263 box	do	$0.379 box.
Pfizer, Pakistan	Methacycline HCL	Rondomycin	Capsule	150 mg	8 per bottle	$1.64 bottle	8 per bottle	$1.95 bottle.
Do	do	do	do	do	16 per bottle	$3.01 bottle	16 per bottle	$3.54 bottle.
Do	do	do	do	300 mg	4 per bottle	$1.64 bottle	4 per bottle	$1.95 bottle.
Do	Methacycline	do	do	do	8 per bottle	$3.01 bottle	8 per bottle	$3.54 bottle.
Do	do	do	Sirup	5.75 mg per ml	60 ml bottle	$1.50 bottle	60 ml. bottle	$1.77 bottle.

Pfizer, Colombia	do	do	Capsule	300 mg	8 per bottle	$1.947 bottle	8 per bottle	$2.667 bottle.
Do	do	do	Sirup	900 mg	60 cc bottle	$1.045 bottle	60 cc bottle	$1.432 bottle.
Upjohn, Colombia	Methylprednisone	Cordex F.Y	Tablet	1.5 mg	24 per bottle	$0.721 bottle	24 per bottle	$1.046 bottle.
Do	do	do	do	4 mg	30 per bottle	$2.871 bottle	30 per bottle	$4.161 bottle.
(Winthrop)								
Sydney Ross, Brazil	Nalidixic acid, standard	Wintomylon	Tablet	500 mg	28 per box	$3.37 box	28 per box	$4.32 box.
Do	do	do	do	do	56 per box	$6.72 box	56 per box	$8.64 box.
Do	Nalidixic acid, micropulverized.	Wintomylon suspension	Liquid	250 mg per 5 cc	60cc bottle	$1.32 bottle	60 cc bottle	$1.70 bottle.
Do	do	do	do	do	120 cc bottle	$2.65 bottle	120 cc bottle	$3.40 bottle.
Sydney Ross, Colombia	Nalidixic acid	Wintomylon	Tablet	500 mg	24 per box	$2.73 box	24 per box	$4.201 box.
Wyeth, Chile	Oxazepam	Serax	do	10 mg	30 per box	$0.74 box	30 per box	$1.03 box.
Do	do	do	do	15 mg	do	$0.87 box	do	$1.22 box.
Do	do	do	do	30 mg	do	$1.30 box	do	$1.82 box.
Wyeth, Colombia	do	Serapax	do	15 mg	30 per bottle	$0.858 bottle	30 per bottle	$1.238 bottle.
Do	do	do	do	30 mg	do	$1.839 bottle	do	$2.651 bottle.
Cyanamid, Colombia	Chlortetracycline	Aureomicina	Capsule	250 mg	8 per box	$0.779 box	8 per box	$1.094 box.
Do	do	do	do	do	16 per box	$1.512 box	16 per box	$2.123 box.
Do	do	do	Bottle	50 mg. per 3 gr	36 gr. bottle	$0.597 bottle	36 gr. bottle	$0.838 bottle.
Do	do	Aureomicina Unguento Afta (ears & eyes).	Tube	1 percent	3.5 gr. tube	$0.82 tube	3.5 gr. tube	$0.115 tube.
Do	do	Aureomicina Topico	do	3 percent	14.2 gr. tube	$0.24 tube	14.2 gr. tube	$0.336 tube.
Do	do	Aureamicina	Tablet	15 mg	100 per box	$1.049 box	100 per box	$1.444 box.
Do	Chlortetracycline (micronized).	Aureomicina (veterinary)	Powder	25 gr. per lb	5 lb. can	$22.582 can	5 lb. can	$30.109 can.
Cyanamid, Pakistan	Demethylchlortetracycline	Ledermycin	Capsule	150 mg	8 per bottle	$1.67 bottle	8 per bottle	$1.97 bottle.
Do	do	do	do	do	16 per bottle	$3.05 bottle	16 per bottle	$3.58 bottle.
Do	do	do	do	300 mg	8 per bottle	do	8 per bottle	do.
Do	do	Lederstatin	do	150 mg	do	$1.69 bottle	do	$2.00 bottle.
Do	do	do	Sirup	75 mg. per 5 cc	20 oz. bottle	$1.61 bottle	2 fl. oz. bottle	$1.90 bottle.
Cyanamid, Colombia	do	Ledermycin	Capsule	300 mg	4 per box	$0.935 box	4 per box	$1.312 box.
Do	do	do	do	do	8 per box	$10.76 box	8 per box	$15.103 box.
Do	do	do	do	do	50 per box	$1.813 box	50 per box	$2.545 box.
Do	do	do	Drops	60 mg. per 1 cc	10 cc bottle	$0.614 bottle	10 cc bottle	$0.862 bottle.
Do	do	Ledermycin Pediatric	Injection	900 mg	10 cc bottle	$1.326 bottle	60 cc bottle	$1.862 bottle.
Pfizer, Pakistan	Oxytetracycline	Terramycin	Capsule	250 mg	8 per bottle	$1.49 bottle	8 per bottle	$1.77 bottle.
Do	do	do	do	250 mg	16 per bottle	$2.74 bottle	16 per bottle	$2.23 bottle.
Do	do	do	Sirup	125 mg. per 5 ml	60 ml. bottle	$1.44 bottle	60 ml. bottle	$1.70 bottle.
Do	do	do	Tablet	100 mg	10 per bottle	$1.71 bottle	10 per bottle	$2.02 bottle.
Do	do	do	Injection	250 mg. per 2 ml	2 ml. ampule	$0.78 ampule	2 ml. ampule	$1.02 ampule.
Do	do	do	Ointment	N.G	6.5 gm. tube	$0.39 tube	6.5 gr. tube	$0.52 tube.
Pfizer, Colombia	do	do	Ampule	50 mg	1 cc. ampule	$0.163 ampule	1 cc. ampule	$0.224 ampule.
Do	do	do	do	100 mg	2 cc. ampule	$0.23 ampule	2 cc. ampule	$0.315 ampule.
Do	do	do	Capsule	250 mg	8 per bottle	$0.88 bottle	8 per bottle	$1.206 bottle.
Do	do	do	do	do	16 per bottle	$1.713 bottle	16 per bottle	$2.347 bottle.
Do	do	do	do	125 mg	do	$1.402 bottle	do	$1.921 bottle.
Do	do	Terrabron	Sirup	3,000 mg	60 cc. bottle	$1.791 bottle	6 cc. bottle	$2.454 bottle.
Do	do	Terra-Cortril	Ointment—Ophthalmic.	175 mg	3.5 gr. tube	$ .416 tube	3.5 gr. tube	$0.571 tube.
Do	do	do	Ointment—Topical	150 mg	5 gr. tube	$0.623 tube	5 gr. tube	$0.854 tube.

FINISHED DOSAGE PRICES—PHARMACEUTICALS MANUFACTURED FROM SELECTED AID FINANCED INGREDIENTS—Continued

Importer and country	Finished product: Generic name	Finished product: Trade name	Dosage form	Strength	Unit packaging to pharmacist	Current unit price to pharmacist	Unit packaging to consumer	Current unit price to consumer
Bristol, Colombia	Politetracycline	Bristacin A I.v	Vials	150 mg	150 mg. vial	$0.388 vial	150 mg. vial	$0.517 vial.
Do	do	do	do	350 mg	350 mg. vial	$0.806 vial	350 mg. vial	$1.075 vial.
Do	do	do	do	do	do	$0.836 vial	do	$1.115 vial.
Cyanamid, Pakistan	Tetracycline HCL	Achromycin	Capsule	250 mg	8 per bottle	$1.35 bottle	8 per bottle	$1.59 bottle.
Do	do	do	do	do	16 per bottle	$2.19 bottle	16 per bottle	$2.58 bottle.
Bristol, Pakistan	Tetracycline HCL phosphate complex	Tetrex	do	do	8 per bottle	$1.62 bottle	8 per bottle	$1.91 bottle.
Cyanamid, Colombia	Tetracycline HCL	Achromycin	do	do	100 per bottle	$10.072 bottle	100 per bottle	$14.137 bottle.
Do	do	Achromycin Pediatric	Drops	100 mg. per cc	10 cc. bottle	$0.471 bottle	10 cc. bottle	$0.662 bottle.
Do	do	Achromycin	Bottle	50 mg. per 3 gr	36 gr. bottle	$0.737 bottle	36 gr. bottle	$1.035 bottle.
Do	do	Achromycin Unguento (ears and eyes)	Tube	1 percent	3.5 tube (gr.)	$0.091 tube	13.5 tube	$0.128 tube.
Do	do	Achromycin Topical	do	3 percent	14.2 gr. tube	$0.266 tube	14.2 gr. tube	$0.373 tube.
Do	do	Achromycin Troches	Tablet	15 mg	100 per box	$1.049 box	100 per box	$1.472 box.
Cyanamid, Brazil	Triamcinolone glucocorticoid	Ledercort	Tablet	4 mg	10 per vial	$1.66 vial	10 per vial	$2.25 vial.
Do	do	do	do	8 mg	5 per vial	$1.51 vial	5 per vial	$2.04 vial.
Cyanamid, Pakistan	do	do	do	4 mg	10 per bottle	$2.19 bottle	10 per bottle	$2.58 bottle.
Do	do	do	do	do	30 per bottle	$5.91 bottle	30 per bottle	$6.95 bottle.
Do	do	Ledercort D	Cream	0.10 percent	15 gr. tube	$0.56 tube	15 gr. tube	$0.66 tube.
Cyanamid, Colombia	Triamcinolone alcohol	Ledercort	Tablet	4 mg	10 per bottle	$1.102 bottle	10 per bottle	$1.547 bottle.
Do	do	do	do	8 mg	do	$1.277 bottle	do	$1.792 bottle.
Do	Triamcinolone acetonide	Ledercort D	Ointment	0.01 percent	28.4 gr. tube	$0.619 tube	28.4 gr. tube	$0.87 tube.
Do	do	do	do	do	56.8 gr. tube	$1.083 tube	56.8 gr. tube	$1.52 tube.
Cyanamid, India	Triamcinolone alcohol	Ledercort	Tablet	4 mg	10 per bottle	$1.02 bottle	10 per bottle	$1.17 bottle.
Do	Triamcinolone Diacetate	Ledercort Diacetate	Pacentecal	25 mg. per ml	1 ml. vial	$1.05 vial	1 ml. vial	$1.20 vial.
Do	Triamcinolone acetonide	Ledercort with Neomycin	Cream	0.1 percent	5 gr. tube	$0.39 tube	5 gr. tube	$0.44 tube.
Do	do	Ledercort topical	Ointment	do	do	$0.37 tube	do	$0.41 tube.
Cyanamid, Brazil	Trihexypherdyl Hydrochloride.	Artane	Tablet	2 mg	100 per vial	$0.64 vial	100 per vial	$0.86 vial.
Do	do	do	do	5 mg	do	$1.34 vial	do	$1.81 vial.
Cyanamid, Pakistan	do	Pacitane	do	2 mg	100 per bottle	$1.73 bottle	100 per bottle	$2.04 bottle.
Cyanamid, Colombia	do	Artane	do	do	do	$1.273 bottle	do	$1.787 bottle.

Source: USAID mission in importing countries.

(Upon the direction of the chairman, information pertaining to the subject of the hearings is included:)

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PHARMACEUTICAL COMPANIES IN MAHARASHTRA—FINANCIAL STRUCTURE AND OWNERSHIP

(By R. K. Hazari and H. G. Lakhani)

This paper analyses the balance sheets, profit and loss accounts, shareholders' lists and directors' particulars of 88 pharmaceutical private limited companies registered up to the end of March 1962 in Maharashtra under the Companies Act. The authors' purpose is to explore and present facts relating to a small but qualitatively important part of the corporate sector.

The data presented here reveal that most of the pharmaceutical manufacturing business in Maharashtra is under foreign control, mainly American, British and Swiss. In 1964 the wholly foreign owned companies were earning a cash profit (profit after tax but before depreciation) which would bring their investment back within two years. Foreign majority companies were taking a little more than four years to get back their investment.

[This study was completed as the first phase of a research project on Financial Structure and Ownership of Private Limited Companies in Maharashtra at the Centre of Advanced Study in Economics, University of Bombay. Indu Kale, V D Lall, and K K Subramanian helped in the tabulation of data. Thanks are due to the Government of India, Department of Company Affairs, for permission to inspect the necessary documents with the Registrar of Companies, Maharashtra State, Bombay.]

Most of the pharmaceutical companies in India are registered in Maharashtra State, almost all of them in Bombay City, and most of these, in turn, are private limited companies. Some of the larger and foreign controlled among these have recently converted themselves into public companies and have offered their shares to the public; this development took place in most cases after 1964, the cut-off year for this study.

This paper analyses the balance sheets, profit and loss accounts, shareholders' lists and directors' particulars of 88 pharmaceutical private limited companies registered upto the end of March 1962 in Maharashtra under the Companies Act. Its purpose is to explore and present facts relating to a small but qualitatively important part of the corporate sector. No attempt is made to arrive at policy conclusions regarding the pharmaceutical industry or the role of foreign capital in it. While following the analysis of data, it should be remembered that several leading pharmaceutical companies carry on non-pharmaceutical manufacturing and/or trading activities also, e g, toilet products, dyestuffs, chemicals, etc. It is not possible to isolate data for these activities from pharmaceutical business.

FOREIGN CONTROL PREDOMINATES

Of these 88 companies in 1964, 9 wholly foreign owned companies accounted for 35 per cent of total assets and 42 per cent of sales (net of excise). Another 15 companies with foreign majority ownership had 50 per cent of total assets and 40 per cent of sales. Thus, 24 foreign controlled companies had 85 per cent of total assets and 82 per cent of total sales (Table 1).

There were, in 1964, 5 Indian majority companies (including one fifty-fifty company) which accounted for 9 per cent of total assets and 11 per cent of sales. In other words, the 29 companies which had foreign control or financial participation accounted for roughly 93 per cent of the assets and turnover of the 88 companies.

Of the 59 wholly Indian owned companies, 39 had accumulated losses. The remaining 20 companies accounted for 5 per cent of total assets and 6 per cent of sales.

SIZE DISTRIBUTION

There is a comparable skewness in the size distribution of companies (Table 2). Nearly all companies with foreign control or participation have assets exceeding Rs 10 lakhs each, and 17 have assets in excess of Rs 1 crore each. Only 11 (including 3 with accumulated losses) wholly Indian owned companies have

assets exceeding Rs 10 lakhs each, and none had crossed the Rs 1 crore barrier through 1964.

AGE DISTRIBUTION

The industry is largely a post-war development. Only 15 (including 9 wholly Indian owned) companies were registered before 1946 (Table 3). Most of the larger companies with foreign control or participation were registered in 1946-50 and 1955-59. There has been a considerable growth in the number of wholly Indian owned companies but most of these are in trade, not manufacture.

FOREIGN PRODUCER, INDIAN TRADER

Of the companies with foreign control or participation, the majority in terms of numbers, assets and turnover is in manufacture (Table 4). Indian owned companies are mostly in trade. Among trading companies (defined as those having nil or negligible plant and machinery), the wholly Indian owned account for roughly one-half of assets and turnover. Among manufacturing companies, their share is 4 per cent or less.

TABLE 1.—OWNERSHIP DISTRIBUTION OF COMPANIES, 1964

Category	Ownership	Number of companies	Total assets (Rs lakhs)	Percentage of total assets	Sales [1] (Rs lakhs)	Percentage of total sales
A	Wholly foreign owned	9	22,17	34.8	26,19	41.9
B	Foreign majority, Indian minority	15	[2] 31,97	50.1	25,00	40.0
C	Indian majority, foreign minotity	5	5,45	8.5	7,04	11.3
Dp	Wholly Indian, making profits	20	2,97	4.7	[3] 3,78	6.0
Di	Wholly Indian, maing losses	39	[4] 1,22	1.9	54	0.8
Total		88	[5] 63,78	100.0	[6] 62,55	100.0

[1] Net of excise duty.
[2] Including accumulated losses of Rs 11 lakhs.
[3] Figure for 18 companies whose total assets amounted to Rs 2,24 lakhs.
[4] Including accumulated losses of Rs 54 lakhs.
[5] Including accumulated losses of Rs 65 lakhs.
[6] Figure for 85 companies whose total assets amounted to Rs 63,05 lakhs.

TABLE 2.—SIZE DISTRIBUTION OF COMPANIES, 1964

Total assets (Rs '000)	A	B	C	Dp	DI	Total
0 to 10					1	1
11 to 20					2	2
21 to 50					4	4
51 to 100			1	2	8	11
101 to 200				3	9	12
201 to 500				6	8	16
501 to 1,000		1		1	4	4
1,001 to 5,000	2	3		6	3	14
5,001 to 10,000	1	2	2	2		7
Above 10,000	6	9	2			17
Total	9	15	5	20	[1] 39	[1] 88

[1] Including one with total assets of Rs 10,000 for which profit and loss account is not available.

TABLE 3.—AGE DISTRIBUTION OF COMPANIES

Period of Registration	A	B	C	Dp	DI	Total
Before 1946	3	1	2	4	5	15
1946-1950	4	7		4	10	25
1951-1954	1		1	1	4	7
1955-1959	1	6	1	8	8	24
1960-1962		1	1	3	12	17
Total	9	15	5	20	39	88

MANAGEMENT

Only 1 company each is managed by managing agents and manager (Table 5). There are managing directors in 17 out of 24 foreign controlled companies and, in all, 48 out of 88 companies. The remaining 38 companies, including 29 wholly Indian owned, are deemed to be managed by their boards of directors since they have no managerial personnel within the meaning of the Companies Act.

The 88 companies have 403 directors between them (Table 6). The 24 foreign controlled companies have 137 directors, of whom 61 are Indian and 76 are foreigners; they have only 2 women directors. The proportion of Indian directors is fairly high in both wholly foreign owned companies (44 per cent) and foreign majority companies (45 per cent). Among them, Raptakos Brett has 8 Indians on its 10-member board, Cilag Hind 5 out of 7, Cyanamide 2 out of 4 and Merck, Sharp Dohme 3 out of 5. Out of the 61 Indian directors in these companies, 37 appear to be company executives in service, and the rest are merchants, financiers, solicitors, etc.

Foreign directors are not altogether missing in the category of Indian controlled companies but their number is negligible. On an average, the 59 wholly Indian owned companies have about 4 directors each, against 6 in those with foreign control and participation. Women directors are, curiously, quite prominent; 46 out of a total of 238 directors or 19 per cent are women. One company, Lenec Institute, has an all-female 11-member board.

OWNERSHIP

The over-all pattern of ownership of share capital is heavily weighted with the large size of foreign controlled companies. In 1964, the 88 companies had a total share capital of Rs 14.45 crores, owned by 817 shareholders. The 24 foreign controlled companies among these accounted for a share capital of Rs 12.26 crores, owned by 161 shareholders (Table 7).

TABLE 4.—OCCUPATIONAL DISTRIBUTION OF COMPANIES, 1964

[Amounts in Rs lakhs]

	A	B	C	Dp	DI	Total
Manufacturing:						
Number of companies	7	11	4	11	9	42
Total assets	21,31	[1] 31,15	5,44	1,96	[2] 62	60,48
Percentage	(35.2)	(51.5)	(9.0)	(3.2)	(1.0)	(100.0)
Total sales	24,34	23,77	7,04	[3] 1,39	24	56,78
Percentage	(42.9)	(41.9)	(12.4)	(2.4)	(0.4)	(100.0)
Trading:						
Number of companies	2	4	1	9	30	46
Total assets	86	82	1	1,01	[4] 60	3,30
Percentage	(26.1)	(24.8)	(0.3)	(30.6)	(18.2)	(100.0)
Total sales	[5] 1,85	1,23	—	2,39	[6] 30	5,77
Percentage	(32.1)	(21.3)	(—)	(41.4)	(5.2)	(100.0)

[1] Including accumulated losses of Rs 7 lakhs.
[2] Including accumulated losses of Rs 28 lakhs.
[3] 9 companies only.
[4] Including accumulated losses of Rs 26 lakhs.
[5] One company (May and Baker) has only commission income and no sales.
[6] 29 companies.

TABLE 5.—PATTERN OF MANAGEMENT

(Number of Companies)

	A	B	C	Dp	DI	Tota
Managing director	6	11	3	10	18	48
Board of directors	3	4	2	9	20	38
Managing agent				1		1
Manager					1	1
Total	9	15	5	20	39	88

TABLE 6.—PATTERN OF DIRECTORSHIPS [1]

	A	B	C	Dp	DI	Total
Number of companies	9	15	5	20	39	88
Number of directorships	55	82	28	89	149	403
of which —						
(a) Indian	24	37	22	87	147	317
(b) Foreign	31	45	6	2	2	86
(i) Males	55	80	26	79	113	353
(ii) Females		2	2	10	36	50

[1] Including alternate directors.

Taking all the 88 companies together, 70 per cent of the share capital is owned by foreign companies and another 3 per cent by foreign individuals. Indian (mainly industrial and finance) companies hold 14 per cent, Indian individuals 12 per cent, and trusts less than 1 per cent. Though all the 88 companies studied are private, the major part of the share capital held by Indian companies as shareholders comes from public companies.

Among Indian individual shareholders, the breakdown by linguistic/communal groups indicates that Gujarati-speaking Hindus/Jains and Parsis are the largest single category of owners, followed by Maharashtrians (among whom solicitors are prominent), Marwaris, Southerns and Christians, in that order.

The individual shareholding is almost entirely urban, and that, too, largely from Greater Bombay, which is hardly surprising because the companies are highly localised in the metropolis. Slightly less than three-fifths of the individual shareholding is in the hands of males, and more than two-fifths is held in the names of women. Most of it, four-fifths, is registered in single names, and only one-fifth in joint names.

Only a little more than 8 per cent of the total share capital is owned by directors and their families in their own names; this includes the holdings of directors who are, for instance, solicitors, and are associated with the company only in a professional capacity. Slightly more than 3 per cent of the share capital is owned by persons whose connection with the controlling families or interests could not be identified; for private limited companies whose share capital is owned largely by corporate bodies, this is a fairly high proportion.

FOREIGN PARTICIPATION

The shareholding in wholly foreign owned companies is predominantly corporate. What little is owned by foreign individuals is largely in Raptakos Brett, through and executor and trustee holding. It is difficult to trace the ultimate ownership and control of foreign companies but it appears that, in this category, most of the companies are British: Boots, British Drug, Burroughs Wellcome, and Glaxo. Abbott and Pfizer are American, Franco-Indian and May and Baker are French and Raptakos Brett is Greek.

The foreign shareholding in foreign majority companies is 72 per cent of total share capital, and most of the balance, 23 per cent, is owned by the companies of Indian partners. Among these 15 companies, only 3, Boehringer Knoll, W T Suren, and Evans are British-controlled. The first two are with Rallis (i e, Tata Fison) participation and the third is part of the Glaxo group. The Swiss control 4 companies—Anglo-French Drug (Roche-Tata). Ciba (Ciba-Kasturbhai), Roche (Roche-Tata) and Sandoz (Sandoz-Shaw Wallace-Jasdenwala). The Americans control 6—Cilag Hind (Johnson-Premchand), Cynamide (Cynamide-Kasturbhai), Johnson and Johnson (Johnson-Premchand), Merck, Sharpe and Dohme (Merck-Tata), Parke Davis (Parke Davis-C H Bhabha) and Wyeth (American Home-Maheshwari, a close associate of Birla). The Germans control 2—Bayer India (Bayer-Ghia) and German Remedies (Bauer).

In companies with Indian majority and foreign minority, the foreign shareholding is 45 per cent, and the remainder is divided between Indian companies and individuals. Among these five companies, two, Excel (Shroff, Tata-Fison) and Francis Klein (Binani-Klein) have British participation and another two, Alta (Dhote-Monsanto 50:50) and Geoffrey Manners (Birla/Maheshwari-American Home), have American participation. The fifth, Hoechst Pharmaceuticals is a joint venture of Mallya of Bangalore (United Distilleries) and Hoechst of Germany.

TABLE 7.—PATTERN OF OWNERSHIP, 1964

[Amounts in Rs thousand]

	A (9)		B (15)		C (5)		Dp (20)		DI (39)		Total (88)	
	Amount	Percent	Amount	Percent	Amount	Percent	Amount	Percent	Amount	Percent	Amount	Percent
Number of shareholders	[1](14)		(147)		(73)		(223)		(360)		(817)	
Total share capital	4,86,47	100.0	7,39,75	100.0	95,30	100.0	62,10	100.0	61,03	100.0	14,44,65	100.0
Owners:												
(1) Foreign companies	4,45,10	91.5	5,25,24	71.0	42,43	44.5					10,12,77	70.1
(2) Foreign individuals	[2]41,37	8.5	6,71	0.9	14	0.1					48,22	3.3
(3) Indian companies			1,71,23	23.1	23,28	24.4			11,00	18.0	2,05,51	14.2
(a) Banks			(6,25)	(0.8)							6,25	(0.4)
(b) Insurance			(18,75)	(2.5)	(75)	(0.8)					19,50	(1.3)
(c) Finance			(59,74)	(8.1)	(7,86)	(8.2)			31	(0.5)	67,91	(4.7)
(d) Industrial			(69,71)	(9.4)	(14,67)	(15.4)			70	(1.2)	85,08	(5.9)
(e) Service			(16,78)	(2.3)					999	(16.2)	26,77	(1.9)
(i) Public			(1,15,28)	(15.6)	(16,42)	(17.2)			999	(16.2)	1,41,69	(9.8)
(ii) Private			(55,95)	(7.5)	(6,86)	(7.2)			101	(1.7)	63,82	(4.4)
(4) Trusts									885	14.5	885	0.6
(5) Indian individuals			36,58	4.9	29.45	30.9	62,10	100.0	41,18	67.5	1,69,31	11.7
(a)(i) Gujaratis, Hindus and Jains			(11,71)	(1.6)	(4,99)	(5.2)	(20,04)	(32.3)	(13,23)	(21.7)	49,97	(3.5)
(ii) Parsis			(11,62)	(1.6)			(5,15)	(8.3)	(3,42)	(5.6)	20,19	(1.4)
(iii) Marwaris					(14,42)	(15.1)			(1,41)	(2.3)	15,83	(1.1)
(iv) Maharashtrians			(1,22)	(0.2)	(9,01)	(9.5)	(18,73)	(30.2)	(10,44)	(17.1)	39,40	(2.7)
(v) Muslims			(2,15)	(0.3)	(6)	(0.1)			(1)	(neg)	2,21	(0.2)
(vi) Sindhis					(20)	(0.2)	(50)	(0.3)			70	(neg)
(vii) Christians			(62)	(neg)			(12,75)	(20.5)	(5)	(neg)	13,42	(0.9)
(viii) Southern			(5,10)	(0.7)	(77)	(0.8)	(2,18)	(3.5)	(5,00)	(8.2)	12,95	(0.9)
(ix) Others			(4,16)	(0.6)			(2,75)	(4.4)	(7,63)	(12.5)	14,54	(1.0)
(b) (i) Bombay			(31,53)	(4.3)	(29,01)	(30.4)	(50,00)	(80.5)	(30,41)	(49.8)	1,40,95	(9.8)
(ii) Other urban			(5,01)	(0.7)	(44)	(0.5)	(11,73)	(18.9)	(10,57)	(17.3)	27,75	(1.9)
(iii) Rural			(5)	(neg)			(37)	(0.6)	(20)	(0.3)	62	(neg)
(c) (i) Males			(20,80)	(2.8)	(16,82)	(17,6)	(37,13)	(59.8)	(28,06)	(46.0)	1,02,81	(7.1)
(ii) Females			(15,78)	(2.1)	(12,63)	(13.3)	(24,97)	(40.2)	(13,12)	(21.5)	66,50	(4.6)
(d) (i) Joint			(8,16)	(1.1)	(4,08)	(4.3)	(14,28)	(23.0)	(4,35)	(7.1)	30,87	(2.1)
(ii) Single			(28,41)	(3.8)	(25,37)	(26.6)	(47,82)	(77.0)	(36,83)	(60.3)	1,38,44	(9.6)
(e) (i) Directors			(6,20)	(0.8)	(9,54)	(10.0)	(30,76)	(49.5)	(22,10)	(36.2)	68,60	(4.7)
(ii) Directors' families			(5,34)	(0.7)	(16,57)	(17.4)	(24,34)	(39.2)	(6,38)	(10.4)	52,63	(3.6)
(iii) Others			(25,04)	(3.4)	(3,34)	(3.5)	(7,00)	(11.3)	(12,70)	(20.8)	48,07	(3.4)

Note: Share capital is almost wholly in the form of ordinary shares, but deferred and preference shares are also included.

[1] 6 in Raptakos Brett alone.
[2] Including State Bank executor and trustee holding in Raptakos Brett.

In the aggregate, 10 companies with American control or participation account for 35 per cent of the total assets and 38 per cent of the sales (net of excise) of the 88 companies studied. Another 10 companies with UK control or participation have 26 per cent of assets and turnover; these include Glaxo, by far the largest company in the sample, which had total assets exceeding Rs 11 crores in 1964. The 4 companies under Swiss control have 23 per cent of total assets and 18 per cent of sales. Three companies associated with West Germany have 6 per cent of assets and sales. Among foreign associated companies, the companies under Swiss control appear to have a low ratio of sales to total assets (Table 8).

INDIAN OWNED COMPANIES

Those 20 of the 59 wholly Indian owned companies which had no accumulated losses in 1964 are owned entirely by individuals, mainly Gujarati Hindus/Jains and Parsis, Maharashtrians and Christians resident predominantly in Bombay (Table 7). About 60 per cent of the holding is with males and the remaining 40 per cent with females. Most of the shareholding is in single names. Nearly 90 per cent of the share capital comes from directors and their families.

There is some inter-corporate holding in the remaining 39 wholly Indian owned companies which had accumulated losses in 1964, but this comes to only 18 per cent of total share capital and originates almost wholly from service (i e, trading and real estate) companies—mostly public companies. Trusts, which do not figure as shareholders in any other category, contribute 15 per cent of share capital. Individuals, nevertheless, account for more than two-thirds of share capital. Most of them are Gujarati Hindus/Jains, Maharashtrians and Southerners, with a sprinkling of Marwaris, again resident predominantly in Bombay. The proportion of shares held by females is somewhat lower in this category as compared with others, though it has a much higher frequency of women directors (see Table 6). Slightly less than one-third of the share capital contributed by individuals, i e, one-fifth of total share capital, comes from persons who are neither directors nor (so far as could be identified) members of directors' families.

BALANCE SHEET STRUCTURE

In 1964, private pharmaceutical companies had 22 per cent of their total funds from share capital, 25 per cent from reserves, 18 per cent from loans, and the remaining 35 per cent from current liabilities and provisions (Table 10).

The significance of reserves varied considerably between the different categories of companies. Foreign controlled companies had, in proportionate terms, much larger reserves than Indian owned companies, which depended to a much greater extent upon loans. Moreover, wholly foreign owned companies got a considerable part of their relatively small loans from associate companies abroad; this source of funds was a poor second to banks in foreign majority companies. Loans from foreign associates amounted to Rs 61 lakhs in wholly foreign companies and Rs 153 lakhs in foreign majority companies. Indian owned companies tended to rely in large measure on unsecured rather than secured loans, mainly from sources other than banks.

Of the total funds in 1964, 37 per cent were utilised for fixed assets, 31 per cent for inventory, 22 per cent for receivables, and 9 per cent for cash. Indian majority and wholly owned companies had, as compared with foreign controlled companies, a smaller proportion of fixed assets and a larger proportion of receivables.

TABLE 8.—RATIO OF SALES AND ASSETS OF FOREIGN ASSOCIATED COMPANIES TO TOTAL SALES AND ASSETS

Country of foreign control or participation	United States	United Kingdom	Switzerland	West Germany	Total
Number of companies	10	9	4	3	26
Total assets (Rs lakhs)	22,55	16,34	14,79	3,69	57,37
Percent of 88 companies	(35.4)	(25.6)	(23.2)	(5.8)	(90.0)
Total sales (Rs lakhs)	24,02	16,63	11,41	3,81	55,87
Percent of 88 companies	(38.4)	(26.6)	(18.2)	(6.1)	(89.3)

TABLE 9.—FOREIGN INVESTMENT IN SAMPLE COMPANIES

[Rs crores]

	Wholly foreign (9)	Foreign majority (15)	Foreign minority (5)	Total (29)
(1) Paid-up capital	4.86	[1] 5.71	[2] 0.41	10.98
(a) Cash	(1.46)	(5.10)	(0.23)	(6.79)
(b) Bonus shares	(1.37)		(0.16)	(1.53)
(c) Other noncash	(2.03)	(0.61)	(0.02)	(2.66)
(2) Reserves	7.48	[1] 4.99	[2] 0.37	12.84
(3) Loans from associates	0.61	1.53	0.07	2.21
Total	12.95	12.23	0.85	26.03

[1] 72% (being foreign holding of total share capital) of relevant aggregate amounts.
[2] 45% (being foreign holding of total share capital) of relevant aggregate amounts.

TABLE 10.—STRUCTURE OF BALANCE SHEET 1964, 1962, 1960, AND 1958

[Percentages]

Category	Number of companies	Paid-up capital	Reserves	Loans	Current liabilities	Total liabilities	Fixed assets	Investment	Inventories	Receivables	Cash	Miscellaneous expenditure	Losses	Total assets
		1	2	3	4	5	6	7	8	9	10	11	12	13
1964														
A	9	21.9	33.7	4.0	40.3	100.0	32.2		32.8	21.6	12.7			100.0
	(7)	(21.3)	(34.7)	(3.8)	(39.1)	(100.0)	(33.3)		(33.7)	(20.0)	(12.5)			(100.0)
B	15	22.2	21.7	24.5	31.6	100.0	41.4		28.0	23.4	6.4		0.3	100.0
	(11)	(22.4)	(21.7)	(24.9)	(30.9)	(100.0)	(41.9)		(28.0)	(23.0)	(6.4)			(100.0)
C	5	16.7	15.2	33.9	34.1	100.0	27.1	2.9	35.2	23.3	11.0			100.0
	(4)	(16.7)	(15.2)	(34.0)	(34.1)	(100.0)	(27.2)	(2.9)	(35.2)	(23.1)	(11.0)			(100.0)
Dp	18	20.6	8.2	34.2	36.8	100.0	22.4	0.9	36.8	34.1	2.3	3.1		100.0
	(11)	(19.9)	(10.7)	(26.5)	(42.3)	(100.0)	(33.7)		(25.5)	(33.7)	(3.0)	(3.6)		(100.0)
Total	47	21.5	24.9	18.3	35.1	100.0	36.1	0.5	30.7	23.2	8.9	0.2	0.2	100.0
	(33)	(21.8)	(25.4)	(18.2)	(34.5)	(100.0)	(37.2)	(0.5)	(30.7)	(22.3)	(8.9)	(0.2)	(0.5)	(100.0)
DI	38	44.2	0.8	36.0	18.0	100.0	14.7		14.7	21.3	2.4	2.4	44.2	100.0
	(9)	(48.4)	(1.6)	(33.9)	(14.5)	(100.0)	(24.2)		(17.7)	(11.3)	(1.6)		(45.2)	(100.0)
1962														
A	9	21.3	23.4	5.5	49.8	100.0	31.6	1.6	28.0	15.5	23.1			100.0
	(7)	(21.8)	(24.2)	(5.7)	(52.7)	(100.0)	(33.3)	(1.6)	(29.4)	(22.7)				(100.0)
B	15	23.1	19.1	26.8	31.0	100.0	34.4		36.2	20.9	8.1		0.3	100.0
	(11)	(23.5)	(18.7)	(27.4)	(30.3)	(100.0)	(34.9)		(36.5)	(8.1)				(100.0)
C	5	15.0	16.9	33.2	34.8	100.0	29.6		42.7	18.2	8.2		0.9	100.0
	(4)	(15.0)	(16.9)	(33.2)	(34.8)	(100.0)	(29.5)		(42.7)	(8.1)				(100.0)
Dp	18	21.9	9.0	18.1	51.0	100.0	14.2	4.5	43.3	29.0	6.5	2.0		100.0
	(11)	(26.5)	(7.8)	(25.0)	(42.2)	(100.0)	(32.8)		(29.6)	(7.8)				(100.8)
Total	47	21.7	19.8	20.6	37.9	100.0	32.2	0.8	34.6	19.3	12.6	0.2	0.3	100.0
	(33)	(22.1)	(20.0)	(21.4)	(36.4)	(100.0)	(33.8)		(34.9)	(12.6)	(13.2)	(1.3)		(100.0)
DI	38	45.7	0.9	35.2	18.1	100.0	15.0		18.9	17.9	3.8	1.9	42.3	100.0
	(9)	(49.1)	(1.8)	(34.5)	(14.5)	(100.0)	(25.4)		(14.5)	(1.8)	(1.8)		(45.5)	(100.0)

1960														
A	7	27.9	13.1	10.7	48.2	100.0	20.4		47.5	23.9	6.4		1.2	100.0
	(6)	(29.1)	(13.4)	(11.7)	(45.7)	(100.0)	(21.6)		(51.4)	(20.5)	(4.3)		(1.3)	(100.0)
B	13	25.9	12.2	24.7	37.0	100.0	27.3	1.0	38.0	22.0	10.1		1.1	100.0
	(9)	(27.0)	(11.7)	(25.5)	(35.6)	(100.0)	(29.0)	(0.8)	(39.2)	(21.1)	(9.8)			(100.0)
C	4	18.1	11.5	38.8	31.4	100.0	30.1		36.7	21.9	10.3	1.0		100.0
	(3)	(25.9)	(12.1)	(24.8)	(37.0)	(100.0)	(27.8)	(0.9)	(38.0)	(22.0)	(10.1)			(100.0)
Dp	15	23.1	4.3	29.9	42.6	100.0	15.2		32.3	26.8	12.8	11.6	1.0	100.0
	(6)	(32.9)	(5.0)	(29.1)	(32.9)	(100.0)	(25.3)		(26.6)	(25.3)	(6.3)	(15.2)		(100.0)
Total	39	25.3	11.7	23.5	39.4	100.0	25.4	0.5	39.6	22.8	9.4	1.1	1.0	100.0
	(24)	(27.0)	(12.0)	(23.1)	(37.8)	(100.0)	(27.2)	(0.7)	(40.3)	(21.5)	(9.0)	(0.5)	(0.6)	(100.0)
DI	24	45.5	1.0	30.6	22.8	100.0	21.8	1.0	18.8	15.8	3.0	3.0	36.6	100.0
	(6)	(51.0)		(34.6)	(14.3)	(100.0)	(26.5)	(2.0)	(14.3)	(8.2)	(2.0)		(44.9)	(100.0)
1958														
A	7	18.4	4.7	17.1	59.7	100.0	18.9	0.5	50.3	20.3	7.4		2.6	100.0
	(6)	(18.3)	(4.2)	(18.3)	(59.2)	(100.0)	(20.0)	(0.6)	(53.8)	(17.2)	(5.6)		(2.8)	(100.0)
B	8	17.6	10.2	27.1	45.1	100.0	12.9	1.6	46.2	29.9	4.7		4.1	100.0
	(4)	(19.5)	(8.9)	(29.4)	(42.1)	(100.0)	(13.2)	(2.0)	(52.4)	(27.4)	(4.3)		(0.6)	(100.0)
C	4	15.9	8.6	15.2	60.3	100.0	20.5		45.7	19.2	13.2	1.3		100.0
	(3)	(15.9)	(8.6)	(15.2)	(60.3)	(100.0)	(20.5)		(45.7)	(19.2)		(0.8)	(0.8)	(100.0)
Dp	12	19.4	3.1	29.6	47.9	100.0	8.2	4.1	48.9	28.6	5.1	7.1		100.0
	(4)	(43.2)	(2.7)	(32.4)	(21.6)	(100.0)	(24.3)		(37.8)	(24.3)	(2.7)	(5.4)	(5.4)	(100.0)
Total	31	17.8	7.7	22.8	51.7	100.0	15.4	1.3	47.6	25.5	6.6	0.7	2.8	100.0
	(17)	(19.4)	(7.1)	(23.7)	(49.8)	(100.0)	(17.0)	(1.1)	(51.4)	(22.6)	(6.0)		(1.4)	(100.0)
DI	20	54.7		34.5	10.7	100.0	20.0	1.2	20.0	16.4	2.4	3.5	36.5	100.0
	(6)	(54.3)		(36.9)	(8.7)	(100.0)	(28.3)	(2.2)	(17.4)	(13.0)			(39.1)	(100.0)

Note: Figures in parentheses relate to manufacturing companies.

TABLE II.—STRUCTURE OF EXPENDITURE AND APPROPRIATION 1964 AND 1962

[Percentages]

Category	1964						1962					
	A	B	C	Dp	Total	DI	A	B	C	Dp	Total	D
Number of companies	9 (7)	15 (11)	5 (4)	18 (11)	47 (33)	38 (9)	6 (4)	14 (10)	5 (4)	15 (1)	46 (24)	37 (9)
	A. Expenditure items (as percent of total income [1])											
Materials	43.0 (42.9)	41.7 (41.4)	51.5 (51.5)	57.0 (40.3)	44.2 (43.3)	53.3 (44.4)	43.8 (44.5)	46.9 (46.4)	50.3 (50.2)	60.7 (40.0)	47.4 (46.2)	63.3 (44.0)
Labour	15.5 (14.8)	11.9 (12.0)	10.3 (10.3)	11.2 (16.7)	13.1 (13.1)	16.7 (18.5)	14.1 (12.7)	11.9 (12.0)	10.3 (10.3)	9.7 (16.8)	12.2 (12.1)	12.2 (16.0)
General administration	7.9 (7.4)	10.7 (10.3)	16.2 (16.4)	9.9 (13.9)	10.1 (9.9)	13.3 (14.8)	9.8 (2.7)	11.9 (2.5)	14.4 (3.2)	9.1 (5.3)	11.3 (2.7)	12.2 (4.0)
Selling expenses	2.1 (2.2)	3.9 (4.0)	0.4 (0.4)	5.7 (7.6)	2.9 (2.9)	8.3 (11.1)	2.7 (2.6)	2.4 (2.4)	4.8 (4.8)	2.7 (6.3)	2.8 (2.9)	4.1 (4.0)
Royalties	1.4 (1.5)	0.8 (0.8)	----------	1.0 ----------	1.0 (1.0)	----------	2.6 (2.7)	----------	----------	----------	1.1 (1.2)	----------
Managerial remuneration	0.2 (0.2)	0.4 (0.4)	0.4 (0.4)	1.3 (1.4)	0.4 (0.3)	8.3 (7.4)	----------	----------	0.7 (0.7)	1.8 (2.1)	0.5 (0.3)	(4.0) 6.1) (8.0)

Others	4.5 (4.7)	9.4 (5.3)	3.7 (3.8)	2.9 (4.2)	4.7 (4.8)	3.3 (3.7)	2.7 (2.7)	2.0 (2.5)	3.2 (3.2)	3.9 (5.3)	2.7 (2.7)	4.1 (4.0)
Interest	0.5 (0.5)	1.7 (0.5)	1.2 (1.3)	2.1 (2.8)	1.2 (1.2)	1.6		2.4 (2.5)	1.3 (1.3)	1.2 (1.0)	1.5 (1.5)	2.0
Depreciation	1.8 (1.8)	3.7 (3.9)	2.2 (2.2)	1.0 (2.8)	2.6 (2.8)	3.3 (3.7)	2.0 (2.1)	2.5 (2.6)	2.0 (2.0)	1.0 (2.1)	2.2 (2.3)	2.0 (2.4)
Profit before tax	23.2 (23.8)	19.7 (20.0)	14.1 (14.3)	7.8 (10.4)	19.8 (20.7)	−8.1 (−3.6)	21.7 (22.5)	18.6 (18.6)	12.9 (12.9)	9.7 (15.8)	18.2 (19.0)	−6.0 (−13.6)
Total	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)
	B. Appropriation (as percent of profit before tax)											
Tax	50.5 (50.2)	60.0 (59.8)	69.1 (69.1)	73.3 (66.7)	56.4 (56.0)		43.2 (43.0)	38.0 (37.8)	40.3 (40.2)	46.9 (46.7)	40.5 (40.2)	
Dividend	6.1 (6.0)	17.4 (15.9)	10.9 (10.9)	6.7 (6.7)	11.1 (10.5)		26.2 (25.5)	22.7 (22.2)	20.8 (20.8)	28.1 (26.6)	24.1 (23.5)	
Development rebate	0.5 (4.7)	15.6 (16.1)	4.5 (4.5)	3.3 (6.7)	7.0 (7.3)		6.1 (6.3)	9.2 (9.7)	16.7 (16.6)		8.3 (8.8)	
Other reserves	43.0 (43.3)	6.9 (8.0)	15.4 (15.4)	1.7 (20.0)	25.4 (26.2)		24.5 (25.2)	30.1 (30.3)	22.2 (22.2)	25.0 (26.6)	27.0 (27.4)	
Total	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)	100.0 (100.0)

[1] Total income is sales (net of excise) adjusted for changes in stocks plus other income and revenue receipts.

Note: Figures in parentheses refer to manufacturing companies.

TABLE 12.—BREAK-DOWN OF VALUE OF PRODUCTION 1964

[Percentages]

	Total	A	B	C	Dp
(1) Profit before tax	19.8	23.2	19.7	14.1	7.8
(2) Depreciation	2.6	1.8	3.7	2.2	1.0
(3) Interest	1.2	0.5	1.7	1.2	2.1
(4) Managerial remuneration	0.4	0.2	0.4	0.4	1.3
(5) Royalties	1.0	1.4	0.8	----------	1.0
(6) Labour	13.1	15.5	11.9	10.3	11.2
Gross value added	38.1	42.6	38.2	28.2	24.4

TABLE 13.—SOURCES AND USES OF FUNDS FOR 31 COMPANIES 1958-64

[Amounts in Rs lakhs]

	Wholly foreign owned (7)	Foreign majority (8)	Indian majority (4)	Wholly Indian making profits (12)	Total (31)
			SOURCES		
(1) Reserves	229	387	65	9	690
(a) Development rebate	(23)	(37)	(10)	(1)	(71)
(b) Other free	(135)	(209)	(46)	(7)	(397)
(c) Specific	(71)	(141)	(9)	(1)	(222)
(i) As percent of total	29.6	36.7	17.1	11.7	30.2
(2) Capitalized reserves (bonus shares)	17	----------	33	----------	50
(ii) As percent of total	2.2	----------	8.7	----------	2.2
(3) Depreciation	92	145	48	9	294
(iii) As percent of total	11.9	13.7	12.6	11.7	12.9
(4) Internal resources (1+2+3)	338	532	146	18	1034
(iv) As percent of total	43.7	50.4	38.4	23.4	45.3
(5) Paid up share capital	105	106	24	16	251
(a) Cash subscription	(95)	(66)	(22)	(16)	(199)
(b) Noncash excluding bonus shares	(10)	(40)	(2)	----------	(52)
(v) As percent of total	13.6	10.0	6.3	20.8	11.0
6) Loans	33	276	144	29	416
(a) Secured	(−27)	(158)	(138)	(23)	(292)
Banks	(−27)	(158)	(135)	(22)	(288)
Other companies	----------	----------	(3)	----------	(3)
(b) Unsecured	(−6)	(118)	(7)	(6)	(125)
(i) Directors and associate companies	(−3)	(77)	(7)	(5)	(81)
(ii) Banks	----------	(−7)	(−1)	----------	(−8)
(vi) As percent of total	−4.2	26.2	37.9	37.7	18.2
(7) Current liabilities and provisions	363	141	66	14	584
(a) Tax [1]	(281)	(58)	(53)	(38)	(431)
(vi) As percent of total	47.0	13.4	17.4	18.2	25.6
(8) External resources (5+6+7)	435	523	234	59	1251
(viii) As percent of total	56.3	49.6	61.6	76.6	54.7
Total	773	1055	380	77	2285
Percent	(100.0)	(100.0)	(100.0)	(100.0)	(100.0)
			Uses		
(1) Gross fixed assets	286	709	147	33	1175
(a) Land, buildings, plant, and machinery	(245)	(658)	(147)	(27)	(1077)
(i) As percent of total	37.0	67.2	38.7	42.9	51.4
(2) Investments	−1	−5	16	−2	8
(a) Private	----------	(−6)	(15)	(−2)	(7)
Within same group	----------	(5)	(15)	(1)	(20)
(ii) As percent of total	−0.1	−0.5	4.2	−2.6	0.3
(3) Inventory	239	211	115	19	584
(iii) As percent of total	30.9	20.0	30.3	24.5	25.6
(4) Receivables	233	121	66	27	447
(a) Within same group	(10)	(10)	(3)	----------	(23)
(iv) As percent of total	30.1	11.5	17.4	35.1	19.6
(5) Cash	16	19	36	----------	71
(v) As percent of total	2.1	1.8	9.5	----------	3.1
Total	773	1055	380	77	2285
Percent	(100.0)	(100.0)	(100.0)	(100.0)	(100.0)

[1] Net of tax advances.

TABLE 14.—SOURCES AND USES OF FUNDS FOR 17 MANUFACTURING COMPANIES 1958-64

[Amounts in Rs Lakhs]

	Wholly foreign owned	Foreign majority	Indian majority	Wholly Indian making profits	Total
	(6)	(4)	(3)	(4)	(17)
Sources					
(1) Reserves	228	369	65	4	666
(a) Development rebate	(23)	(32)	(10)	(2)	(67)
(b) Other free	(134)	(195)	(46)	(2)	(377)
(c) Specific	(71)	(142)	(9)	—	(222)
(i) As percent of total	30.6	34.8	17.2	10.3	30.0
(2) Capitalised reserves (bonus shares)	17		33		.50
(ii) As percent of total	2.3		8.7		2.2
(3) Depreciation	92	145	48	8	293
(iii) As percent of total	12.4	13.7	12.7	20.5	13.2
(4) Internal resources (1+2+3)	337	514	146	12	1007
(iv) As percent of total	45.3	48.5	38.5	30.8	45.4
(5) Paid-up share capital	105	106	24	2	237
(a) Cash subscription	(95)	(65)	(22)	(2)	(184)
(b) Noncash excluding bonus shares	(10)	(41)	(2)		(53)
(v) As percent of total	14.1	10.0	6.3	5.1	10.7
(6) Loans	−33	290	144	12	413
(a) Secured	(−27)	(151)	(138)	(2)	(264)
Banks	(−27)	(150)	(135)	(2)	(261)
Other companies			(3)		(3)
(b) Unsecured	(−6)	(138)	(7)	(10)	(149)
Directors and associate companies	(−8)	(96)	(7)	(3)	(98)
Banks		(−28)	(−1)		(−29)
(vi) As percent of total	−4.4	27.4	38.0	30.8	18.6
(7) Current liabilities and provisions	334	151	66	13	564
(a) Tax [1]	285	63	53		401
(vii) As percent of total	44.9	14.2	17.4	33.3	25.4
(8) External resources (5+6+7)	406	547	234	27	1214
(viii) As percent of total	54.6	51.6	61.7	69.2	54.6
Total	744	1060	379	39	2223
Percent	(100.0)	(100.0)	(100.0)	(100.0)	(100.0)
Uses					
(1) Gross, fixed assets	286	706	147	21	1160
(a) Land, buildings, plant and machinery	(245)	(660)	(147)	(18)	(1070)
(i) As percent of total	38.4	66.6	38.8	54.0	52.2
(2) Investments	−1	−6	16		9
(a) Private		(−7)	(15)		(8)
Within some group	(1)	(3)	(15)		(19)
(ii) As percent of total	−0.1	−0.6	4.2		0.4
(3) Inventory	239	212	115	10	576
(iii) As percent of total	32.1	20.0	30.4	25.6	26.0
(4) Receivables	211	126	65	6	408
Within same group	(10)		(2)		(12)
(iv) As percent of total	28.4	11.9	17.1	15.4	18.4
(5) Cash	8	21	36	1	66
(v) As percent of total	1.1	2.0	9.5	2.5	3.0
(6) Miscellaneous expenditure and intangibles	1	1		1	3
(vi) As percent of total	0.1	0.1		2.5	0.1
Total	744	1060	379	39	2223
Percent	(100.0)	(100.0)	(100.0)	(100.0)	(100.0)

[1] Net of tax advances.

TABLE 15.—ALLOCATION OF PROFITS AFTER TAX 1964

[Percentages]

		Number of companies	Dividend	Retention
A	Wholly foreign owned	9	12.3	87.7
B	Foreign majority	15	43.7	56.3
C	Indian majority	5	35.3	64.7
Dp	Wholly Indian owned, making profits	18	25.0	75.0
	Total	47	25.1	74.9

TABLE 16.—RESERVE BANK SAMPLE OF 32 PUBLIC PHARMACEUTICAL COMPANIES

	1960–61	1961–62	1962–63	1963–64	1964–65
	Percentages of profit before tax				
(1) Tax provision	44.5 (38.8)	45.0 (43.8)	56.2 (52.7)	62.2 (51.2)	58.0 (50.6)
(2) Dividends	31.0 (37.0)	28.3 (35.7)	24.8 (31.5)	23.2 (29.9)	24.1 (30.0)
(3) Retention	24.5 (24.2)	26.7 (20.5)	19.0 (15.8)	14.6 (18.9)	17.9 (19.4)
	Percentages of profit after tax				
(1) Dividends	55.8 (60.4)	51.4 (63.6)	56.6 (66.6)	61.2 (61.4)	57.3 (60.8)
(2) Retention	44.2 (39.6)	48.6 (36.4)	43.4 (33.4)	38.8 (38.6)	42.7 (39.2)

Source: "Reserve Bank of India Bulletin", November 1966.
Note: Figures in parentheses refer to all 1,333 public companies in the sample.

TABLE 17.—PROFIT AFTER TAX ON NET WORTH IN RESERVE BANK SAMPLE COMPANIES

[Percentages]

	Public companies		Private companies	
	All 1333	Pharmaceuticals (32)	All 501	Metals and chemicals [1] (92)
1960–61	10.9	17.2	12.6	20.0
1961–62	10.0	16.0	12.4	19.1
1962–63	8.6	11.9	9.8	14.5
1963–64	9.4	12.7	9.0	16.0
1964–65	9.2	15.2	n.a.	n.a.

[1] Further breakdown of industries is not available.
Source: "Reserve Bank of India Bulletin," November 1966 and December 1965.

TABLE 18.—PROFITABILITY 1964 AND 1962

			Amounts (in Rs lakhs)				Percentages		
Category	Year	Number of companies	Depreciation	Profits after Tax	Net worth	Sales net of excise	Profit on net worth (5 on 7)	Profit on net sales (5 on 7)	Cash earnings on net worth (4+5 on 6)
1	2	3	4	5	6	7	8	9	10
(A) Wholly foreign owned	1964	9	49	364	889	[1] 2657	40.9	13.7	46.5
	1964	6	33	273	555	1530	49.2	17.8	55.1
	1962	6	27	166	525	1276	31.6	13.0	36.8
(B) Foreign majority	1964	15	102	[2] 214	1403	2500	15.3	8.6	22.5
	1964	14	98	221	1328	2489	16.6	8.9	24.0
	1962	14	52	235	905	1883	26.0	12.5	31.7
(C) Indian majority	1960	5	17	34	174	704	19.5	4.8	29.3
	1962	5	11	43	121	514	35.5	8.4	44.6
(D) Wholly Indian, making profits	1964	18	4	8	89	378	9.0	2.1	13.5
	1964	15	3	7	78	329	9.0	2.1	12.8
	1962	15	3	17	48	312	35.4	5.4	41.7
Total	1964	47	174	620	7555	[1] 6239	23.4	9.9	31.1
	1964	40	152	535	2135	5052	25.1	10.6	23.2
	1962	40	93	461	1599	3985	28.8	11.5	34.6

[1] Including commission income of a company which had no income from sales. The figure consequently differs from that in Tables 1 and 4.
[2] One company made a loss.

TABLE 19.—PROFITABILITY OF FOREIGN CONTROLLED COMPANIES

Company	Country of origin	1964 Profit after Tax as percent of Net woth	1964 Profit after Tax as percent of Net sales	1962 Profit after Tax as percent of Net worth	1962 Profit after Tax as percent of Net sales
1	United Kingdom	56.0	23.2	31.4	14.2
2	United States of America	39.1	9.4	n.a.	n.a.
3	Switzerland	15.2	10.4	30.3	13.0
4	United States of America	20.9	15.5	49.0	32.2
5	do	21.5	10.3	27.9	7.9
6	Switzerland	6.3	2.1	7.9	3.2
7	do	19.7	11.9	11.2	7.6
8	United States of America	12.6	11.8	12.8	11.8
9	United Kingdom	23.5	7.0	36.8	8.7
10	United States of America	16.5	4.2	5.5	1.8
11	United Kingdom	14.3	5.0	n.a.	n.a.
12	do	7.2	2.3	32.8	14.1
13	West Germany	15.6	2.7	16.7	2.6
14	do	39.2	4.3	6.4	1.4
15	France	13.8	1.5	55.1	8.0
16	United Kingdom	7.7	4.2	14.0	7.6
17	Switzerland	26.5	3.7	48.6	12.6
18	United States of America	130.1	9.1	35.8	13.8
19	France	13.1	2.9	2.0	0.5
20	United States of America	26.8	4.3	48.6	8.5
21	United Kingdom	27.5	2.7	20.8	6.1
22	do	5.1	14.9	2.9	14.4
Total 20 companies [1]		26.3	12.3	28.1	12.7
Total 24 companies [2]		(25.2)	(11.2)		

[1] The data in this row are for 20 identical companies in both years.
[2] Including companies for which 1962 data are not available. These also include a Greek company and a new American loss-making company, whose figures should reveal their identity.

TABLE 20.—PROFITABILITY OF FOREIGN CONTROLLED COMPANIES

Country of origin	Year	Number of companies	Profit after tax on net worth	Profit after tax on net sales
United Kingdom	1964	7	16.9	17.2
	1964	6	45.8	18.5
	1962	6	30.5	13.4
United States	1964	8	19.5	8.8
	1964	6	19.3	11.2
	1962	6	28.4	15.8
West Germany	1964	2	25.6	3.2
	1962	4	20.3	2.2
Switzerland	1964	4	20.6	7.9
	1962	4	21.3	8.7
France	1964	2	13.4	1.9
	1962	2	25.9	8.3
Total (including others)	1964	24	25.2	11.2
	1964	20	26.3	12.3
	1962	20	28.1	12.7

TABLE 21.—GROWTH OF GROSS FIXED ASSETS

	1958	1960	1962	1964	1958–60	1960–62	1962–64
	(Rs lakhs)				(Percentage increase)		
(A) Wholly foreign owned (7)	119	170	293	405	43	72	38
(B) Foreign majority (8)	110	310	477	819	182	54	72
(C) Indian majority (4)	37	90	138	184	143	53	33
Total (19)	266	570	908	1453	114	59	55

FOREIGN INVESTMENT

Total foreign investment in the sample companies amounted to Rs 26 crores in 1964. This comprised paid-in cash subscription of Rs 7 crores towards share capital, bonus and non-cash share capital of Rs 14 crores, unsecured loans of Rs 2 crores from overseas principals, and reserves of Rs 13 crores (Table 9).

Comparability over a period of time is vitiated by differences in coverage but it does appear that over the period 1958 to 1964, retained profits have become more significant, especially in companies with foreign control or participation. Correspondingly, dependence upon share capital and loans has been reduced. At the same time, the proportion of fixed to total assets has risen consistently. Over the entire period, net worth exceeded the amount of net fixed assets, except in wholly Indian owned profitmaking companies in 1964.

SOURCES AND USES OF FUNDS

Comparable balance sheet data are available for 31 companies in 1958 and 1964 (Table 13). Over this six-year period, these companies raised 45 per cent of their gross total funds from internal sources (32 per cent from reserves, 13 per cent from depreciation). As mentioned earlier, ploughback has been significant in this sample, more so, however, in foreign associated than in Indian controlled companies. Even then, external sources provided the major part of total funds. Share capital (as in other industries) was of relatively minor importance and even that included some non-cash subscription (other than bonus shares). Loans were of considerable importance, especially in Indian controlled companies. The foreign associated companies raised Rs 266 lakhs from banks as between the two years; in addition, they secured Rs 76 lakhs from associate companies abroad. These two sources were for them substantially less important than current liabilities (excess tax provision and trade creditors, etc).

Surprisingly, only about one-half of gross total funds were used for fixed investment (two-thirds in foreign majority and less than two-fifths in wholly foreign owned). Working capital absorbed the balance, indicating either that they turned over their fixed capital with unusual speed or that their operations were more in the nature of trade than manufacture.

Almost the whole of this expansion was in 17 manufacturing companies (Table 14). Their data correspond closely to those for all companies, and the analysis above applies equally to them.

INCOME AND EXPENDITURE

Excluding those wholly Indian owned companies which had accumulated losses, there are 47 companies for which income and expenditure data are available for 1964. Their profit before tax amounted to nearly 20 per cent of value of production, but varied from 23 per cent in wholly foreign owned companies, 20 per cent in foreign majority, 14 per cent in Indian majority to 8 per cent in wholly Indian owned companies (Table 11).

The data on cost structure are not fully comparable, mainly because the classification of items is not uniform. Materials absorb the bulk, 43 per cent of value of production, labour 13 per cent, general administration and selling expenses (neither of which is satisfactorily or uniformly classified) another 13 per cent. Royalty takes 1 per cent (half as much more in wholly foreign owned companies). Managerial remuneration takes a larger fraction of income in wholly Indian owned companies as compared with the nominal fraction in foreign associated companies.

Gross value added in 1964 was 38 per cent of value of production and net value added was about 35 per cent. The share of labour in net value added was 37 per cent, while that of capital, as measured by profit before tax, interest, managerial remuneration and royalties, was 63 per cent. These overall proportions conceal fairly wide disparities between various categories (Table 12).

Out of the profit before tax, more than one-half (56 per cent) was taken away by taxation in 1964 against a significantly smaller proportion (40 per cent) in 1962, for which year, however, the data are not fully comparable. Strangely enough, Indian controlled companies paid tax in 1964 at a much higher rate than foreign controlled companies. This appears to have resulted largely from disparity in eligibility for tax concessions on fresh investment. For all 47 companies, development rebate (the only major concession which can be quantified) was 7 per cent of profits before tax in 1964 but it was 16

per cent in foreign majority companies and about 3 per cent in wholly Indian companies. In 1962, development rebate was even more significant in companies with foreign control or participation and altogether in wholly Indian owned companies.

Dividend absorbed only 11 per cent of profit before tax, and 32 per cent (44 per cent in wholly foreign owned) was ploughed back.

Taking the appropriation of profits after tax, it is clear that the major part of disposable profit, both in the aggregate and in each ownership category, is ploughed back. (Table 15). Comparison between 1962 and 1964 is difficult owing to the difference in coverage but, on the whole, it does appear that the companies have stepped up their retention percentages. It also appars that the emphasis on retention in this sample of private companies is much greater than in the Reserve Bank sample of 32 public pharmaceutical companies (Table 16).

PROFITABILITY

Profit and loss accounts in 1964 are available for 85 companies. Excluding 38 wholly Indian owned companies which had accumulated losses in that year, the remaining 47 companies earned after tax 24 per cent on net worth and 10 per cent on sales (net of excise). Their cash earning (profit after tax but before depreciation) was 31 per cent on net worth or, to put it in simple terms, they were recovering their investment in about three years. As between the various categories, the wholly foreign owned companies were earning a cash profit which would fetch their investment back within two years; the foreign majority companies were taking a little more than four years to do so while wholly Indian owned companies would take as long as seven years though in the case of the last group the ratio of cash earnings to net worth shows a steep decline from 1962 (Table 18).

Comparable data for both 1962 and 1964 are available for 40 companies. These show a slight decline in profitability between the two years which might be due in part to the freezing of drug prices in 1963. The brunt of this decline was borne by companies under Indian control and with Indian minority participation. The wholly foreign owned companies, on the other hand, improved their profitability further between 1962 and 1964.

The profitability of private pharmaceutical companies in Maharashtra compares very favorably with that of pharmaceutical companies in the Reserve Bank samples of both public and private companies; it is nearly twice the profitability of RBI public companies (Table 17).

INDIVIDUAL PROFITABILITY

The individual profitability of 24 foreign controlled companies is shown in Table 19. The profit on net worth ranges from 130 per cent to 6 per cent, but relative profitability is not closely related to sales or assets. In general, it appears that, on the whole, there was some decline in the profitability of these companies between 1962 and 1964, but this was confined to US, Swiss and French companies. British and German companies actually improved their profitability during this period (Table 20).

GROWTH

Betwen 1958 and 1964, the gross fixed assets of 31 identical companies (this number excludes Glaxo, the largest company) increased about 5 times, from Rs 278 lakhs to Rs 1453 lakhs. The highest growth was that of foreign majority companies from Rs 110 lakhs to Rs 819 lakhs. Wholly Indian owned companies yearly growth rates of foreign associated companies are given in Table 21. The spurt in investment took place in 1958-60 and was substantially supplemented by the entry of new companies which are not included in Table 21. The growth rate has remained impressive since 1960.

Data on growth of sales are available only for 1962-64 (Table 18, col 7). Over these two years, sales of 40 identical companies expanded by 27 per cent. The expansion was 20 per cent in wholly foreign owned companies, 32 per cent in foreign majority, 37 per cent in Indian majority and only 5 per cent in wholly Indian owned companies.

SUMMING UP

The analysis in this paper suffers from two main limitations. Some of the major pharmaceutical companies have non-pharmaceutical business which can-

not be segregated in the available financial statements. And, comparable data are not available for all companies for the entire period.

Most of the pharmaceutical manufacturing business in Maharashtra carried on by private limited companies is under foreign control, mainly American, British and Swiss. Most of the companies are Indian owned but these are mostly small trading enterprises and include many with accumulated losses.

The proportion of Indian directors in foreign controlled companies is fairly high.

About 73 per cent of the share capital of the sample companies is owned by foreign companies and individuals. Indian companies hold 14 per cent, and the rest is owned by Indian individuals, led by Gujarati-speaking communities.

Total foreign investment in the sample amounted in 1964 to Rs 26 crores, comprising paid-in cash share capital Rs 7 crores, bonus and non-cash share capital Rs 4 crores, reserves Rs 13 crores and unsecured loans Rs 2 crores.

Retained profits have become more important as a source of finance between 1958 and 1964 and the proportion of fixed to total assets has risen consistently. During this period, only about one-half of gross total funds raised were, however, fixed investment and working capital absorbed the balance.

In 1964, 47 companies (excluding those wholly Indian owned with accumulated losses) were earning after tax 24 per cent on net worth and 10 per cent on sales. The wholly foreign owned companies were earning a cash profit (profit after tax before depreciation) which would fetch their investment back within two years. The foreign majority companies were taking a little more than four years to do so. The profitability of this sample compares favourably with that of companies in the Reserve Bank samples of public and private companies.

Gross fixed assets increased about 5 times between 1958 and 1964, the highest growth being in foreign majority companies. There was a spurt in investment in 1958-60. The growth of both investment and sales has remained impressive since 1960.

LIST OF PHARMACEUTICAL COMPANIES, 1964

(A) WHOLLY FOREIGN OWNED

(1) Abbott Laboratories.
(2) Boots.
(3) British Drug.
(4) Burroughs Wellcome.
(5) Franco Indian.
(6) Glaxo.
(7) May and Baker.
(8) Pfizer.
(9) Raptakos Brett.

(B) FOREIGN MAJORITY, INDIAN MINORITY

(1) Anglo French Drug.
(2) Bayer India.
(3) Boehringer Knoll.
(4) Ciba.
(5) Cilag Hind.
(6) Cynamide.
(7) Evans Medical.
(8) German Remedies.
(9) Johnson and Johnson.
(10) Merck, Sharpe, Dohme.
(11) Parke Davis.
(12) Roche.
(13) Sandoz.
(14) Wyeth.
(15) W T Suren

(C) INDIAN MAJORITY, FOREIGN MINORITY (INCLUDING 50:50)

(1) Alta.
(2) Excel Industries.
(3) Geoffrey Manners.
(4) Hoechst.
(5) Francis Klein.

(DP) WHOLLY INDIAN, PROFIT MAKING

(1) Alarsin.
(2) All India Herb Supply.
(3) Chremosyn.
(4) D K Sandu.
(5) Delhi Pharm Dist.
(6) Dr Sahib Singh.
(7) Enzo Chem.
(8) Fair Deal.
(9) Hico Products.
(10) Indo Pharma.
(11) K P Motilal.
(12) Mac Lab.
(13) Navshakti Ayurvedic.
(14) Neo Pharma.
(15) Pathological Labs.
(16) Pharmax.
(17) Pharmpak.
(18) Poly Pharm.
(19) Semit Products.
(20) Zenith Chemical.

(DL) WHOLLY INDIAN WITH ACCUMULATED LOSSES

(1) Alpha Lab.
(2) Amba Tannin Pharma.
(3) Apollo Lab.
(4) Arcies Lab.
(5) Ar-Ex Lab.
(6) Ayurvedic Dhanwantray Pharm.
(7) Asian Agencies.
(8) Bharat Rasashala.
(9) Bombay Drug House.
(10) Bombay Pharmacy.
(11) Bombay Surgical and Medical.
(12) Chem Drugs.
(13) Chemica India.
(14) Choonilal Dahyabhai.
(15) Continental Drug.
(16) Deelabs.
(17) Deenbandhu.
(18) Eisen Pharm.
(19) Ethical Products.
(20) Farmaxin.
(21) Health Products.
(22) Indye Kem.
(23) Kalpatru Ayurvedic.
(24) Kab Pharma.
(25) Lakdawala.
(26) Lenec Institute of Pharm.
(27) Lyra Pharma.
(28) Neo Pharma Industries.
(29) Oriental Medical and Surgical Stores.
(30) Patel Pharm.
(31) Pharma Medico.
(32) Ruma Laboratories.
(33) Sunways.
(34) Syncoma Lab.
(35) Thilo Mody.
(36) Vibro Pharma.
(37) Worli Chemicals.
(38) Aurum Pharm.
(39) Bombay Oriental Chemical.

(Whereupon, at 12:55 p.m., the subcommittee adjourned, to reconvene at 10 a.m., on Tuesday, August 11, 1970.)

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

(Present Status of Competition in the Pharmaceutical Industry)

TUESDAY, AUGUST 11, 1970

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

The subcommittee met, pursuant to recess, at 10:10 a.m., in room 318, Old Senate Office Building, the Hon. Gaylord Nelson (chairman of the subcommittee) presiding.

Present: Senators Nelson, Hatfield, and Dole.

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

Senator NELSON. We will open the hearings this morning. Our witness today is Mr. Donald E. Johnson, the Administrator of Veterans' Affairs.

Mr. Johnson, the committee welcomes your appearance here this morning. Your statement may be printed in full in the record and you may present it however you desire.[1] If you wish to extemporize from it or add to it from time to time, or if you wish any of your associates from the department to make additional comments, feel free to do so. I assume you have no objection to being interrupted for questions, as you go along.

STATEMENT OF HON. DONALD E. JOHNSON, ADMINISTRATOR OF VETERANS' AFFAIRS; ACCOMPANIED BY JOHN J. CORCORAN, GENERAL COUNSEL; ALFRED T. BRONAUGH, ASSOCIATE GENERAL COUNSEL; OF THE DEPARTMENT OF MEDICINE AND SURGERY: DR. BENJAMIN B. WELLS, DEPUTY CHIEF MEDICAL DIRECTOR; DR. PAUL A. L. HABER, DIRECTOR, EXTENDED CARE SERVICE; DONALD P. WHITWORTH, DIRECTOR, SUPPLY SERVICE; CLYDE C. COOK, DEPUTY DIRECTOR, SUPPLY SERVICE; ROBERT A. STATLER, DIRECTOR, PHARMACY SERVICE; AND ROLAND F. HARDING, CHIEF, DRUGS AND PHARMACEUTICALS DIVISION

Mr. JOHNSON. Thank you, Mr. Chairman, and members of the committee.

[1] See complete prepared statement beginning at p. 7473.

I welcome the opportunity to appear before this subcommittee to describe to you the policies and practices of the Veterans' Administration in the selection and procurement of drugs and to acquaint you with the role we play within the Federal Government in this important field of medicine.

I would like, Mr. Chairman, at this time to introduce those who are accompanying me to this hearing.

First of all, to my immediate right is Dr. Benjamin B. Wells, the deputy chief medical director.

In addition we have Dr. Paul Haber, director of the extended care service;

Donald P. Whitworth, director, supply service; Clyde Cook, deputy director of the supply service; Robert A. Statler, director, pharmacy service; Roland F. Harding, chief, drugs and pharmaceuticals division; John J. Corcoran, our general counsel; and Alfred T. Bronaugh, associate general counsel.

As the Administrator of Veterans' Affairs, I am directing an agency which is the largest Federal consumer of drugs and medicines outside the military.

In fact, except in times of war or major military action, we are the largest Federal consumer.

In addition, by delegation and assignment under the Federal Property and Administrative Services Act of 1949, as amended, we are the commodity manager for all nonmilitary users. Our procurement and contracting for this commodity thus provides logistical support for many Federal programs as well as for the Veterans' Administration medical and clinical programs. I will describe in some detail the operations of our program, which may serve to amplify the meaning of the data already provided this subcommittee.

As a small businessman myself for a number of years, I personally as well as officially wholeheartedly subscribe to the principles of the Small Business Act (15 USC 631), particularly section 2(a) which provides that a fair proportion of Federal procurement shall be from small business. The data furnished to this subcommittee might lead to the conclusion that a rather small proportion of the Veterans' Administration drug procurement is from small business.

I would like to supplement that data with the information that of all our drug purchases from both central procurement and individual hospital procurement 16 percent of our dollars are spent directly with small contractors.

Senator NELSON. May I interrupt? Is that 16 percent of your hospital procurements of all drugs, or are you including other items?

Mr. JOHNSON. We are dealing entirely here with drugs and pharmaceuticals.

Mr. GORDON. Mr. Chairman, the staff broke down the figures given by the Veterans' Administration and we found the following:

During the fiscal years 1968 and 1969, the Veterans' Administration purchased over $91 million worth of pharmaceuticals. This is on the basis of the data the VA gave us. Of this amount only $2.1 million or 2 percent involved purchases where actual competitive bidding took place, $1.3 million or 65 percent, that is, 65 percent of that 2 percent, went to small firms, and approximately $744,000 or 35 percent went to large firms.

The figures on pharmaceutical purchases and figures on competitive bidding provided by the VA were, we felt, inflated, since both included purchases of nonprescription drugs such as aspirin, alcohol and other such commodities.

Dr. WELLS. Well, we are going to come to that, Mr. Gordon, just a little later, but I think Mr. Whitworth should address himself to that at this point.

Mr. WHITWORTH. Well, Mr. Gordon, you realize, sir, that the information you received was only on about 50 percent of our total purchases, those from our national purchasing program.

Now, this 16 percent, sir, is both central procurement and the other 50 percent, which takes place outside our national procurement program.

Senator NELSON. You are talking about the drugs procured for veterans who are not in hospitals?

Mr. WHITWORTH. Not entirely, sir. We buy about 50 percent of our drugs on a national basis, stock them in our depots and locally, about 50 percent. Our central purchasing is the information we previously furnished this committee. For the other 50 percent, the orders are placed by our 166 hospitals, against open end contracts let by the national organization, or drugs bought locally on the local market. Some of this latter 50 percent, that which the hospitals themselves placed orders for, you did not get small business information on the specific data we furnished. It would have taken too long for us to have gotten it for you.

Senator NELSON. Then on the 50 percent that is purchased centrally by the Veterans' Administration, about 1¼ percent, a little less, is purchased from small businesses?

Mr. WHITWORTH. Well, Mr. Gordon used the term of $91 million. For the $91 million the 16 percent applies, yes, sir. To that portion which is centrally procured and covered by the information we have previously supplied you, the 16 percent does not apply.

Mr. GORDON. We are concerned in these hearings with small drug manufacturers.

Mr. WHITWORTH. Yes, sir.

Mr. GORDON. We are not considering drugs bought from a small drug store.

Mr. WHITWORTH. That is not what we are talking about.

Senator NELSON. So that I have it clear, do you include in your 16 percent, purchases made from retail pharmacists?

Mr. WHITWORTH. No, sir. These are from manufacturers, and we go on further, I think, in the Administrator's statement to comment upon the possibility of some of that which is bought from the small retailer or wholesalers where actually they were manufactured by large manufacturing firms.

If you listen to that part of the whole statement, sir, this part may become clear. I may be wrong, but I think it will. Our 16 percent applies to our total procurement program, the $91 million.

Senator NELSON. And you are saying that 16 percent of all drug purchases are drugs manufactured by a small business drug manufacturer?

Mr. WHITWORTH. Some of that is an estimate, sir, but that is our

best estimate from small business—from small business manufacturers.

Senator NELSON. This documentation does not appear in the contracts you submitted to us. We end up with 1¼ percent. Where is the discrepancy?

Mr. JOHNSON. Sir, the discrepancy is in this area, that the data that you have is approximately 50 percent of the total purchases made by the VA, the 50 percent that is made through the central office and is deposited in the depot centers, of which we have three.

The hospitals and clinics also have the authority to make purchases of drugs and can do so on their own initiative as they are needed, and this 50 percent, we were unable to furnish you within the time span, the data, the detailed data which you requested.

Senator NELSON. But do I understand that you are saying that by the hospital purchases that you achieve this 16 percent?

In other words, your central purchasing out of the Veterans' Administration is only about 1¼, 65 percent of the 2 percent?

Why is that so low when you say that you have such a high percentage of acquisition of drugs from small businesses done by the individual hospitals?

Mr. WHITWORTH. Sir, most of the hospital purchasing is done from open end Federal supply schedule contracts made by the Veterans' Administration, and many of these are with small manufacturers. So, the percentage is rather higher there than it is on our national basis.

Senator NELSON. Why would it be higher there?

Mr. WHITWORTH. Well, we are dealing in larger quantities in the national program, and we are dealing in many cases with a sole-source drug that is produced by a large manufacturer. Actually, 80 percent plus, sir, of our drugs, in the 50 percent we have furnished you, are sole-source items, and mostly from big business. About 80 percent of that which you have information on are sole source items, and most of those sole-source items are manufactured by other than small business.

Mr. JOHNSON. Sir, I think also that it would be true that open-end contracts with small business, small contractors, are very appealing to them because it allows them to spread their manufacturing distribution over a period of time, and this is the kind of contract that we use with the individual hospital that can order against that open-end contract.

Senator NELSON. We have some more questions later on sole-source purchasing, but we will get to that further on.

Please continue.

Mr. JOHNSON. Thank you, sir.

An additional 5 percent is for prescriptions purchased from local private pharmacies, almost all of which are small businesses; and a significant proportion of the remaining 79 percent, although the product of large manufacturers, may be procured from small business distributors and drug wholesalers. This is not the optimum situation for the Veterans' Administration, and I shall see that strong and sincere efforts are extended to improve our posture in support of small business.

Unfortunately, as the chairman and members of this subcommittee well know, the procurement of drugs is considerably more complex and complicated than almost any product purchased both for Federal and private programs.

It has been fraught with controversy and is not free from strongly held divergent opinions. It is an area in which those of opposing views can find competent expert opinions in support of any particular viewpoint as to the safety, efficacy, relative therapeutic merits or—to use a term not often related to human life and health—the cost effectiveness of any given drug, drug manufacturer or therapeutic drug category.

It is an area which, as the Administrator of this large drug-consuming agency, I am convinced does not offer "pat" or unequivocal answers.

It is within this framework that the policies on the selection and procurement of drugs evolve within the Veterans' Administration.

The administrative process does not dictate the selection of drugs which will be prescribed and dispensed in our Veterans' Administration hospitals and clinics. We consider that the judgment of the physician is paramount to all other considerations in the drug selection process.

Senator NELSON. What physician?

Mr. JOHNSON. The VA physician, the physician that is an employee of the Veterans' Administration, as well as those who are on a fee basis with the VA, and I think we come later on to tell you what our policies are, sir, within the VA and what controls we do have.

Senator NELSON. When you say the judgment of the physician, you mean the individual physician who is prescribing for his particular patient?

Mr. JOHNSON. Yes, sir.

Senator NELSON. And that the judgment of that individual physician is paramount to all other considerations?

Mr. JOHNSON. Yes, sir.

Senator NELSON. What is the individual physician's qualifications for making an expert judgment about this whole range of drugs as versus the therapeutic committee?

Mr. JOHNSON. Dr. Wells.

Dr. WELLS. In our VA hospitals we have just over 5,000 physicians about whom we know the qualifications. They also work with the therapeutics committee at the hospitals. This is a fairly well controlled group of people from the standpoint of qualifications.

On the other hand, we use, in addition, approximately 90,000 physicians who prescribe on a fee basis, outpatient to veteran patients. These physicians are physicians of the community. Their qualifications are those that usually pertain to the licensed practitioners who are a member of organized medicine.

Senator NELSON. I have a series of questions along that line but I guess we had better proceed with the statement, and I will get to them later.

Mr. JOHNSON. Thank you, Mr. Chairman.

In this agency his judgment is not made as a matter of unen-

lightened preference in an information vacuum. Supplementing his own knowledge and the sources of information is the approval process at both the local hospital and national agency level.

He is also supported by technical and scientific data provided by our pharmacy service and cost and market data provided by our supply service.

I would like to digress slightly to call the subcommittee's attention to the unique and extensive affiliation program between the Nation's medical schools and the Veterans' Administration. This affiliation program provides us with a vast body of fresh information on both laboratory and clinical research, pharmacological studies, new drug developments, in a more comprehensive and timely manner than otherwise might be available. We make full use of this information and do not, as some have charged of private physicians, rely primarily upon promotional and advertising sources for knowledge of drug products.

Senator HATFIELD. I would like to interrupt at this point, Mr. Chairman. I would like to first of all commend you on your digression here, because I think it is a very fundamental point that you are making. I am not sure you are aware of some comments I made on July 6 which are recorded in the record, and I would like to quote from that:

> Several critical VA programs have been neglected because of funding crises. One way to improve medical care in the VA hospitals would be to intensify and expand affiliations between VA hospitals and medical schools. However, valuable programs between medical schools and VA hospitals are dependent upon the assumption that facilities and equipment are comparable at each of the institutions.

Could you expand a little bit on this, because I think this is, frankly, one of the most important ways in which we can improve and expand the Veterans' hospital programs. You are aware of the physical proximity of the Veterans' hospital in Portland, Oreg., to the University of Oregon Medical School, and I know somewhat of the exchange there and the working relationship between the hospital and the medical school.

Are there specific plans that you have in mind to expand this kind of working relationship in other parts of the country?

Mr. JOHNSON. Senator, 79 of the 101 medical schools in the United States are now affiliated in some manner with VA hospitals. It is the policy of this Administration, Dr. James Musser, who is the Chief Medical Director, and myself, that all possible will be done to enhance the relationship and the affiliation. I think I should add at this point that this is not confined entirely to the medical schools, that there are many schools of allied health sciences and, in fact, today it numbers something over 500 affiliations that we have, nursing schools, dental schools and the like, all kinds of activities; that particularly in those general medical and surgical hospitals, the highly active and acute hospitals as well as the psychiatric hospitals, we are meeting constantly with the Council of Deans of the medical schools of the United States, searching for ways in which we can enhance the affiliation, and we are asking for certain legislation now to allow us to expand our sharing agree-

ments, particularly of equipment, which is one area that we can make the medical dollar go further, and this would also go with personnel, as well.

As we move into this very active area of specialized medical services, to use one example, kidney transplant, or organ transplantation, for example.

That we can justify only, not only in terms of dollars but available personnel, as a team that can work both at the university hospital, or what other general hospital that might exist, with the university and the VA hospital in order to fully utilize not only their equipment, but their expertise, and I believe that there is a fine rapport in relationship that has been encouraged very much with the meetings that both Dr. Musser and myself have had with the deans of the medical schools.

Dr. Musser came on board January 2 of this year, and immediately launched into a program of meetings, and we held five regional meetings with the medical deans or their representatives in order to underscore our concern and our desire to move forward in this area that you so eloquently spoke to.

I think perhaps Dr. Wells might have something to add, because he is the professional man and a former member of several faculties.

Dr. WELLS. Well, 93 of our hospitals are affiliated, as Mr. Johnson says, with 79 medical schools. There are 101 medical schools at the present time in some state of existence. We are in negotiations with approximately 20 of the newly developing medical schools, all of whom want to establish an affiliation with VA hospitals.

Mr. JOHNSON. I might say, Senator, if I may interrupt here, that in trying to meet this national problem of medical personnel, that for example in Shreveport, La., at our campus, the VA campus there will be a new medical school established in cooperation with HEW and other agencies that are supplying some funds. We believe that this might be one way in which, so far as MD's are concerned and the expansion of classroom space, that we can work very well so that there can be a quick acceleration of the available medical schools.

Senator HATFIELD. Let me ask you a question in the area of specialties relating to the possibility of expanding relationships with other than Federal programs, such as State programs. There are two areas.

One is the area of mental health and the mental institutions that the VA operates. What kind of working relationships have you developed there, or are you developing, between the VA hospitals of that type and State or private mental hospitals?

Mr. JOHNSON. I am going to let Dr. Wells speak to this. I would say that we are cooperating with State agencies and in some instances city governments and outpatient mental health clinics and so on.

In fact, we are even letting some of our doctors become involved in those programs on an active basis.

Dr. WELLS. We have a full State hospital program that we support, Senator Hatfield, that is important in this area. I might call on Dr. Haber in a moment, but let me say the policy has been now for some years to move out of the area of purely mental hospitals and to establish psychiatric units in our general mental hospitals.

Now, this has, we believe, led to much better care in that setting than in the mental hospital—and the hospital usually relates to the medical school or the community through a medical advisory committee.

In addition to these affiliated hospitals that Mr. Johnson spoke of, 20 of our hospitals operate under a medical advisory committee which then relates that hospital to the community.

Senator HATFIELD. Do you plan, then, to move away from the strictly isolated mental hospital, as such, toward an integrated medical center program?

Dr. WELLS. We would hope to. We think this is a much more stable pattern and it is a way in which we can relate ourselves to the State and local hospitals and to the mental hygiene program of the entire country.

Senator HATFIELD. The other area is the specialty in the field of geriatrics. What are you doing here with respect to a program that would necessitate less than full hospital care but would be more involved, say, in nursing care and others?

Mr. JOHNSON. Senator, Dr. Haber is here, who is in charge of that whole program, and I would let him speak to this.

I do want to preface his remarks by saying this is one of the areas in which I have exhibited particular interest, based strictly upon statistics available that say half of our veterans are World War II veterans whose average age is 50 years of age, and we have been operating, for example, under a 6,000-bed ceiling for nursing home type beds, and we have made request now to expand that, and in our future projections and studies which I initiated last September, there will have to be a dramatic increase in the number of beds available in this decade of the 1970's.

I might say, too, and the doctor might not want to say this, that this is an area in which we need some assistance from anyone of influence, including the U.S. Senate with the medical schools to get them to have an interest in this particular kind of care. Of late, fortunately, there has been some opening on the part of the medical schools in taking an interest, particularly those training general practitioners, because it is found that a great deal of the general practitioner's time is spent with patients of the nursing home type.

Senator HATFIELD. I did not want to discuss too long, but I just want to say in response to your statement that you are planning some expansion of this program, that if there is some legislation that you are preparing, I would be interested in seeing it.

Mr. JOHNSON. Senator, I would be very pleased to send to you our study, which was completed on this, and will do so to your office.

Senator HATFIELD. Why don't you go ahead.

Senator NELSON. Yes, please continue.

Mr. JOHNSON. The process of drug selection begins at the individual Veterans' Administration hospital. When one of our physicians proposes to add a new drug product to those approved for use, he presents his proposal to the therapeutic agents and pharmacy review committee.

This committee, consisting of representative members of the professional, technical and administrative staff meets at least monthly to review the drug selection process. Before approving a new product, the committee considers available date on the item's safety,

efficacy, known side effects, adverse reactions, extensiveness of use in the medical community, and evaluates these factors together with data on duplication of drugs already approved for local use, the cost of therapeutically equivalent drugs, the ready availability of sources for both routine and emergency deliveries.

After considering all these factors, the committee in approving the drug, will direct a period of clinical evaluation followed by its inclusion in the station's drug formulary, which is available to all physicians on the staff, at every nursing station, and is provided to non-Veterans' Administration physicians prescribing for eligible veteran beneficiaries both in and out of our hospitals.

If the committee does not concur in the proposal, the drug may be approved for use by the physician for a specific patient, but it would not be used for additional patients without subsequent review by the committee for each such patient and it would not be described or listed in the station's drug formulary.

The results of each station's local committee proceedings are reported in detail to the central office executive committee on therapeutic agents.

This central committee provides an overview of the agency operations, provides guidance and assistance to individual hospital committees, and digests and disseminates data to Veterans' Administration personnel through a variety of media.

In considering the selection process of drugs procured by the Veterans' Administration, a little known fact must be borne in mind. The historical picture of drug usage by this agency is one of providing drugs and medicine to hospitalized veteran patients.

We formerly provided a limited amount of drugs from our own pharmacies or through financial reimbursement to private pharmacies for outpatients.

Several recent legislative actions have extensively increased the number of veterans who are to receive drugs and medicines at Government expense.

In fiscal year 1968, for the first time in this agency's history, the total expenditure for drugs provided outpatients exceeded that provided inpatients. This trend has steadily increased in fiscal years 1969 and 1970 and is projected to continue upward.

Many of the prescriptions for these drugs are written by private physicians. Although we provide these physicians with data on our drug selections and our formularies, we cannot, and do not, attempt to control their professional practice by administrative direction.

This growing outpatient workload has increased the number and kinds and brands of drugs purchased by the Veterans' Administration to fill these prescriptions.

This subcommittee has in the past expressed the view that the purchase of drugs on a "generic" basis should be increased. We interpret this to mean the procurement on a competitive basis of drugs formulated of the same primary chemicals. It is the official policy of this agency to request and encourage physicians prescribing for our inpatients and outpatients to use generic terminology or nonproprietary nomenclature whenever possible.

The two forms used by physicians to order medications for patients, VA form 10–1158 "Doctors Orders" and VA form 10–2577d "Prescription Form," contain statements authorizing dispensing of

another brand of a generically equivalent product, identical in dosage form and content of active ingredients. If the prescribing physician does not agree to the use of a generic product he must check in the appropriate place provided on the form.

This encourages him to use the generic product but permits him to express his professional right to prescribe a particular item if he feels he can justify the request.

When we can be assured of effective safeguards to adequately assure that chemically equivalent drugs are also biologically and therapeutically equivalent, we promote actively the use of generically produced drugs.

At this time in the critical review and challenge of our historical methods of assuring the safety and efficacy of drug products, we are proceeding with greater caution. There is increasing evidence that many of the drugs marketed for some years as chemically equivalent drugs meeting USP or NF standards will not produce the same clinical response in patients. I am certain this subcommittee is aware of the National Academy of Sciences/National Research Council "white paper" which recommended that manufacturers of generic drugs available on the market for some years be required to prove that their products have the same therapeutic effectiveness as the original drugs they seek to imitate.

As I stated earlier, this entire area is one in which there are divergent views. The promotion of generic equivalent procurement and the criticism of marketing of so-called "me too" drugs is an example of the dichotomy of views.

Generically equivalent drugs almost universally enter the market as "me too" drugs.

Mr. GORDON. Mr. Johnson, may I interrupt for a moment? On the top of that page you say:

> There is increasing evidence that many of the drugs marketed for some years as chemically equivalent drugs meeting USP or NF standards will not produce the same clinical response in patients.

Would you please name these drugs?

Mr. STATLER. An example, Mr. Gordon, is chloramphenicol.

Mr. GORDON. That was a question of blood levels, and there was never any evidence to show that some were not just as good as others from a clinical point of view.

Senator NELSON. That is a batch-tested drug anyway. Do you have——

Mr. STATLER. But, the therapeutical response was not the same in all instances from company to company. We have in our VA an example, tetracycline.

Mr. GORDON. Is this on oxytetracycline?

Mr. STATLER. No, tetracycline hydrochloride, it was reported the patient was not getting the desired clinical response with this particular brand.

Senator NELSON. The statement suggests that clinically equivalent drugs meeting USP or NF standards will not produce the same clinical response in patients. Do you have any examples?

Mr. STATLER. Another example is Theophylline, a formulation for asthma. It has been documented in clinical case abstracts that with the use of Theophylline you do not always have produced the same

clinical response in a patient, you do not get the immediate relief of the asthmatic attack. For example, we have cases where the tablet will not produce the response in the patient because they did not dissolve in the patient and were passed through.

Senator NELSON. That obviously did not meet the USP standard if it did not dissolve. The USP standard requires a certain dissolution rate.

Mr. STATLER. I beg to differ. It did meet the USP standard and it met the so-called in vivo tests, disintegration tests, but in actual practice in the patient the physicians were documenting that the drug was passing through the patient undissolved and, therefore, was not producing therapeutic response.

Mr. GORDON. Could this be due to the patient?

Mr. STATLER. There are physiological differences in make-up of the patients, and this could be, but they have tried no controlled test. But, other drugs have produced the same response.

Mr. GORDON. Have you done any double blind control tests which indicate that certain brands of, let us say, tetracycline——

Mr. STATLER. Not on a daily treatment. Research programs——

Mr. GORDON. You have done no double blind studies to show that?

Mr. STATLER. No; we do not do this in patient treatment. This is reported in other cases of clinical pharmacologists on double blind studies.

Mr. GORDON. Could you give us the studies to which you refer which show that the drugs marketed are such?

Mr. STATLER. These are alluded to, of course, in the white paper produced by NAS–NRC.

Senator NELSON. What white paper is that?

Mr. STATLER. The white paper on the generic equivalency that is alluded to in the National Academy of Sciences and National Research Council, that not all drugs are therapeutically equivalent and do not produce the same therapeutic response.

Senator NELSON. I think that is an entirely different question. Is that not referring to the NAS–NRC study in which they made certain recommendations, for example, that all mixed combination antiinfectives be removed from the marketplace? Is that it?

Mr. STATLER. No; I am referring to the paper that is alluded to as the white paper, as published in the Journal of the American Medical Association in which it was pointed out that not all drugs being chemically equivalent produced the same therapeutic response in all patients.

(The information referred to follows:)

[From the Journal of the American Medical Association, Vol. 208, No. 7, May 19, 1969, pp. 1171–72]

SPECIAL COMMUNICATION—WHITE PAPER ON THE THERAPEUTIC EQUIVALENCE OF CHEMICALLY EQUIVALENT* DRUGS

(Prepared by a subcommittee of the Policy Advisory Committee, Drug Efficacy Study)

Recent reports of considerable variation in the serum levels, and therefore in the probable biological activities, of equal doses of certain drugs marketed by different manufacturers, focus attention upon an important determinant of

* Drugs that meet the current standards of identity, purity, and quality, and quality of the active ingredients established by competent authority.

drug efficacy. These variations indicate that therapeutic equivalence, or equal biological activity, cannot necessarily be inferred from equivalence in the chemical institution of different formulations of the same drug. In the Drug Efficacy Study, it has been found that, in many cases, no data bearing on biological activity of chemically equivalent drugs are available other than those submitted by the manufacturer who originally filed a New Drug Application for his product. For this reason, the following qualifying addendum was approved by the Policy Advisory Committee of the Drug Efficacy Study and was forwarded to the Food and Drug Administration with each of the 26 groups:

"Drugs of identical chemical composition (so-called generic drugs) formulated and marketed by numerous individual firms under generic or trademarked names have been evaluated for efficacy as a group without consideration of 'therapeutic equivalence.' In the event that no evidence for pharmacological availability or therapeutic efficacy in man can be presented for any of the drugs in the attached listing, their classifications of effectiveness may need to be modified if future regulations of the FDA require such proof."

This statement defines the problem but offers no solution. Theoretically, biological tests in man of every formulation of a drug would be needed in order to establish proof of therapeutic equivalency. In many but not all instances, blood levels might be a satisfactory index of therapeutic activity as well as of the absorption of oral preparations. Furthermore, if appropriate chemical or physical tests should be found to correlate consistently with serum concentrations, these in vitro tests might be substituted for the more burdensome tests in animals or man. Indeed, blood levels in animals can be acceptable tests only if they correlate with comparable observations in man. The more potent the pharmacodynamic action of the drug, the more imperative would be the need for proof of the equivalence of biological and physical or chemical tests.

The Policy Advisory Committee of the Drug Efficacy Study is aware that consistent evidence of therapeutic equivalence of oral preparations, even when based upon simple study of blood concentrations in man, might require the testing of each lot of each formulation and so become a large-scale clinical operation requiring consent of large numbers of patients and volunteers. A strict interpretation of therapeutic equivalence might even require biological tests of individual capsules or successive batches of the drug selected at random.

Moreover, variation in biological response of individual subjects would seem likely to be greater than compositional differences among enteric-coated tablets or time-release capsules. Let us not deceive ourselves: if tests in human subjects constitute the only reliable method of demonstrating therapeutic equivalence, an unacceptably large burden will be imposed on drug manufacturers. Such biological tests may represent the most valid measure of comparative therapeutic activities, but the measure is one that is impossible of technical achievement by the pharmaceutical and medical professions.

What, in this less than perfect world, can be done? All producers of drugs should be required, as they are now, not only to provide evidence of composition, purity, and quality but also evidence of physical availability as judged by tests of disintegration, dispersion, and dissolution rates in appropriate solvents. In the majority of cases, this should suffice, but in every case in which there may be doubt of biological equivalence (eg, calcium added to tetracycline), biological tests should be required.

The exploration of possible chemical, physical, and animal tests that might satisfactorily be substituted for biological tests in man has already begun, and this should most certainly be encouraged. Particular attention is being paid to relatively insoluble drugs dispensed in solid forms as tablets or capsules. A Joint Panel of the United States Pharmacopeia and the National Formulary has been at work for some months on the development of standards and test procedures in vitro that will permit better definition of physiological availability. Biological data on the lack of therapeutic equivalence of various preparations of chloramphenicol recently dramatized this problem. Critical investigation of the chemical and physical properties of these preparations is currently in progress, and such investigations should certainly be encouraged.

The whole subject will require extensive scrutiny as well as close attention to process control of the uniformity of the chemical and physical properties of both generic and trademarked preparations. Appraisal of problems concerned with particular drugs will represent various degrees of medical, as well as technical difficulty. For example, are high blood concentrations of short dura-

tion medically more desirable than lower, more prolonged, concentrations? The decision would be quite different in the case of an antibiotic in contrast with an antiepileptic preparation. What if by such criteria a generic formulation turns out to be biologically superior to the original proprietary? What if blood concentrations cannot be measured?

With some drugs, there are reasonably good analytical methods for biological assays, whereas for others a meaningful test is virtually impossible at this time. Consequently, the problem of the biological equivalence of drugs should be approached expectantly and progressively. Critical evidence of chemical and physical equivalence is the first order of business. Obviously, new drugs and accepted drugs of greatest pharmacodynamic action or therapeutic importance may additionally require careful biological scrutiny.

It would seem reasonable for the FDA to require that the generic manufacturer submit, in addition to evidence of chemical equivalence and purity, data on dissolution rate and data from other in vitro tests demonstrating equivalency. However, if there is evidence that in vitro evaluation or animal tests do not correlate well with pharmacodynamic effects in man, there may been need to resort to clinical tests. In this way, the principle of generic prescribing based on therapeutic equivalence may become acceptable to the medical profession and be supported by the pharmaceutical industry.

W. B. CASTLE, M.D., *Chairman.*
E. B. ASTWOOD, M.D.
MAXWELL FINLAND, M.D.
CHESTER S. KEEFER, M.D.

Senator NELSON. I am puzzled about exactly what it means. The most distinguished pharmacologists in the country who have appeared before the committee have consistently taken the position that if the drug meets the USP and NF standards, they are equivalent. The only exception is that USP and NF may have missed something so that at some stage some excipient has a different effect from that of some other excipient for some reason or other. The testimony of the expert witnesses we have had is that the USP and NF standards are the best in the world, and for all practical purposes, drugs meeting their standards are equivalent. There are, I believe, about a half a dozen examples out of the thousands of drugs on the market which may meet USP standards and are not therapeutically equivalent.

That is the general position of Dr. Modell and a whole series of the most distinguished authorities in the country before this committee. Are you saying they are wrong?

Mr. STATLER. No, sir. We, in fact, use those sources and those references as a means for determining the drugs to be used in the VA, but there is a divergence of opinion among clinical pharmacologists as to the efficacy of certain equivalence of chemical drugs.

This is, of course, what we have alluded to. There are problems. Our physicians in our hospitals do weigh their clinical experience on the use on patients and do find from time to time that certain drugs do provide response to a better degree than others.

Senator NELSON. We have had testimonials like yours, but we have yet to have scientific evidence submitted. It is strange that in the 3½ years of our hearings we have not had any scientific evidence to show that where two drugs meet USP standards, the same compound, and yet they are not therapeutically equivalent. Do you have any clinical studies that demonstrate that? We wish that somebody would submit them if they are available, because we have not any yet.

Dr. WELLS. Mr. Chairman, I would concede that the conclusion that you have stated is the one we accept for the most part in medical services, that a drug that does meet these standards is likely to be an equivalent, and I really think that what we best do at this point is ask our pharmacy service to submit for the record any evidence that they have that this has not proved to be true.[1]

Senator NELSON. With respect to the widely cited case of chloramphenicol, the specific testimony of the Commissioner of the FDA, was simply that additional brands of chloramphenicol that came into the marketplace simply did not achieve the same blood level within the same time period as Chloromycetin did.

Commissioner Ley's testimony was that there was no evidence that one was more efficacious than the other. One achieved the blood level in a certain shorter time than did the others, but there was no clinical evidence that the therapeutic effect, in fact, was any better for the one that achieved a higher level more quickly. However, the FDA position was that since the first one in the marketplace achieved a certain blood level in a certain length of time they wanted consistency in the achievement of blood levels, so any chloramphenicol could be used and there would not be any differences.

It is not really a case of saying that they were not therapeutically equivalent because to date there have been no clinical tests to demonstrate that this is so. This is the testimony we have from the FDA.

So, that is not a valid example. But, the committee, for the record, would be interested in receiving any clinical tests which demonstrate that two drugs meeting USP standards were not clinically equivalent. We have yet to get this material from the witnesses that we have had.

Dr. Goddard, the former FDA Commissioner, stated that there probably have been a half a dozen such cases. All it means is that the best experts in the country, including the drug companies who participated in establishing the standards, omitted something that they did not understand at the time and then, of course, it was necessary that that be corrected.

The U.S. Pharmacopeia and the National Formulary have the best established standards and exceptions are rare. Frequently we hear that stated, as there were many such cases. I would think this would require some evidence, if it does indeed exist, I would like to have it furnished to the subcommittee.

Dr. WELLS. Mr. Nelson, we do not conduct clinical studies that pertain to this field, but we will have our pharmacy service submit literature on which this statement was based.[2]

Senator NELSON. I think we probably have all of the literature but if you have something that we do not have, we would like to have it for the record.

Thank you. You may proceed.

Mr. JOHNSON. Senator, taking your initial suggestion, and for those who are following the written text, I will skip the last paragraph on page 6, because I think we have covered the balance of that other paragraph.

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[1] No such information was supplied by the Veterans' Administration.
[2] See subsequent information beginning at p. 7478.

Your staff has expressed interest in our policy toward the use of combination drugs. It is our policy to discourage the use of these drugs. We do not prohibit their use when the prescribing physician determines that a combination drug is required for his patient. It is noteworthy that over 86 percent of the expenditures in our central drug program were for single entity drugs during a period when the combination drugs were enjoying an increasing share of the national market.

We, of course, continually monitor our drug program to guard against use of drugs producing previously unsuspected adverse reactions. We participate in the Food and Drug Administration's adverse reaction reporting system, both providing and receiving data from them on a regular basis.

Information on adverse reactions is promptly disseminated to our hospitals and clinics and drug recalls handled through a system of double safeguards.

In addition to the notifications provided through the FDA drug recall system, we also inform our stations on those items which are standardized for our use.

There have been several instances lately where either the safety or effectiveness of specific drugs have been called into question prior to actual suspension or recall. We alert our hospitals and clinics to these by special announcements, telegrams, or other prompt notifications. If these items are procured through our central procurement program, we either discontinue procurement or purchase minimum quantities to meet only immediate needs pending resolution of the controversy.

The decision as to continued use of a product under special review is left to the prescribing physician, but with the assurance that he is fully informed of any findings about the possible continued marketing of the drug.

There is widespread evaluation under organized and controlled studies in the Veterans' Administration into the uses of and efficacy and safety of drug products. In addition to these organized individual and cooperative studies, there is continuing evaluation in the everyday practice of medicine by our staff of 5,000 physicians. The dissemination of the knowledge from these sources has continually contributed to the improved health care not only of veterans but the entire Nation.

Several major medical breakthroughs, such as the chemotherapy used in treatment of tuberculosis, either originated in our Veterans' Administration medical research or were possible because of our cooperative ventures with medical and pharmacological inquiries initiated by others.

Turning to our procurement practices, I would like to again emphasize that the question of selection of which specific drugs will be procured is a professional and not an administrative decision. The responsibility of our procurement staff located within the supply organization is to purchase the drugs selected for use at the lowest cost, to assure their distribution to our pharmacies in an efficient and timely manner and to provide quality control and inspection processes during manufacture needed to insure that drugs

meet the Veterans' Administration specifications and quality requirements.

Approximately one-half our annual drug requirements are provided by purchase from our Veterans' Administration Marketing Center in Hines, Ill., and distribution through our three supply distribution centers at Somerville, N.J., Hines, Ill., and Bell, Calif.

Thirty-five percent are purchased by our individual hospitals and clinics from Federal supply schedules, executed by the Veterans' Administration Marketing Center for use of all Federal agencies. The remainder are purchased by special negotiation and from local sources by our hospitals and clinics.

The data furnished your committee related to those drug items purchased by our marketing division for drugs and chemicals located at our Veterans' Administration Marketing Center. In determining which will be supplied through our central purchase and distribution program we apply the following criteria: (1) volume purchases are necessary to secure timely delivery and advantageous prices; (2) price advantages through bulk buying is sufficient to assure greatest economy through central distribution; (3) items are physically adaptable to storage and distribution; (4) the frequency of issue, repetitive use, physical characteristics, and stability of requirements justify central purchase and distribution.

Items which do not meet these criteria are provided through the Federal Supply Schedule for Federal Supply Groups 6505 and 6810, drugs, medical chemicals and reagents. A reporting system on frequency of drug use permits the periodic re-evaluation of our methods of supply.

This reporting system does not produce data your subcommittee desired on individual items procured locally, since it did not contain names of suppliers, or bidder information. It does provide us with usage trends to permit movement of items from one method of supply to another.

Our quality control process consists of the following elements:

1. Professionally developed specifications, including USP or NF requirements, and any other additional descriptive or performance requirements considered necessary.

2. Inspection of manufacturers' facilities before inclusion on the Veterans' Administration bidders' list.

3. Laboratory analysis by the Food and Drug Administration of random samples selected by Veterans' Administration personnel from various lots before acceptance by our central distribution points.

4. Physical inspection of random samples by professional personnel either at our supply depots or our hospital and clinic pharmacies.

5. A reporting system which we call quality improvement reports to be submitted by using activities in case of dissatisfaction with products or need for improvement.

6. Periodic reinspection of our suppliers' facilities and suspension from participation in Veterans' Administration procurement of those not meeting our standards. We work in close cooperation with the Defense Supply Agency in exchanging information on bidder performances, inspection reports, product suitability, et cetera.

We accept the quality control findings and vendor inspection reports of the Defense Supply Agency as an integral part of our own quality control program.

We also interchange quality control information with the Food and Drug Administration and other elements of the Department of Health, Education, and Welfare.

I previously mentioned that we procure or contract for drugs for other Federal users. In 1961 the Administrator of General Services Administration, as provided in the Federal Property and Administration Services Act, assigned to the Veterans' Administration the responsibility and authority for the procurement and distribution of drugs, biologicals, medical chemicals and reagents required by Federal agencies.

Since that time we have contracted for and administered the Federal supply schedules for these items. We have also provided them from our central depot stocks to those agencies who have placed requisitions upon us.

During the fiscal year 1970, we estimate that other Federal agencies acquired $37.5 million worth of drugs and chemicals and reagents through or from us, broken down as follows: $33,500,000 ordered from Federal supply schedules executed by the Veterans' Administration; $3,500,000 ordered from our supply depot stocks; $500,000 ordered from stocks at our hospitals.

We also procure from time to time items made available to us from the Defense Supply Agency when that agency is able to acquire them at a lower cost than our own direct procurement.

In closing, I would like to assure this subcommittee that we are interested in effective control of drug purchasing, and in the greatest economy consistent with our needs and the effective and safe treatment of our veteran patients.

We do strive to bring competitive conditions into the drug market and to economize wherever possible.

Senator NELSON. May I ask a question at this point?

Mr. JOHNSON. Yes, sir.

Senator NELSON. I realize now that we have all of the purchases that are made, of the $91 million purchases made in the fiscal years 1968 and 1969. It appears from our examination of the contract that only 2.07 percent was by competitive bid. The rest was sole-source purchase. How is that reconciled with your statement:

> We do strive to bring competitive conditions into the drug market and to economize whenever possible?

Mr. JOHNSON. Mr. Donald Whitworth.

Mr. WHITWORTH. Sir, our figures show that of the VA marketing center purchases that we supplied you information on, that we bought 12.66 percent competitively of the items that could have been bought competitively.

In other words, we bought single source, where competition was available, on 12.66 percent. That is, in 1969, competition was not available—and I am talking now strictly about the data we furnished you—competition was not available on 81.46 percent. Therefore, our percentage that we bought after advertising was 5.88 percent. This does not jibe with your 2 percentages, but it is 5.88. It is not impressive, but we bought competitively about 5.88 percent.

However, if you take out the 81 percent, sir, that could not have been bought competitively, we bought 33.72 percent competitively of that part on which competition was available.

Senator NELSON. What was the reason it could not be bought competitively?

Mr. WHITWORTH. Well, sir, we buy sole-source procurement for three basic reasons. One, that is the only source available—obviously.

Senator NELSON. When you say the only source, are you saying it was the only brand name——

Mr. WHITWORTH. There was only one manufacturer who manufactures the item.

Senator NELSON. Only one manufacturer made the particular drug that you desired?

Mr. WHITWORTH. Yes, sir; and, two, only one source met our standards. Competition is ostensibly available, but only one source—only one product—meets the VA standards.

Senator NELSON. What percentage of your purchases did that involve—where there was more than one drug but only one source met your standards?

Mr. WHITWORTH. Well, sir, we are running into a little problem here. You are talking about $91 million total procurement, and we are talking about now the central procurement. We have given you data on that, but in answer to your question, I would have to say about two-thirds of the items on which competition was available we did not seek competition on 33 percent—33.72 percent in 1969—of the items that we could have bought competitively we did buy competitively. The balance, sir, we did not buy competitively for three reasons.

Mr. JOHNSON. As I understand your question, Senator, and I confine my remarks to the central procurement, but of those items that are manufactured by more than one manufacturer, but with only one manufacturer meeting our standards in 1969, about 12½ percent of our purchases were made on that basis.

Senator NELSON. Did you give the third reason, the third category?

Mr. WHITWORTH. I am sorry, sir, I did not hear you.

Mr. JOHNSON. The third category is to satisfy professional requirements, only source available, only one source meeting standards, and to satisfy professional requirements.

Senator NELSON. What does that mean, "professional requirements"?

Dr. WELLS. That is largely a matter of the opinion of the physician prescribing. In other words, we do not impose upon the physician an administrative direction that he must use a particular drug, but allow him a range of selection, this particularly applies to our fee-basis physicians.

Mr. JOHNSON. You see, today, sir, there are over 90,000 physicians on a fee basis as compared with 3 or 4 years ago of only half that number, and there is some problem of controlling. There is also a matter of professional judgment involved here, so that there is more of the possibility of brand names, rather than generic names, used in the outpatient treatment, and as I stated earlier in the testimony, the outpatient usage today is greater than the inpatient usage, and this only took place in 1968.

Senator NELSON. Now, as I understand your testimony, the large drug expenditure that you have for outpatients—regardless of the price, regardless of the fact that there may be no difference in their therapeutic value, regardless of the fact that the doctor may prescribe the highest priced one in the marketplace—do I understand under item 3 that you do not in any way interfere with that?

Dr. WELLS. Oh, yes. We are not passive in that connection at all. If the prescription is presented on an emergency basis it may be filled, indeed, as you say, pending some examination of this.

On the other hand, these fee-basis physicians are contacted, they are given our formulary information, they are asked to prescribe the less expensive equivalent drug so that we make every effort to correct these faults as we learn about them, as the prescriptions come through for examination.

Senator NELSON. You furnish to the physician a list of all of the brand and generic names of a particular compound and the price, and encourage physicians to prescribe the lowest priced one?

Dr. WELLS. Yes, sir. We furnish them a list of the drugs that are stocked in our pharmacies which are purchased on this basis; that is, the lowest possible cost for the equivalent product.

Senator NELSON. How many of these are being bought from pharmacies?

Dr. WELLS. Do you mean in total patients?

Senator NELSON. Outpatients. Your outpatients are all over the country.

Dr. WELLS. That is right.

Mr. JOHNSON. Yes, sir; but the bulk, the bulk of outpatients are within range of a facility, of a VA facility, and we encourage those facilities to be used.

Now, of course, it stands to reason that in your State and mine there are many who are too far away, and they have to use a local pharmacy.

Mr. STATLER. Senator, 80 percent of all outpatient prescriptions by fee-basis physicians are filled in the VA pharmacies and these physicians are given a formulary or listing of the drugs we have available, and are encouraged to prescribe what we have already standardized as a therapeutic equivalent. Occasionally we have a new physician who writes for a drug we do not stock and we will make an effort to get him to prescribe a therapeutic equivalent, if he has one, if he is not unable to be reached, or has a particular requirement.

Senator NELSON. Please proceed.

Mr. JOHNSON. I would like to mention a couple of examples of this. The largest recovery in the history of this Nation for overcharges on drugs sold at prices in restraint of trade involved the antibiotic tetracycline hydrochloride. Recognizing that competition was apparently not being developed despite availability of this item from several manufacturers, Veterans' Administration reported information suggesting restraint of trade or price regulation to the Federal Trade Commission and the Department of Justice in 1955.

In the widespread publicity attendant upon the Federal Trade Commission and court actions which resulted in the ordered refund

of millions of dollars, the fact that the Vetreans' Administration initiated this action has been largely overlooked.

We have taken action where we felt there was supporting evidence and alternative courses to exert the pressure of the Federal process in promoting competitive procurement for drugs.

Mr. GORDON. Mr. Chairman, has the VA reported any other situation to the antitrust agency?

Mr. WHITWORTH. Yes, sir; we have.

Mr. GORDON. You have?

Mr. WHITWORTH. Yes. Not in recent months, but we can supply for the record this information.

Mr. GORDON. Can you name any, offhand?

Mr. WHITWORTH. No; I cannot at the moment.

Mr. GORDON. Well, could you supply that?

Dr. WELLS. We will supply that information for the record, Mr. Gordon.

(The information follows:)

BIDS REPORTED TO DEPARTMENT OF JUSTICE AS IDENTICAL

Date	Name of bidders	Item	Prices
May 14, 1964	Lederle Labs	Triamcinolone tabs., 4 mg 500's	$35.55
	E. R. squibb	do	35.55
May 10, 1965	Halsey Drug Co	Sodium Diphenylhydantion capsules 1½ gr.	4.00
	Premo Pharm. Labs	do	4.00
May 13, 1965	Consolidated Midland Corp	Pyridoxine hydrochloride ¾ gr	5.25
	Leo Linden Labs, Inc	do	5.25
	Halsey Drug Co	do	4.45
	Xttrim Labs, Inc	do	4.45
	Davis Edwards Pharm. Co	do	5.10
	Nysco Labs, Inc	do	5.10
Aug. 17, 1965	Consolidated Midland Corp	Pentobarbital sodium capsules 1½ gr	2.25
	Halsey Drug Co., Inc	do	2.25
Sept. 28, 1965	Mallinckrodt Chem. Works	Cocaine hydrochloride 28.35 gm	14.80
	S. B. Penick & Co	do	14.80
	Quinton Co., Div. of Merck & Co	do	14.80
Sept. 9, 1965	Premo Pharm. Labs, Inc	Triamcinolone tabs, 4 mg	2.10
	Pfizer Labs, Inc	do	2.10
Sept. 9, 1965	Lederle Labs	Hydrocortisone tabs, 20 mg	35.55
	E. R. Squibb & Sons	do	35.55
Jan. 27, 1966	Mallinckrodt Chem. Works	Cocaine hydrochloride 28.35 gm	14.80
	S. B. Penick & Co	do	14.80
Jan. 27, 1966	S. B. Penick & Co	Codeine phosphate	10.64
	Mallinckrodt Chem	do	10.64
Jan. 27, 1966	American Pharm. Co	Ferrous sulphate tabs, 5 gr	1.40
	Leeds Dixon Labs	do	1.40
Sept. 28, 1966	Bristol Labs	Sodium Oracilin caps, 250 mg	10.50
	Squibb & Sons	do	10.50
Sept. 28, 1966	Nysco Labs, Inc	Cortisone acetate, 25 mg	1.75
	Panray Div. Ormont Drug & Chem. Co	do	1.75
Sept. 30, 1966	Kasar Labs	Digitalis tabs., 1½ gr	.93
	Lederle Labs	do	.93

Note: VA pioneered the reporting of identical bids on drug items beginning in 1955.

Mr. JOHNSON. Another example of our cost awareness is our action in procurement of rubella measles vaccine for the immunization programs sponsored by Health, Education, and Welfare.

When we were first requested to procure this item, the cost was $1.41 per unit dose. As a result of our efforts to obtain a better price and our encouragement to several firms to manufacture this product, we have negotiated the unit price down to 72 cents. The savings to the Government for this product was approximately $2,900,000 during this last fiscal year alone.

I assure this subcommittee that we will be constantly alert to improve the quality, safety, and therapeutic effectiveness of drug products and to expend the Federal dollars entrusted to the Veterans' Administration in a prudent and thrifty manner.

Mr. Chairman, this concludes my statement.

Senator NELSON. Thank you.

Mr. JOHNSON. I will answer any questions you might have. Thank you.

Senator NELSON. Let us go back to the question about competitive bidding and sole-source purchasing. The three exceptions that you cite—that you purchase sole source when it is the only drug available, or when there are others available but which do not meet your standards, or based upon the physician's preference. Do I understand the law correctly, that any Federal agency may purchase a drug any place in the world, that is, even though there is a patent or an exclusive license for a drug to be sold in this country. Although it has to be a sole source for any private hospital or any private physician to prescribe from, that nevertheless, under the law, a Federal agency is not required to observe, is not forced to observe a patent or exclusive licensing arrangement and may buy the same drug in the world market?

Is that the law? Does that law apply to the Veterans' Administration?

Dr. WELLS. We are at liberty to purchase in the world market under the limitations of the Buy American Act; yes, we could. We are also allowed to use patents for the exclusive use of the agency, if there were someone who would manufacture for VA alone. We could use this, the eminent domain principle over the patent, if this were manufactured and used solely within the VA.

Mr. CORCORAN. By way of clarification, recovery against the United States for the unlicensed use of a domestic patent is limited to that authorized by the provisions of section 1498 of title 28 of the United States Code. By the terms of this section, recovery against the Government cannot be had on any claim arising in a foreign country. Hence, where the American manufacturer is a licensee under a foreign patent, the United States can procure from foreign sources without subjecting itself to liability for patent infringement. In the case of domestic patents, however, although the United States is free to utilize the patent for its own use, if it does so, it subjects itself to possible liability under section 1498 of title 28. Ordinarily, but not in all cases, the Government protects itself by the use of a patent indemnity clause in the contract by which the contractor indemnifies the Government against any liability which might attach because of patent infringement.

Senator NELSON. Now, in doing your purchasing and looking at the prices—when you are not able to accept competitive bids because there is only one manufacturer in this country, or for some other reason—do you compare the price, the sale price offered by the American sole source versus the price available in the world market as a matter of regular practice?

Dr. WELLS. These prices are available, and I will ask Mr. Whitworth to what degree this is done.

Mr. WHITWORTH. Sir, we do not normally advertise for foreign products. American brokers get our bids and bid on the foreign product, and in those instances we do apply the Buy American Act; but we do not normally send our invitations to bid to foreign sources, foreign manufacturers. This is not a practice of ours.

Senator NELSON. Aren't their foreign prices readily available on all drugs, just as are domestic prices?

Mr. WHITWORTH. Not to our buyers, sir. We have no need for these.

Senator NELSON. Well, we get them any time we want them. We ask the State Department, and immediately they supply us with price information for any country.

Dr. WELLS. Mr. Nelson, the prices are available, of course, and rather readily so. It is just our practice not to bid in the foreign market.

Mr. WHITWORTH. The agency has always had this policy, sir, not to send our invitations to foreign suppliers. However, brokers in this country sometimes do bid on foreign items.

Senator NELSON. I am just wondering why you should not do this. We had incredible testimony last week showing that in our foreign aid program prices were being paid as high as 8,000 percent over the world price. I cannot understand why the Government should allow itself, using the taxpayers' dollars, to pay these kinds of prices. If the difference was nominal, it might seem tolerable, but we have had a series of cases where the price we paid was anywhere from 200 to 1,200 percent to 2,000 percent to 8,000 percent over the world price.

In your negotiating, since 80 percent of these contracts are sole source, wouldn't good sensible bargaining require that you have available the world price on any of these drugs, and that in negotiation you make some comparison, and when you encounter an excessive price you say, "We will not pay it"? Why shouldn't that be a built-in, automatic policy of any Government purchasing agency in order to protect the taxpayers' dollars?

Dr. WELLS. Mr. Chairman, there have been instances when, indeed, we have done just this, where prices were way out of range.

Senator NELSON. On Panalba?

Dr. WELLS. Yes; and tetracycline was another one. But, one of our great difficulties here was we submit offers to purchase to qualified bidders only, which means we have to have some previous knowledge of the supplier.

Mr. WHITWORTH. We are hard put to conduct the necessary inspections in domestic manufacturing, and so have no resources in foreign locations. In those instances where we can, we use the Department of Defense inspection people to certify the suppliers.

Senator NELSON. Why not use the FDA, who already does that? It is also a Federal agency, and I don't see any sense in duplicating its functions.

Mr. WHITWORTH. There are no foreign manufacturers of end items we buy other than those we have done business with—or there are very few—that FDA gives approval to, sir.

We read, of course, your testimony of last week where you were talking about big, bulk drugs, and larger packaging, but the foreign

bidders of VA-bought items are not FDA-approved as a rule. This, I am sure, you will find to be true.

Senator NELSON. There are lots of drugs purchased by our own drug companies from overseas and resold in this country, and I will wager that a substantial number of drugs that the VA pays for are purchased by American companies from either foreign subsidiaries or foreign manufacturers. The testimony is full of that. In the case of an anti-infective, they meet exactly the same standards the FDA has. Every anti-infective imported into this country is batch tested.

Mr. WHITWORTH. FDA, sir, has certified all of those from whom we buy, even though the source of a raw material is foreign and this is an FDA-approved item or manufacturer from whom we are buying. The point is it has to be FDA-approved before we can do business with them.

Senator NELSON. Since 80 percent is sole source, why not, as a matter of policy, check the price of the foreign product in the world market, of which there are many excellent suppliers. There are companies selling drugs in the United States who have exclusive licenses in America and never have made an ounce of the bulk material. Every single ounce is imported, with only the finished product being made here. The price charged here is tremendously higher than in the foreign market for the same compound manufactured by the same foreign firm.

But, what I am saying is, how do we protect the taxpayers' dollar unless when you are negotiating you exercise all the power you have? Why can't you say: Here is the price of a distinguished foreign company, here is the world price, yours is 500 percent, 1,000 percent, 300 percent above it, and unless your price comes somewhere close to the world price, we will not purchase. Why shouldn't that be a matter of automatic, consistent policy of any Federal purchaser of large numbers of drugs?

Mr. WHITWORTH. Mr. Chairman, as Dr. Wells said a while ago, it is a matter of quality control, sir. We feel we do not have the resources to determine that we are getting the quality that we require.

Senator NELSON. Well, I understand from the testimony that you regularly check for quality of your drug. It is no problem for any other buyer, New York City, for example, which buys its own drugs. It takes bids, then checks to see whether they meet USP standards and if they do, they accept the lowest bid.

With the kind of purchasing that Government is doing, why is that any more difficult for the Federal Government to do this than for New York City?

Mr. WHITWORTH. Well, sir, the foreign buying that we have done, we have depended solely upon the military and FDA for our quality control.

The quality control the Administrator described in his statement, sir, strains our resources to keep up with the domestic market. Any purchase we have made foreign we have asked the Department of Defense and the FDA to check for quality control.

Senator NELSON. If you do not monitor the prices as a regular matter, how do you decide when you ought to seek foreign contracts?

Mr. WHITWORTH. I can only say, sir, that as a matter of policy we

do not seek foreign business. We consider it when an American representative of a foreign manufacturer submits a bid. This is rare.

Dr. WELLS. Mr. Chairman, may I say at this point that I believe that we should reexamine our policy in this connection with a view to seeing what the foreign prices are by comparison to what we have. If then we can be assured of quality control by using resources that we have, the resources of DOD and FDA, then we should indeed move into this area, if it is possible.

Up to date it has seemed to people in VA that we were unable to get sufficient assurance of quality control that we could tell our doctors that you are getting, indeed, an equivalent drug and, therefore, we have not gone as far as we should perhaps, in the price exploration.

Senator NELSON. Well, now, you do have meprobamate; correct?

Dr. WELLS. Yes.

Senator NELSON. There is no American supplier. Carter-Wallace is the sole importer of bulk, and if you are buying it from an American market you are paying, I can assure you, a tremendously high, exorbitant price.

Mr. WHITWORTH. Mr. Chairman, we bought it foreign for a number of years, sir.

Senator NELSON. Pardon?

Mr. WHITWORTH. We bought meprobamate foreign for a number of years, and apparently it is coming from Denmark.

Senator NELSON. What do you pay for meprobamate?

Mr. STATLER. $2.85 for 500 tablets, roughly $2.85 for 500 tablets.

Senator NELSON. You are buying your meprobamate from a foreign source?

Mr. STATLER. It is bought competitively by generic name, and some of the successful bidders have been from Denmark. We have also had small business firms in the United States be successful in it also. Riverton Laboratories was one.

Mr. WHITWORTH. But not in the last buys, sir.

Senator NELSON. Now, meprobamate is a case which, as I understand it, is imported by one company and is resold to other companies. The increase in the bulk price over what they pay, I assure you, is quite dramatic.

Why shouldn't the policy be the same as that which you followed respecting meprobamate? Why shouldn't that be applied as a regular matter in testing against your sole source whether or not you are getting a fair price for the taxpayer's dollar? I do not know of any other way to keep a sole source honest in terms of pricing.

Dr. WELLS. As I understand it, this is one drug we have had out on competitive bidding, so that presumably we get the lowest price in this instance in the world market.

Senator NELSON. That is fine, and I am glad to see that. Why isn't that regular policy? Why not keep a regular tabulation on the world price so that when you have a sole source you are able to say to the sole source, "Your price is way off"?

How do you know that you are paying a fair price when you do not know what the world price for an equivalent product is?

Dr. WELLS. Well, I do not think we could give a good answer to

that unless we were monitoring the world market prices, which I believe we have not done.

Senator NELSON. That is what I am getting at. Why not?

Dr. WELLS. I really cannot answer that. I think that it has not been a policy, and that is why I say I think we must reexamine our policy in this connection, look at the world market prices; but we, in addition, must be assured of quality control and an opportunity for appropriate inspection by FDA and DOD.

Senator NELSON. Nobody would argue with that. I am just concerned about what I saw last week, where the price is 8,000 percent over the world price. I guess AID could not do anything about it under their particular circumstances and the peculiarity of the way the requests come from the foreign countries, but paying that price or anything near it unnecessarily is a waste of the taxpayer's dollar and I assume that if you could show the competitive price, you would get it met. This has been the case domestically. In New York City, the prices being charged for prednisone were $17 and $18 a hundred tablets to the pharmacist, yet on the same day the same company bid $1.20 a hundred to New York City and lost the bid to somebody who bid 45 cents. I think you have to demonstrate that there is some competition here in order to be sure that you are not paying an exorbitant price.

I would think that you ought to take a look at the prices of the drugs you purchase, and compare them with the world price and see what the difference is.

Mr. GORDON. May I interrupt here?

Since you and the Defense Department are very large buyers of drugs, have you ever considered the possibility of buying bulk, whether overseas or in this country, and then contracting out for tableting and bottling?

Dr. WELLS. For repackaging and reformulating?

Mr. GORDON. That is right.

Dr. WELLS. I do not know, to be perfectly honest, whether this has been considered, if at all.

Mr. WHITWORTH. We certainly have not done any of this.

Mr. GORDON. Have you ever considered it?

Mr. WHITWORTH. To my knowledge, we have not considered it with the military or unilaterally, sir.

Mr. GORDON. Perhaps it might be worthwhile to consider that.

Senator NELSON. On the question of the formularies, I am sure we are all agreed that we have an obligation to establish procedures—at least in teaching hospitals and in Federal institutions—that would maximize the chances of establishing a program of rational prescribing and rational purchasing.

Do I understand from the testimony that each of the veterans' hospital has a formulary committee or therapeutics committee?

Mr. JOHNSON. Yes, sir.

Senator NELSON. And so each veterans' hospital has a formulary of its own?

Dr. WELLS. Correct.

Mr. STATLER. They use the American Hospital Formulary Services as a basis for developing in their individual hospitals.

Dr. WELLS. Then they add whatever is locally required.

Senator NELSON. As you may know from the Task Force on Prescription Drugs, published August 30, 1968, the HEW Task Force on Prescription Drugs recommends the establishment of a review committee, or utilization review, as follows:

> Any drug program utilization review is a dynamic process aimed first at rational prescribing and the consequent improvement of the quality of the health care; and, second, at minimizing needless expenditures. Many hospital staff committees of experts have long taken the responsibility of reviewing their records of their fellow physicians and offering such advice or taking such disciplinary action as they deem necessary. During the past 2 years, utilization review programs have been instituted to improve the quality of the medical care under the hospital program of medicare. Similar reviews are used in several American and foreign drug programs to improve the quality of the drug prescribing.

Has the Veterans' Administration hospitals instituted a utilization review program?

Dr. WELLS. Actually this has long been one of the functions of our therapeutic committees of the hospitals, to monitor utilization as well as the specific selection of drugs. Our great difficulty in this connection is in our fee-basis program, where we have much less opportunity to monitor utilization in the 90,000 prescribing physicians who are essentially part of the private sector.

Mr. JOHNSON. Senator, I would like to ask Dr. Haber to respond further.

Dr. HABER. Senator, I think the question of the control over the types of drugs which are prescribed by our physicians is basically as has been——

Senator NELSON. Basic to what?

Dr. HABER. Basically, as has been elucidated, a function of the therapeutic committee which exists at every VA hospital. Part of their oversight exists in the utilization and review of the kinds of drugs that are afforded the physicians for the treatment of their patients.

Now, the problem is that although all of our inpatients are treated by our own staff, 5,000 physicians employed by the VA hospitals, whose qualifications we have exclusive control over, a certain number of our patients are treated as outpatients. We record about 8 million outpatient visits a year. Of these, the vast majority are performed at VA hospitals by the same 5,000 physicians and by some consultants and attendants, and again, these people are exceedingly sensitive to our methods of control.

The greater degree of the problem comes from those veterans that do not live near VA hospitals, service-connected veterans whose treatment by authorized physicians is permitted under law, and they are the 90,000 physicians, where we have less precise controls, as Mr. Johnson mentioned to you before.

The fact of the matter is that the number of physicians under this program has increased in the last several years, basically because we wanted to give the veteran greater freedom of choice in getting a physician of his own choosing to treat him in his own hometown. The fact further is that the number of prescriptions ordered by these physicians is a small percentage of the total prescriptions which the

VA authorizes. Most of those are, of course, done in our own hospitals, and we do exercise a degree of control over these physicians in that we review the prescriptions which are mailed into us for filling in our own pharmacy.

The problem here is one in which we try to accord the greatest latitude of choice to the individual veteran and still exercise the highest degree of control over the kind of drugs these physicians use.

Senator NELSON. Well, what puzzles me a bit is that in your statement you say that the VA has therapeutic committees and is careful to make certain that they establish a good formulary. However, in looking at the drugs listed here it is apparent that the National Academy of Sciences-National Research Council and the Medical Letter, are very critical of a number of the drugs being purchased by your agency.

I will give you a few examples: One of them is Zactirin, a drug mixture of ethoheptazine citrate and aspirin used as an analgesic. Aspirin costs 70 cents a thousand. Zactirin, a trade name, is $15.75 a thousand.

Now, the NAS–NRC report says Zactirin is "possibly effective" as an analgesic—but only because it contains aspirin. It is questionable whether the additional ingredient, ethoheptazine citrate, adds anything to this effect. NAS–NRC concludes:

> This combination may be no more effective as an analgesic than the amount of aspirin present.

Now, anybody following the National Academy of Sciences-National Research Council would say "We are not going to allow in our formulary a drug costing $15.75 a thousand when aspirin is available at 70 cents a thousand."

The National Academy of Sciences has come to this conclusion. How do you explain that this drug gets by your formulary committee?

Dr. WELLS. This is one of the many combination drugs that by policy we would discourage the use of. I think we could only say that our control is by no means perfect and we have many physicians who will ask for a drug and insist upon it, even though our policy is opposed to it.

Mr. STATLER. If I may just elucidate a second, our last purchase of that on the centralized purchase program was in April 1968. We have made copies of the NAS–NRC different efficacy studies and made it available to all our therapeutic committees, and they have taken this into their judgment. Obviously, they may be getting this on local purchases from time to time in response to prescriptions written by the outside, private physician, but as long as the drug is still legally on the market and the physicians are permitted to prescribe it, our pharmacists have to provide that medication to fill these prescriptions from time to time. But, it is not standardized for formulary use in very many of the facilities.

Dr. WELLS. The report I am looking at here right now, Mr. Chairman, indicates we bought none of this in the past year.

Senator NELSON. There is another one, an analgesic, Fiorinal. It is an APC plus butalbital as an analgesic. The last purchase of that

was in 1969. The following comment on that is from the Medical Letter, volume 3, page 21:

> It has never been convincingly shown that the combination of aspirin, phenacatin and caffeine, as in Fiorinal, has greater analgesic effectiveness than aspirin alone.

Why would you purchase that when aspirin is 70 cents a thousand and Fiorinal is $9.45 a thousand?

Mr. STATLER. Well, if there are some purchases probably of Fiorinal it is because again of the outpatient prescriptions but as I said before——

Senator NELSON. You mean to say that none of this was bought directly by contract?

Mr. STATLER. Yes; it was bought in response to the demand for prescriptions that were generated by fee-basis physicians, by the outside physicians, but most of the in-house physicians, of the 5,000, they have access to the Medical Letter comments and have formed their judgment, and Fiorinal probably is not standardized for in-house prescription items.

Senator NELSON. But this gets me back to my original question. The contract was for 1969, $18,106.92 worth of this drug. Regardless of the individual physician's demands, why should the Veterans' Administration spend $9.45 a thousand when the best evidence in America, by the pharmacologists and clinicians, is that it is no better than aspirin at 70 cents?

Why does not the Veterans' Administration say we will not supply this drug?

Mr. STATLER. By far the biggest purchases are aspirin tablets, and we dispensed 52½ million doses of aspirin and 46½ million doses of phenobarbital as opposed to a few thousand, 100,000, of Fiorinal that we had to buy for prescriptions from the outside.

Senator NELSON. But you are purchasing them and putting them in the veterans' hospitals.

Mr. STATLER. Filling prescriptions for physicians in our outpatient program; yes, sir.

Senator NELSON. All I am saying is that if we are going to have rational prescribing in this country, you have it in your authority to say no, we will not pay $9.45 a thousand for something that is no better than phenobarbital at 50 cents or aspirin at 70 cents. Why should the taxpayers pay it? They would generally not do that in any teaching hospital in this country, would they?

Dr. WELLS. I think they would. I have had 25 years in teaching hospitals in the United States and I think you would accede to the judgment of the physicians, even though it might be wrong, and even though you had supplied them with information such as we have available.

Senator NELSON. If it happens in the teaching hospitals, then they do not have very good formulary committees. Is there any evidence—the testimony speaks of testing, efficacy, and so forth—do you have any evidence at all from any source that the Medical Letter is wrong and that, in fact, Fiorinal is better than aspirin or phenobarbital?

Dr. WELLS. No, no; we have no such evidence at all.

Senator NELSON. Now, if the Veterans' Administration is going to let itself be pushed around because of an irrational prescription by an individual physician, who is to protect the taxpayer's dollar or, indeed, promote good medical practice?

Dr. WELLS. This is a very difficult question, sir, but we are in the position not infrequently of having to accede to the demands of the physicians and their judgment on their patient.

This is a tradition we must follow.

Senator NELSON. So what you are saying is, if an individual physician, against the expertise of the best pharmacologists and clinicians in the country, still insists on prescribing a drug, then you will spend the money and let him have the drug?

Dr. WELLS. On a limited basis, sir. I think we do everything we can to discourage that, but we, under pressure, I suspect would succumb.

Senator NELSON. Well, one of the largest purchases is Librium as a tranquilizer, and that is for about $2.4 million. Is there any clinical evidence that those drugs are superior to barbiturates as an anxiety agent, superior to phenobarbital, for example?

Dr. WELLS. Very different from phenobarbital. I think we are talking about two entirely different classes here, and many physicians find they get much better results with Librium as a tranquilizer than they would with phenobarbital, and also it lacks some of the side effects of phenobarbital particularly, which has a cumulative depressant effect.

Senator NELSON. Well, the Medical Letter says both drugs are effective sedatives, but it is still not clear that they have any important advantage over barbiturates. Now, again, the cost of phenobarbital is 50 cents a thousand; Librium is $43.50 a thousand, and Valium is $53 a thousand. If there is no evidence that they have any advantage or any more effectiveness or advantage over barbiturates, why pay $43.50 versus 50 cents?

Dr. WELLS. I think we are in an area here of very honest differences of opinion among physicians, pharmacologists, and people who study drugs, that we are talking about very different kinds of actions, and physicians at least have very definite opinions about the use of Librium versus phenobarbital.

Dr. HABER. Mr. Chairman, we have a great number of patients who come to us, highly sedated on barbiturates, particularly the aging patient who comes to the nursing home and the intermediate care facilities, and we find many of these people have been oversedated for long periods of time on barbiturates.

In such cases, with the possibility of side reactions, particularly on the skin and other parts of the nervous system, we find that changing to the chlordiazepoxide or diazepam is frequently of much more use to the aging patient and helps to break the vicious cycle where he becomes more sedated and becomes more confusional and requires more sedation.

We find this particularly useful in the aging population, at least, on initial entry into our system.

Senator NELSON. Are these testimonials, or do you have some clinical studies which support what you just said?

Dr. WELLS. As a matter of fact, I believe the first really large-scale trials of Librium really took place in the VA, the Coral Gables Hospital, at which time there were comparisons made. We could supply the record of that work. I think if you look in your own literature you will see that Dr. Kaim was one of the first people to use this large-scale trial.

We satisfied ourselves at that time that this was a useful drug.

Senator NELSON. If you have some clinical studies since the Medical Letter's comments of June 5, 1964, we would like to have them for the committee. Let me read these comments:

> Few well-controlled studies have directly compared any of these drugs with phenobarbital or other barbiturates and clinical experience does not clearly point to any one of them as outstanding in the relief of anxiety, in incidence of such side effects as drowsiness and impairment of intellectual or manual skills, or in addicting potential. In the absence of a sound basis for a choice, picking a drug for a patient hampered by anxiety must be more or less arbitrary. . . .

Dr. HABER. Mr. Chairman, may I answer that, please? I have here a personal communication from Dr. Kenneth Lifshitz, of the Rockland State Hospital in Orangeburg, N.Y., an outstanding authority and contributor to the newly published volume entitled "The Principles of Psycho-pharmacology," edited by W. G. Clark, K. Ditman, D. X. Freedman, and C. Leake, one of the most eminent pharmacologists in the country.

Dr. Lifshitz' letter advocates the use of these tranquilizing drugs in the use, as I said specifically before, in geriatric psycho-pharmacology.

Senator NELSON. Is the $2.4 million worth of Librium being used mainly for that purpose?

Dr. HABER. A large proportion of it is used for that portion; yes, sir.

Senator NELSON. What kind of a check do you have on that?

Dr. HABER. I cannot answer that question specifically. I do not know the ages of all patients who get all of our drugs, but since half of our population is in that category, I am sure at least half of it is being used for that purpose.

Dr. WELLS. A great deal of it is also being used in our alcoholic treatment program.

Senator NELSON. Under first choice in the Medical Letter it says:

> If the choice is to be made by trial and error, it would seem wise to begin the drug treatment of disabling anxiety with one that appears to be as effective as any other, has the benefit of long use, low cost and a good record of safety. Phenobarbital in non-hypnotic doses of such a drug has the further advantage that most clinicians are thoroughly familiar with it.

Dr. WELLS. That is a very good opinion. I think there are opinions to the contrary.

Senator NELSON. There are opinions to the contrary?

Dr. WELLS. I say, I think there are opinions to the contrary.

Senator NELSON. Are there any controlled studies that show that it is superior that it, in fact, contradicts the Medical Letter, which witnesses before this committee have cited as the most distinguished authority of its kind in these matters? [1]

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[1] See Appendix I, p. 7740.

Dr. WELLS. I am not aware of controlled studies that would counter that. On the other hand, I believe that the language of the Letter itself simply says that there are none, there is nothing to prove this. It does not say positively.

Senator NELSON. Therefore, why pay $53 for Valium or $43.50 for Librium when phenobarbital is available for 50 cents. Why not follow the Medical Letter's procedure of starting with phenobarbital?

Dr. WELLS. We have literally thousands of physicians who simply do not subscribe to that viewpoint, sir.

Senator NELSON. Just to cite for the record the testimony of Dr. Harry L. Williams, professor of pharmacology, Emory University School of Medicine, Atlanta, Ga.,[1] who also is affiliated with the Grady Hospital. In answering a question on Librium, he said:

> Librium [sells] somewhere around $50 a thousand. Faced with a choice between whether to use that drug or to use phenobarbital, which we use at Grady Hospital, and which in many cases is equal to and in some cases superior to, Librium, which cost us 9 cents per thousand, this is 9 cents versus $50. . . .

Here is a statement by a distinguished pharmacologist, in a large general hospital in Atlanta, and I am puzzled why we would spend this amount of taxpayers' dollars when there are no controlled clinical studies demonstrating the superiority of either Librium or Valium to phenobarbital.

Dr. WELLS. I think your point is well taken, but I am afraid we are in an area of opinion, and we are uncertain and, therefore, simply must go along with our doctors who say we think this is the best for our patients.

Mr. JOHNSON. Senator, I can only speak here as a layman in this, and know nothing at all about clinical studies and so on, but I want to point out to you that the population at the Grady Hospital or any other that you mention is considerably different than the population that we do have in some of our veterans' hospitals, particularly in the matter of the aging, particularly these that come in, particularly the comment that was made by Dr. Wells awhile ago that some of these drugs have been successful in our alcoholism treatment centers and so on, and that I want at this point to speak up for the doctors within the VA system, those within our rolls. I am sure it is not their desire to spend taxpayers' dollars just to be spending dollars, but they are wanting to deliver the very best there is in medicine, and I have confidence in their competency to make these kinds of decisions and to bring about the kind of results that they are looking for.

And I see every day, as I visit hospitals, what they are doing, and if there is any measure of success, I believe they are reaching it.

Senator NELSON. Well, the purpose, of course, of establishing your therapeutic committee is to use the best expertise there is in the country to be sure that drugs are rationally prescribed.

There is a tremendous amount of expert testimony by the best medical experts in the country that there is a lot of irrational prescribing.

Mr. JOHNSON. Senator, I think that the testimony is taken into

[1] Hearings, Part 2, p. 457.

account by these committees, coupled with their own experience, and I believe that they are exercising prudent action as they prescribe these drugs.

Senator NELSON. I am sure your intention is good and you have established formularies and therapeutic committees. Nevertheless, it seems to me that it is not working as well as it ought to.

Here is another example: Deprol, a drug mixture containing benactyzine HCL and meprobamate, an antidepressant. The Medical Letter says:

> Deprol is of no value for the treatment of either neurotic or psychotic depression.

The Medical Letter also says:

> Neither of the ingredients in Deprol is effective against depression. Furthermore, there is "no convincing evidence that this drug has any value except in cases amenable to placebo therapy."

Why buy it? Is there any evidence to refute what the Medical Letter says?

Dr. WELLS. I am not aware of any evidence on that, and I personally would subscribe to the opinion expressed in the Letter. I think again we are back to the whole problem of the fallibility of the absolute control, and of our necessity to a degree to go along with, while we educate and persuade the physicians that prescribe for the veteran population.

Senator NELSON. I have a whole list of examples here. It just seems to me that if we cannot get our top executive levels, where you have the authority and the availability of the expertise to establish a sound prescribing policy, then we cannot do it any place.

Darvon is also currently being purchased and it is bought as an analgesic. The Medical Letter says there is no evidence to "establish the superiority of 65-milligram doses of propoxyphene to two tablets of either aspirin or APC."

Then it goes on to say that the 32- to 65-milligram doses of Darvon "has consistently proven inferior to aspirin."

Dr. WELLS. Well, my answer to that would be that again I think the Letter is quite correct. I think that one, Darvon, can be equated to a certain amount of aspirin or a visit from the chaplain. But here we are again in an area of incomplete control.

Senator NELSON. Well, I will just recite a couple more here. It seems to me that with the expertise that the Department has available, with the support of all of the best medical scientists, clinicians, pharmacologists in the country, that the Veterans' Administration could establish some formulary control at the national level for all of its hospitals, using the best scientific knowledge we have.

Panalba is another example. In 1957, Dr. Harry Dowling, whom I am sure you know as one of the most distinguished physicians and scientists in this country, at that time chairman of the drug council for the AMA, together with eight other distinguished people signed an editorial in the AMA Journal. The other signers were Dr. Maxwell Finland, who I am sure you know, Dr. Morton Hamburger, Dr. Ernest Jawetz, Dr. Vernon Knight, Dr. Mark H. Lep-

per, Dr. Gordon Meiklejohn, Dr. Lowell A. Rantz, and Dr. Paul S. Rhoads. The editorial states:

> There are no data or experience which would justify the employment of any mixed combination of two antibiotics in a single ampule or single capsule or tablet for systemic use. It is our firm conviction that promotion or sale of such combination should be discouraged until or unless adequate data from controlled investigation justifies its practice, and then only with respect to definite combinations for specific purposes.

That was in 1957. In 1968 the National Research Council of the National Academy of Sciences recommended we remove from the marketplace all mixed combinations of anti-infectives. The experts, as far back as 1957, were discouraging the use of mixed combinations, and yet the Veterans' Administration all through those years purchased it.

Then even after the NAS–NRC recommended their removal from the marketplace, including Panalba, it was purchased by the Veterans' Administration—3 months after it was recommended for removal from the marketplace. There have been no studies to prove that it was effective as a fixed combination, and that is why it was removed.

If you have a formulary committee of medical experts, why would that be bought?

Dr. WELLS. This I think is really a classical example of our whole problem, Mr. Chairman. Indeed, at least two people who were on that committee that you named there have been or were with our special medical advisory committee to the Veterans' Administration.

Here was a combination antibiotic that practically the entire medical profession at one time fell into believing that it was better. Our doctors were not different from the doctors elsewhere.

Senator NELSON. Starting with Dr. Dowling as early as 1957, the best of the clinicians who were acquainted with the drug were simply saying you should not——

Dr. WELLS. That is right, but despite that, that is why I say this is the classical example of our problem, despite that the drug continued to be sold at a fairly high level and was, indeed, that pharmaceutical manufacturer's leading drug for even some years after it was known generally by the best people and the best advice that it was not effective as a combination drug.

So there was a lag there in control until it was pulled off the market, and I think this is exactly the problem we are up against when our advisors know, we know that something is not the ideal drug at the ideal price, and still there is the traditional lag, an inertia in the system which takes us quite a little time to catch up with, and that is what happened in this particular case, that it was being used quite widely throughout the country, not only in VA.

Mr. JOHNSON. Senator, I think it has to be reiterated here that within the Agency there is strong control and direction made upon our own physicians through this series of committees, but that there is less control, and perhaps there are suggestions on how it could be exercised without infringing upon the professionalism of outside doctors who treat our veterans but within, and I reiterate again, within the agency I believe we are exercising strong control and direction on the use of these drugs.

Now, these pharmacy committees, through these therapeutic committees——

Senator NELSON. But you are, in fact, spending substantial amounts of the taxpayers' money to buy drugs which the best medical experts say there is an equivalent at a much cheaper price than the one being bought—or that the one being bought has no effectiveness at all.

Mr. JOHNSON. But this has come about, sir, largely as a result of good legislation which allowed us to give that veteran the kind of service in the local community to which the Congress thought, and I believe correctly, he is entitled. And yet, yet we have the problem of the matter of the professionalism and infringing here and how much direction we can give to the private physician or general practitioner as to exactly what he should prescribe.

At this point, if he comes in, as was stated earlier for an emergency filling of a prescription, it is filled, but at every opportunity we have, we make that doctor aware of the list that we have and we use and recommend.

Dr. HABER. Senator, may I make two points with respect to VA's practice of irrational prescription, which I think may have some bearing here?

One is the fact that even though the Medical Letter may point out that a drug has, in their opinion, limited effectiveness, the Medical Letter is not above errors in the past, either.

I am merely trying to indicate that the bulk of medical opinion does change. Several years ago it was a rare physician who did not believe that you could affect the course of diabetes by prescribing oral hypoglycemic drugs.

Now, some ten years after they have been introduced in the market there is serious question as to whether they have, indeed, been serving our patients well by the broad use of these drugs, so that there has to be always, at some time a dissenting body of physicians whom we come to grips with at some point.

The second thing I would like to point out is we also do not always serve the taxpayer best by concern for his dollar at the moment, in the sense that sometimes long-range effectiveness of drugs turns out to be more important than immediate economies. The history of the Veterans' Administration in the treatment of tuberculosis, I think, is an excellent example. The conquest of tuberculosis in this country is due in no small measure to the effective use of these drugs in large scale programs in the Veterans' Administration.

At the time there was considerable question about the expense of these drugs because their efficacy had not been widely demonstrated, yet the VA did demonstrate it.

Tuberculosis has dropped in preeminence as a killer of patients to one I think now in 12th to 13th place, so again in the long run of the story it is sometimes more important than the most immediate economies which can be effected.

Senator NELSON. We are not really talking about that kind of case. We are talking about the cases that I have cited, and there are a number of them, where well-established drugs are in the marketplace, for example phenobarbital, and a new expensive drug is put

on the market which has no demonstrated superiority over the others. The Medical Letter says any rational prescribing would take the established, lower priced one.

Now, if evidence develops in clinical studies that the newer drug has superiority for some purpose over all others, that is the time to purchase it. On what grounds can it be prescribed, when there is no superiority at all? On the hope that because it costs $43 that it might do better than the 50-cent-per-thousand drug if you use it long enough?

I do not think there is a valid basis for making a decision that way.

Dr. HABER. Senator, anyone who has seen large numbers of people, aging people, admitted to psychiatric or to general medical institutions for the purpose of caring for them in nursing homes, cannot but be struck with the fact that many of these patients have for years been maintained on small doses of inexpensive barbiturates.

The number of side reactions is legion, of course. I am not trying to condemn the barbiturates, I am just trying to say many, many times when an antianxiety agent or tranquilizer is required and the barbiturate has been used, and abused, we must have recourse to some of the other drugs, albeit they are not the least expensive, and I have seen situations in which the long-term use of barbiturates has been the most effective barrier to treatment of this particular patient, and another tranquilizer could be substituted.

Senator NELSON. That does not get at the question, and I still have a whole series here where the best medical evidence was that there was another drug available, much cheaper, and the clinical evidence was that the one being purchased was no more effective, or in some cases less effective, than the drug being purchased at a tremendously higher price. Certainly you are not arguing against the proposition that we use the best scientific, medical, and pharmacological evidence available today for deciding on drug purchases at Government institutions, are you?

Dr. HABER. No, sir. I am arguing that there are conditions and there are variances in the human psyche and sometimes it is difficult to argue which is the best or the cheapest drug to use.

Senator NELSON. I do not think anybody would argue with that. Could you, on the question of the purchases, submit more detail on the small business purchases and percentages so that we have it clear for the record?

I do not think our discussion and dialog back and forth made it clear.

Dr. WELLS. You want us to elaborate on the small business purchases?

Senator NELSON. Yes, please.

Dr. WELLS. We will do this, certainly.

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

The question was raised as to the percentage of procurement from Small Business. Our statement indicated that approximately 16% was acquired from Small Business firms, 5% from local pharmacies and the remaining 79% from other sources. This was not reconcilable with the data we had previously furnished you.

The data that was available to your staff prior to the Hearings related only to those purchases from our central buying program. The percentages we

quoted at the Hearings, which were for the Fiscal Year 1969, related to our entire drug procurement program. In Fiscal Year 1969 $1,531,194 was purchased from Small Business firms under our central buying program. We could identify $6,717,359 for this Fiscal Year as coming from Small Business through Federal Supply Schedule contracts executed by our national buying office, but purchased by our local hospitals and clinics. This $8,248,553 represents 15.84% of the 52,072,550 in direct purchases both central and local. No purchases from retail or wholesale concerns of items that may have been manufactured by big business concerns are included in these figures.

There is an additional amount purchased by our local hospitals directly from Small Business concerns which we cannot identify. Five years ago 156 of our 276 Federal Supply contractors were Small Business concerns. We reduced the number of contractors during this period by discontinuing contracts with those whose volume of business did not justify the expense of making the individual contracts or who did not offer the Federal Government any price advantage over direct local procurement. Many of the items formerly supplied through these extra contractors are still purchased by these hospitals. However, since they are purchased on a local basis only, we do not have data on the quantity of these drugs which come from Small Business.

Mr. GORDON. Mr. Chairman, the staff has prepared some charts showing the concentration of purchasing and I ask that they, as well as VA submissions, be put in the record at this point.

Senator NELSON. That will be done.

(The material follows:)

VA—COMPETITIVE BIDDING, FISCAL YEARS 1968 AND 1969

Product	Winning bidder	Amount of purchase	Other bidders
Alcohol (8 orders)	DPSC (3)	$1,586	0
	Shell (4)	29,049	4
	Public Ker (1)	18,750	1
Alcohol dehydrated (8 orders)	DPSC (2)	15,391	0
	Warner Graham (4)	60,160	1
	U.S. Industries (1)	13,296	0
	National Distillers (1)	17,563	0
Alcohol USP (10 orders)	DPSC (2)	18,450	0
	Union Carbide (3)	29,179	2
	USI Chem (3)	17,861	0
	Warner Graham (1)	7,115	0
	National Distillers (1)	3,993	1
Aminophylline (4 orders)	Torrigian (1)	5,184	1
	Premo (1)	605	0
	DPSC (1)	2,624	0
	American Quinine (1)	6,534	2
Ascorbic (1 order)	Kasar (1)	1,554	6
Aspirin tabs (7 orders)	Dewey (3)	19,894	5
	Kasar (2)	11,772	3
	DPSC (1)	7,452	0
	PHS-Stockpile (1)	1,704	0
Bacitracin (6 orders)	Premo (4)	14,921	3
	Day Baldwin (2)	5,916	2
Bacitracin ointment (7 orders)	Day Baldwin (3)	15,118	2
	Fougera (1)	1,728	2
	Premo (3)	14,141	2
Belladonna tincture (6 orders)	Certified Labs (1)	1,049	1
	DPSC (5)	2,579	0
Cascara (4 orders)	Lannett (3)	6,688	3
	Halsey Drug (1)	2,660	0
Cascara (5 orders)	Certified Labs (2)	2,523	2
	Halsey (2)	1,939	0
	Lannett (1)	1,238	0
Chlorpheniramine maleate (7 orders)	Anabolic (2)	2,244	6
	Kasar (1)	1,115	5
	American Quinine (1)	482	8
	DPSC (3)	2,791	0
Codeine phosphate (3 orders)	Lilly (2)	25,932	1
	Kirkman (1)	9,576	1
Codeine phosphate (4 orders)	Kirkman (2)	5,985	1
	Lilly (2)	10,554	0
Colchicine tablets (6 orders)	American Quinine (1)	4,212	4
	Anabolic (5)	13,931	8
Cyanocobalamin inj. (12 orders)	Torigian (1)	7,920	4
	Anabolic (1)	1,269	2
	Philadelphia Labs (1)	1,629	4
	American Quinine (9)	25,949	8

VA—COMPETITIVE BIDDING, FISCAL YEARS 1968 AND 1969—Continued

Product	Winning bidder	Amount of purchase	Other bidders
Ephedrine sulfate (6 orders)	Lannett (2)	$1,831	3
	DPSC (3)	2,842	0
	DHW Stockpile (1)	1,797	0
Ether (6 orders)	DPSC (3)	5,031	0
	Mallinckrodt (2)	6,119	1
	DHEW Stockpile (1)	1,270	0
Ferrous sulfate tablets (7 orders)	Zenith (3)	8,294	3
	American Quinine (3)	9,757	5
	Davis Edwards (1)	2,700	1
Griseofulvin (5 orders)	McNeil (4)	19,130	2
	Ayers (1)	7,076	2
Hexachlorophene liquid soap (6 orders)	Harley Chem. Co. (3)	−21,959	1
	National Chem., Pa. Labs (3)	18,425	4
Hexa vitamin tablets (7 orders)	American Quinine (4)	23,936	2
	Lannett (3)	13,821	2
Hexa vitamin tablets (5 orders)	Gyma (1)	4,633	3
	USV (1)	2,847	1
	Bolar (1)	6,977	5
	American Quinine (2)	11,276	3
Hydrogen peroxide (9 orders)	American Peroxide (4)	29,446	3
	Dewey (3)	24,730	3
	DPSC (2)	2,678	0
Isopropyl alcohol (8 orders)	Union Carbide (4)	48,395	3
	DPSC (1)	2,155	0
	Phipps Prod. (2)	11,834	2
	Shell Chem (1)	8,598	3
Isopropyl rubbing alcohol (5 orders)	Dewey (4)	25,771	1
	Halsey Drug (1)	8,372	1
Meprobamate (4 orders)	Gyma (2)	156,000	6
	Wallace (1)	25,000	1
	Durst (1)	69,600	0
Meprobamate (3 orders)	Halsey Drug (2)	3,766	1
	Davis Edwards (1)	2,082	2
Mineral oil (8 orders)	Halsey Drug (4)	9,162	3
	Lannett (2)	4,620	1
	Dewey (1)	2,039	0
	Certified Labs (1)	5,083	1
Neomycin sulfate (5 orders)	Copanos (3)	28,146	2
	Premo (2)	31,279	1
Neomycin sulfate (10 orders)	DPSC (2)	4,218	0
	Upjohn (1)	8,136	1
	Premo (7)	49,269	5
Nitroglycerin (6 orders)	Lilly (6)	12,435	1
Papaverine HCL (5 orders)	Merrell (3)	3,195	3
	USV (2)	1,992	5
Penicillin G inj. (8 orders)	Copanos (3)	61,191	1
	Lilly (3)	67,482	1
	Squibb (1)	3,335	0
	Romar (1)	35,679	0
Phenabarbital (6 orders)	Kasar (3)	12,198	7
	Massengill (3)	10,991	5
Phenabarbital and belladonna extract tablets (7 orders)	Kasar (3)	3,270	2
	Massengill (4)	3,972	4
Potassium penicillin G (4 orders)	Copanos (1)	2,713	3
	Zenith (1)	2,227	0
	DPSC (2)	2,976	1
Potassium penicillin G tablets (4 orders)	Zenith (2)	6,862	3
	Copanos (1)	3,948	3
	Pfizer (1)	4,105	0
Prednisone tabs (5 orders)	Davis Edwards (2)	22,150	8
	Halsey (1)	8,381	2
	Zenith (2)	22,579	7
Prednisolone (5 orders)	Lannett (2)	3,838	6
	Zenith (2)	3,425	4
	Massengill (1)	1,161	5
Pyridoxine (2 orders)	American Quinine (1)	1,241	6
	Lannett (1)	1,697	7
Pyridoxine HCL (6 orders)	Lannett (1)	2,783	4
	Anabolic (2)	3,184	8
	American Quinine (2)	1,876	4
	Bolar (1)	1,356	7
Quinidine sulfate (8 orders)	Davis-Rose-Hoyt (3)	24,254	9
	Davis-Edwards (2)	19,905	10
	American Quinine (1)	6,278	2
Sodium pentobarbital (6 orders)	Davis Edwards (2)	5,448	6
	Anabolic (2)	4,487	9
	American Quinine (2)	10,616	9
Sodium salicylate (4 orders)	Panray (3)	21,179	4
	Kirkman (1)	13,997	0

VA—COMPETITIVE BIDDING, FISCAL YEARS 1968 AND 1969—Continued

Product	Winning bidder	Amount of purchase	Other bidders
Sodium secobarbital (5 orders)	Anabolic (2)	$5,282	8
	Halsey Drug (1)	5,445	5
	Prmo (1)	1,778	1
	Davis Edwards (1)	6,168	4
Tetracycline HCL (8 orders)	Rachelle (6)	348,850	6
	Zenith (1)	89,845	2
	Halsey (1)	22,011	1
Therapeutic formula vitamin capsules (7 orders)	American Quinine (4)	68,479	4
	Lannett (3)	23,493	2
Thiamine HCL tablets (7 orders)	Bolar (1)	445	9
	Davis Edwards (2)	33,666	
	American Quinine (4)	7,512	14
Digitalis (1 order)	Kasar (1)	775	6
			3

PURCHASES OF DRUG BY MAJOR THERAPEUTIC CATEGORIES

	Fiscal year— 1968	1969
Psycho therapeutic agents	$4,106,501	$5,613,634
Antibiotics	4,887,632	4,528,380
Analgesics and antipruritics	1,790,578	2,376,419
Antidiabetic drugs	633,868	874,526
Topical preps	931,998	1,020,837
Cardiovascular drugs	746,635	1,089,762
Respiratory	748,850	928,929
Diagnostic agents	699,868	956,028
Urinary antiseptics	703,394	1,052,332
Fecal softeners and (Laxatives)	652,464	739,382
Antacids	454,779	433,071
Muscle relaxants	340,024	562,715
General anesthetics	492,369	430,070
Gastrointestinal antispasmodics	290,324	328,993
Diuretics	183,234	391,852
Hypnotics and sedatives	303,525	343,790
Antituberculosis	232,627	180,006
Systemic steroids	233,121	265,043
Sulfa drugs	159,852	185,084
Chemicals, basic	149,536	132,126
Vitamins	130,022	162,805
Anticonvulsants	123,527	208,944
Eye, ear and nose preps	82,337	145,810
Cough preps	91,461	113,515
Anticancer drugs	49,904	67,646
Hormones	46,496	51,955
Antihistamines	92,495	63,922
Oral enzymes	26,974	42,860

ITEMS OBTAINED SOLE SOURCE DURING FISCAL YEARS 1968 AND 1969 WHERE ONLY ONE SOURCE WAS AVAILABLE

Item	Fiscal years 1968 Company	1968 Amount	1969 Date standardized	1969 Amount
Innovar injection (2 ml.)	McNeil Laboratories	$12,498.00	July 15, 1968	$12,169
Premarin injection (20 mg.)	Ayerst Laboratories	3,510.00	Feb. 13, 1967	5,985
Adrenosem injection (5 mg. per ml. 2 ml.)	S. E. Massengill & Co	None	Sept. 30, 1968	5,893
Medrol tablets (4 mg. 500)	Upjohn Co	16,584.00	June 22, 1964	15,016
Librium capsules (10 mg. 500)	Roche Laboratories	1,301,644.00	Aug. 15, 1960	1,291,524
Librium capsules (5 mg. 500)	do	97,280.00	Apr. 30, 1965	132,587
Librium capsules (25 mg. 500)	do	540,331.00	Mar. 22, 1961	903,060
Lasix tablets (40 mg. 1,000)	Hoechst Pharm. Co	77,971.00	Apr. 5, 1967	108,153
Tofranil tablets (25 mg. 5,000)	Geigy Pharm	265,278.00	May 24, 1960	166,780
Ismelin tablets (25 mg. 100)	Ciba Pharm. Co	6,463.00	Oct. 20, 1961	12,650
Dulcolax suppositories (10 mg. 500)	Giegy Pharm	92,702.00	Aug. 4, 1961	112,468
Dulcolax suppositories (10 mg. 50)	do	81,042.00	do	103,134

ITEMS OBTAINED SOLE SOURCE DURING FISCAL YEARS 1968 AND 1969 WHERE ONLY ONE SOURCE WAS AVAILABLE—Continued

Item	Fiscal years 1968 Company	1968 Amount	1969 Date standardized	1969 Amount
Tofranil tablets (25 mg. 1,000)	do	$212,013.00	Dec. 21, 1959	$177,577
Butazolidin tablets (100 mg. 1,000)	do	75,642.00	Aug. 4, 1961	76,074
Aerolone compound solution (1 oz.)	Eli Lilly & Co	15,738.00	Mar. 25, 1964	18,604
Hygroton tablets (100 mg. 1,000)	Geigy Pharm	21,373.00	Feb. 21, 1963	22,831
Duo-Medihaler (22.5 ml. w/adapter)	Riker Laboratories	33,985.00	June 27, 1963	53,222
Taractan tablets (100 mg. 500)	Roche Laboratories	50,487.00	do	43,310
Taractan tablets (50 mg. 500)	do	25,807.00	do	36,512
Angio Conray injection (50 ml.)	Mallinckrodt Chemical Works	28,440.00	Sept. 26, 1963	25,830
Conray injection (30 ml.)	do	37,801.00	Sept. 27, 1963	46,691
Librax capsules (500)	Roche Laboratories	31,500.00	Apr. 30, 1965	35,790
Hygroton tablets (100 mg. 100)	Geigy Pharmaceuticals	2,473.00	Feb. 21, 1967	4,114
Cyclospasmol capsules (200 mg. 100)	Ives Laboratories	39,882.00	Apr. 8, 1963	58,954
Orinase tablets (0.5 Gm. 500)	Upjohn Co	286,961.00	Dec. 7, 1964	306,301
Doxidan capsules (1000)	Hoechst Pharm. Co	24,171.00	June 6, 1961	46,158
Loridine injection (1 Gm.)	Eli Lilly & Co	None	Aug. 9, 1968	297,000
Innovar injection (5 ml.)	McNeil Laboratories	13,004.00	July 15, 1968	16,019
Hypaque-M 75 percent injection (50 ml.).	Winthrop Laboratories	None	Aug. 9, 1968	67,896
Tofranil tablets (50 mg. 1000)	Geigy Pharm	11,292.00	Apr. 11, 1968	68,554
Lasix tablets (40 mg. 500)	Hoechst Pharm	None	Apr. 25, 1969	97,937
Alevaire solution (500 ml.)	Breon Laboratories	3,910.00	Prior to Nov. 13, 1964.	4,596
Selsun susp. 2.5 percent (4 oz.)	Abbott Laboratories	12,609.00	Feb. 5, 1965	20,966
Levophed injection (4 ml.)	Winthrop Laboratories	4,052.00	Apr. 18, 1952	15,280
Macrondantin capsules (100 mg. 1000)	Eaton Laboratories	None	Sept. 18, 1969	102,881
Macrodantin capsules (50 mg. 1000)	do	None	do	89,815
Probanthine tablets (15 mg. 100)	G. D. Searle & Co	25,610.00	Prior to Jan. 19, 1965	43,086
Atarax tablets (25 mg. 500)	J. B. Roerig & Co	32,527.00	Apr. 29, 1965	38,650
Hypaque injection (50 percent, 30 ml.)	Winthrop Laboratories	184,316.00	Sept. 16, 1955	190,706
Probanthine tablets (15 mg. 1000)	G. D. Searle & Co	65,621.00	Prior to Nov. 20, 1964.	58,565
Probanthine injection (30 mg.)	do	18,705.00	do	15,265
Senokot granules (8 oz.)	Purdue-Frederick Co	None	Mar. 18, 1969	4,039
Erythrocin filmtabs (250 mg. 100)	Abbott Laboratories	41,102.00	Aug. 31, 1955	76,730
Mercuhydrin sodium amps (2 ml.)	Lakeside Laboratories	3,640.00	Feb. 3, 1966	10,548
Ritalin tablets (10 mg. 1,000)	Ciba Pharm. Co	50,039.00	Aug. 15, 1956	89,872
Ritalin tablets (20 mg. 1,000)	do	9,602.00	Feb. 9, 1967	23,113
Pathilon tablets (25 mg. 1,000)	Lederle Laboratories	4,598.00	June 28, 1965	7,797
Trilafon tablets (2 mg. 500)	Schering Corp	4,673.00	Prior to Oct. 16, 1964	10,413
Trilafon tablets (4 mg. 500)	do	22,984.00	Prior to Oct. 12, 1964	24,480
Trilafon tablets (4 mg. 5,000)	do	44,978.00	Prior to Nov. 13, 1964	58,442
Trilafon tablets (8 mg. 500)	do	26,942.00	do	22,787
Trilafon tablets (8 mg. 5,000)	do	42,486.00	do	52,482
Trilafon tablets (16 mg. 500)	do	7,526.00	do	7,830
Trilafon tablets (16 mg. 5,000)	do	16,130.00	do	16,979
Diamox tablets (250 mg. 1,000)	Lederle Laboratories	68,526.00	July 8, 1965	111,717
Alevaire solution (60 cc)	Breon Laboratories	7,685.00	do	7,342
Telepaque tablets (6 c)	Winthrop Laboratories	34,906.00	Aug. 8, 1952	26,179
Choledyl tablets (200 mg. 1,000)	Warner-Chilcott Laboratories	41,585.00	Prior to Oct. 12, 1967	58,167
Choledyl tablets (200 mg. 500)	do	3,522.00	do	7,384
Acetest tablets (100)	Ames Co	35,432.00	June 9, 1965	47,394
Solu Cortef injection Mix-O-Vial (100 mg. 2 ml.)	Upjohn Co	116,280.00	Feb. 6, 1965	124,847
Orthoxine tablets (100 mg. 500)	do	19,736.00	Feb. 24, 1966	19,308
Placidyl capsules (500 mg. 100)	Abbott Laboratories	27,430.00	May 5, 1965	33,753
Seromycin pulvules (250 mg. 500)	Eli Lilly & Co	84,474.00	Mar. 25, 1964	98,104
Orinase tablets (500 mg. 50)	Upjohn Co	114,057.00	Prior to Jan. 25, 1965	119,446
Mucotin tablets (100)	Warner-Chilcott Labs	1,889.00	Apr. 19, 1948	1,653
Imferon injection (50 mg per ml. 10 ml.).	Lakeside Laboratories	15,291.00	Sept. 23, 1965	13,440
Entozyme tablets (500)	A. H. Robins Co	19,306.00	Prior to Apr. 25, 1965	19,837
Clinitest tablets (100)	Ames Co	53,138.00	June 9, 1965	56,389
Furadantin tablets (100 mg. 1,000)	Eaton Laboratories	121,775.00	Nov. 17, 1958	220,079
Furadantin tablets (50 mg. 1,000)	do	101,546.00	do	147,962
Robaxin tablets (500 mg. 500)	A. H. Robins Co	143,408.00	Sept. 5, 1958	203,499
Arlidin tablets (6 mg. 1,000)	USV Pharm. Corp	42,117.00	June 2, 1967	83,137
Antivert tablets (500)	J. B. Roerig Co	None	Sept. 25, 1965	29,731
Kemadrin tablets (5 mg. 1,000)	Burroughs-Wellcome & Co	17,969.00	Apr. 29, 1965	13,183
Trilafon concentrate (16 mg. per 5 ml. 120 ml.).	Schering Corp	25,906.00	Prior to Nov. 13, 1964	18,390
Talwin injection (30 mg. per ml. 1 ml.)	Winthrop Laboratories	None	Aug. 5, 1968	57,619
Orenzyme tablets (500s)	National Drug Co	7,669.00	Apr. 29, 1965	6,390
Tace capsules (12 mg. 500)	Wm. S. Merrell Co	19,801.00	July 7, 1964	18,963
DBI/TD capsules (50 mg. 1,000)	USV Pharm. Corp	70,794.00	June 2, 1967	220,168
Darvon capsules (32 mg. 500)	Eli Lilly & Co	106,280.00	May 8, 1962	108,492
Phospholine Iodide (12.5 mg.)	Ayerst Laboratories	None	Sept. 25, 1968	3,840

ITEMS OBTAINED SOLE SOURCE DURING FISCAL YEARS 1968 AND 1969 WHERE ONLY ONE SOURCE WAS AVAILABLE—Continued

Item	Fiscal years 1968 Company	1968 Amount	1969 Date standardized	1969 Amount
Cordran cream (.05%, 60 Gm.)	Eli Lilly & Co	$27,635.00	May 14, 1965	$31,400
Rezipas powder (1 lb.)	E. R. Squibb & Sons	25,220.00	May 3, 1965	19,096
Robaxin tablets (750 mg. 500)	A. H. Robins Co	5,939.00	June 12, 1967	24,682
Cytoxin tablets (50 mg. 100)	Mead-Johnson Labs	36,868.00	June 22, 1964	48,829
Renografin injector (76 percent 20 ml.)	E. R. Squibb & Sons	None	Aug. 19, 1968	10,440
Nardil tablets (15 mg. 100)	Warner-Chilcott Labs	1,903	Dec. 18, 1959	3,695
Sebulex (4 oz.)	Westwood Pharm	12,087.00	June 22, 1964	12,546
Parafon forte tablets (500)	McNeil Laboratories	19,218.00	Apr. 18, 1967	77,688
Riopan suspension (12 oz.)	Ayerst Laboratories	8,921.00	Mar. 2, 1966	8,803
Quibron capsules (100)	Mead-Johnson Laboratories	None	July 15, 1968	10,787
Penthrane (125 ml.)	Abbott Laboratories	41,702.00	Dec. 27, 1965	66,463
Noludar capsules (300 mg. 500)	Roche Laboratories	55,578.00	Apr. 30, 1965	82,305
Persantin tablets (25 mg. 1000)	Geigy Pharmaceuticals	30,807.00	Feb. 5, 1965	13,702
Gantanol tablets (500 mg. 500)	Roche Laboratories	33,782.00	Nov. 30, 1965	38,189
Vistaril capsules (50 mg. 500)	Pfizer Laboratories	41,830.00	May 6, 1966	64,668
Vistaril capsules (100 mg. 500)	do	18,615.00	do	22,015
Dymelor tablets (500 mg. 500)	Eli Lilly & Co	31,783.00	Nov. 4, 1965	42,636
Cytoxin injection (200 mg.)	Mead-Johnson Laboratories	13,036.45.00	June 22, 1964	18,816
Mucomyst solution (20 percent 10 ml.)	do	56,219.00	June 23, 1964	82,619
Solu-Medrol injection (40 ml.)	Upjohn Co	46,485.00	June 22, 1964	69,105
NegGram caplets (500 mg. 1,000)	Winthrop Laboratories	150,758.00	Apr. 29, 1965	173,722
Mandelamine forte suspension (8 oz.)	Warner-Chilcott Labs	40,318.00	Feb. 28, 1967	45,334
Ser-Ap-Es tablets (1,000)	Ciba Pharm. Co	5,331.00	do	38,869
Robaxisal tablets (500)	A. H. Robins Co	14,990.00	June 22, 1964	21,493
Renacidin powder (500 Gm.)	Guardian Chemical Co	44,651.00	Nov. 20, 1962	48,376
Isordil tembids (40 mg. 100)	Ives Laboratories	46,822.00	Apr. 29, 1965	50,083
Panalba capsules (250 mg. 100)	Upjohn Co	23,979.00	Feb. 24, 1966	25,578
Mucomyst solution (20 percent, 30 ml.)	Mead-Johnson	91,233.00	June 23, 1964	51,490
Lotocreme (8 oz.)	Abbott Laboratories	17,072.00	Feb. 5, 1965	19,751
Robinul tablets (1 mg. 500)	A. H. Robins Co	22,873.00	June 22, 1964	25,602
Valium tablets (5 mg. 500)	Roche Laboratories	602,208.00	June 23, 1964	1,128,168
Darvon Compound-65 capsules (500)	Eli Lilly & Co	572,804.00	May 18, 1962	700,543
Conray-400 (25 ml.)	Mallinckrodt Chemical Works	30,081.00	Dec. 27, 1965	19,298
Chymoral tablets (500)	Armour Pharm. Co	None	Sept. 24, 1965	16,632
Modumate (25 gm. 100 ml.)	Abbott Laboratories	26,862.00	Feb. 5, 1965	4,360
Tandearil tablets (100 mg. 1,000)	Geigy Pharmaceuticals	18,270.00	do	22,837
Diabinese tablets (250 mg. 250)	Pfizer Laboratories	130,272.00	May 9, 1966	195,974
Keflin injection (4 gm.)	Eli Lilly & Co	65,040.00	Oct. 19, 1967	369,600
Tofranil tablets (25 mg. 100)	Geigy Pharmaceutical Co	5,828.00	Jan. 21, 1959	9,483
Tinactin solution (1 percent, 10 ml.)	Schering Corp	17,081.00	June 30, 1967	36,713
Ismelin tablets (10 mg. 100)	Ciba Pharm. Co	13,742.00	Oct. 20, 1961	10,061
Fluothane (125 ml.)	Ayerst Laboratories	434,760.00	April 29, 1965	338,358
Haldol tablets (1 m4. 5,000)	McNeil Laboratories	None	July 11, 1968	82,744
Haldol tablets (2 mg. 5,000)	do	None	do	203,232
Haldol tablets (1 mg. 1,000)	do	None	do	32,990
Haldol concentrate (2 mg./ml. 120 ml.)	do	None	July 15, 1968	50,559
Haldol tablets (2 mg. 1,000)	do	None	do	59,905
Renovist injection (50 ml.)	E. R. Squibb & Sons	None	Aug. 19, 1968	7,906
Dulcolax tablets (5 mg. 1,000)	Geigy Pharmaceuticals	52,906.00	Aug. 4, 1961	36,662
Depo medrol (40 mg. per ml. 5 ml.)	Upjohn Co	19,200.00	June 22, 1964	28,910
Dulcolax tablets (5 mg. 100)	Geigy Pharmaceuticals	2,380.00	Aug. 4, 1961	3,502
Vasodelan tablets (10 mg. 1,000)	Mead-Johnson Laboratories	105,094.00	March 18, 1962	132,726
Phenaphen capsules (500)	A. H. Robins Co	8,361.00	Dec. 19, 1961	7,866
Ilosone pulvules (250 mg. 100)	Eli Lilly & Co	42,823.00	June 5, 1959	44,757
Dimetane extentabs (12 mg. 500)	A. H. Robins Co	7,109.00	Dec. 19, 1961	9,541
Antabuse tablets (500 mg. 50)	Ayerst Laboratories	4,666.00	Feb. 28, 1968	8,359
Dianabol tablets (5 mg. 100)	Ciba Pharm. Co	3,485.00	Feb. 21, 1963	6,420
Cordran cream (0.05 percent, 15 gm.)	Eli Lily & Co	15,789.00	May 14, 1965	13,124
Coly-Mycin-M injection (150 gm.)	Warner-Chilcott Labs	276,939.00	Oct. 4, 1961	256,230
Surfak capsules (240 mg. 1,000)	Hoechst Pharm. Co	94,816.00	June 6, 1961	147,317
Tindal tablets (20 mg. 1,000)	Schering Corp	None	Sept. 18, 1968	8,436
Keflin injection (1 gm.)	Eli Lilly & Co	1,858,920.00	Oct. 19, 1967	2,342,130
Coly-Mycin-S otic (5 ml.)	Warner-Chilcott Labs	11,189.64	March 1, 1966	17,273
Bronkometer (10 ml.)	Breon Laboratories	6,480.00	June 7, 1966	13,608
Aventyl pulvules (25 mg. 500)	Eli Lilly & Co	76,416.00	Nov. 4, 1965	65,409
Soma compound tablets (100)	Wallace Laboratories	4,233.00	April 11, 1968	12,583
Valium tablets (10 mg. 500)	Roche Laboratories	None	May 16, 1968	278,568
Lincocin capsules (500 mg. 100)	Upjohn Co	123,534.00	Feb. 24, 1966	135,117
Diuril tablets (500 mg. 1,000)	MSD	47,102.00	May 27, 1958	45,606
Mysoline tablets (250 mg. 1,000)	Ayerst Laboratories	87,264.00	Prior to Jan. 19, 1965	130,706
Aerosporin injection (500,000 U)	Burroughs-Wellcome & Co	37,039.00	May 20, 1967	43,188
Treactor SC tablets (250 mg. 100)	Ives Laboratories	6,960.00	Apr. 8, 1963	4,176
Trecator SC tablets (250 mg. 500)	do	115,973.00	Apr. 8, 1963	58,630
Renografin-60 injection (30 ml.)	E. R. Squibb & Sons	168,064.00	June 30, 1966	144,855
Labstix test strips (100)	Ames Laboratories	None	May 18, 1968	101,348
Lasix injection (10 mg./ml. 2 ml.)	Hoechst Pharm. Co	None	Nov. 4, 1968	31,074

ITEMS OBTAINED SOLE SOURCE DURING FISCAL YEARS 1968 AND 1969 WHERE ONLY ONE SOURCE WAS AVAILABLE—Continued

Item	Fiscal years 1968 Company	1968 Amount	1969 Date standardized	1969 Amount
Lincocin solution, (300 mg./ml. 10 ml.)	Upjohn Co	$57,190.00	Feb. 23, 1966	$65,250
Isuprel mistometer (15 ml.)	Winthrop Laboratories	145,929.00	July 6, 1966	205,323
Norgesic tablets (500)	Riker Laboratories	18,949.00	Sept. 23, 1965	28,327
Darvon capsules (65 mg 500)	Eli Lilly & Co	609,126.00	May 5, 1962	677,387
Conray-400 injection (50 ml.)	Mallinckrodt Chemical Works	5,560.00	Feb. 26, 1968	19,800
Mandelamine suspension (pt.)	Warner-Chilcott Labs	37,286.00	May 16, 1962	24,996
Mycolog cream (15 gm.)	E. R. Squibb & Sons	None	Aug. 19, 1968	21,053
Cyclospasmol tablets (100 mg. 100)	Ives Laboratories	12,319.00	Apr. 8, 1963	13,259
Norflex tablets (100 mg. 50)	Riker Laboratories	47,174.00	Dec. 20, 1962	44,165
Ismelin tablets (25 mg. 1,000)	Ciba Pharm. Co	31,842.00	Mar. 18, 1963	23,499
Dianabol tablets (5 mg. 1,000)	do	11,491.00	Feb. 21, 1963	16,058
Ismelin tablets (10 mg. 1,000)	do	30,844.00	Apr. 14, 1963	24,988
Darvon compound capsules (500)	Eli Lilly & Co	75,016.00	May 8, 1962	75,956
Librium injection (100 mg.)	Roche Laboratories	42,882.00	Mar. 1, 1966	73,305
Deprol tablets (100)	Wallace Laboratories	24,648.00	June 9, 1965	38,603
Keri lotion (6½)	Westwood Pharm	7,567.00	June 12, 1967	6,683
Atromid-S capsules (500 mg. 100)	Ayerst Laboratories	None	Aug. 19, 1968	46,479
Maolate tablets (400 mg. 500)	Upjohn Co	None	May 16, 1968	51,456
Equagesic tablets (100)	Wyeth Laboratories	22,438.00	July 13, 1965	None
Kantrex injection (0.5 gm. 2 ml.)	Bristol Laboratories	33,056.00	Oct. 14, 1968	8,815
Kantrex injection (1.0 gm. 3 ml.)	do	36,391.00	do	None
Serax capsules (15 mg. 500)	Wyeth Laboratories	39,308.00	Sept. 8, 1966	None
Serax capsules (10 mg. 500)	do	7,800.00	do	None
Serax capsules (30 mg. 500)	do	34,793.00	do	None
Phenergan tablets (25 mg. 1,000)	do	12,091.00	Prior to Nov. 16, 1964.	None
Phenergan injection (25 mg./ml. 10 ml.).	do	18,408.00	Prior to Dec. 10, 1964.	None
Phenergan injection (50 mg./ml. 10 ml.).	do	4,612.00	Prior to Jan. 16, 1965.	None
Prozine capsules (50's)	do	5,639.00	Mar. 5, 1959	None
Regitine ampuls (5 mg.)	Ciba Pharm. Co	1,395.00	Prior to Mar. 10, 1965.	None
Sparine tablets (100 mg. 500)	Wyeth Laboratories	11,971.00	Aug. 7, 1956	None
Sparine tablets (50 mg. 500)	do	15,624.00	Aug. 15, 1956	None
Sparine tablets (25 mg. 5,000)	do	8,856.00	do	None
Sparine tablets (25 mg. 500)	do	10,487.00	do	None
Sparine tablets (200 mg. 500)	do	4,393.00	do	None
Sparine concentrate (30 mg./ml. 4 oz.)	do	4,491.00	Prior to Oct. 12, 1964.	None
Zactirin tablets (1,000)	do	14,112.00	June 21, 1965	None
Taractan tablets (25 mg., 500)	Roche Labs	16,294.00	June 27, 1963	27,156
Testape (100 tests)	Eli Lilly & Co	57,781.00	Aug. 15, 1956	102,229
Doriden tablets (500 mg., 1,000)	Ciba Pharm. Co	68,382.00	Prior to Oct. 16, 1964.	74,829
Talwin injection (30 mg./ml. 10 ml.)	Winthrop Labs	None	Aug. 5, 1968	335,580

ITEMS OBTAINED SOLE SOURCE DURING FISCAL YEARS 1968 AND 1969 WHERE MORE THAN ONE SUPPLIER EXISTED

Item	Fiscal years 1968 Company	1968 Amount	1969 Date standardized	1969 Amount
Aludrox suspension (8 oz.)	Wyeth Laboratories	$30,668.00	Prior to Jan. 26, 1965.	None
Aludrox tablets (100s)	do	9,485.00	Prior to Dec. 10, 1964.	None
Polycillin/N (0.5 gm, VI)	Bristol Laboratories	526,930.00	Oct. 4, 1965	$28,490
Amphojel (Pt.)	Wyeth Laboratories	7,672.00	Prior to Jan. 26, 1965.	None
A-M-T suspension (8 oz.)	do	3,529.00	Dec. 21, 1955	None
Denesex ointment (lb.)	WTS Pharmacraft	7,022.00	Prior to Jan. 19, 1965.	None
Desenex powder (1½ oz.)	do	11,735.00	Prior to Jan. 19, 1965.	None
Polycillin capsules (250 mg., 100s)	Bristol Laboratories	639,993.00	Aug. 3, 1965	139,394
Prostaphlin capsules (250 mg.)	do	8,191.00	Oct. 14, 1966	None
Prostaphlin injection (1 gm.)	do	91,103.00	Aug. 3, 1965	26,082
Chloromycetin amps (1 gm.)	Parke-Davis & Co	60,552.00	May 29, 1959	None

ITEMS OBTAINED SOLE SOURCE DURING FISCAL YEARS 1968 AND 1969 WHERE MORE THAN ONE SUPPLIER EXISTED—Continued

Item	Fiscal years 1968 Company	1968 Amount	1969 Date standardized	1969 Amount
Pabalate tablets (500)	A. H. Robins Co	$24,043.00	Prior to Jan. 21, 1965.	$23,998
Tessalon perles (100 mg.)	Ciba Pharm. Co	6,859.00	Mar. 9, 1959	9,240
Maalox suspension (6 oz.)	W. H. Rorer, Inc	121,010.00	Mar. 14, 1965	133,773
KY lubricant jel	Johnson & Johnson	16,731.36	Prior to Dec. 7, 1964	7,417
Lubafax surgical lubricant	Burroughs-Wellcome & Co	23,811.00	Prior to Nov. 20, 1964.	28,968
Peritrate tablets (80 mg., 500)	Warner-Chilcott Labs	79,431.00	May 29, 1958	59,996
Peritrate tablets (20 mg., 5,000)	do	22,686.00	Aug. 15, 1956	8,042
Peritrate tablets (10 mg., 500s)	do	17,558.00	Aug. 8, 1952	10,082
Peritrate tablets (20 mg., 500s)	do	20,960.00	Aug. 15, 1956	19,625
Peritrate tablets (20 mg., 1000s)	do	None	May 6, 1969	1,738
Nupercainal ointment (1 oz.)	Ciba Pharm. Co	7,136.00	Feb. 21, 1963	9,504
Tedral tablets SA (100)	Warner-Chilcott Labs	23,941.00	Oct. 4, 1963	30,845
Tedral tablets (1,000s)	do	44,917.00	Prior to 11/8/65	64,579
Mylanta tablets (100)	Stuart Co	11,337.00	Aug. 11, 1964	12,768
Mylanta suspension (5 oz)	do	67,544.00	do	91,558
Amesec pulvules (500s)	Eli Lilly & Co	49,687.00	Prior to 11/4/64	66,171
Betadine antiseptic sol. (gal.)	Purdue-Frederick	23,080.00	June 22, 1964	46,083
Azulfidine tablets (0.5 gm.)	Pharmacia Labs	50,325.00	Jan. 10, 1966	54,846
Betadine surgical scrub (gal.)	Purdue-Frederick	25,196.00	June 22, 1964	35,488
Isordil tablets (10 mg., 500)	Ives Laboratories	31,881.00	Mar. 22, 1967	59,189
Isordil tablets (5 mg., 100)	do	6,699.00	do	15,561
Prolixin tablets (5 mg., 5,000)	E. R. Squibb & Sons	24,999.00	May 14, 1965	12,498
Osmotrol injection (10 percent, 1,000 ml.).	Travenol Laboratories	4,376.00	Mar. 8, 1966	4,243
Prolixin tablets (2.5 mg., 500)	E R Squibb & Sons	None	Aug 15, 1969	11,676
Thiosulfil forte tabs (0.5 gm., 100s)	Ayerst Laboratories	3,732.00	Oct. 20, 1967	2,799
Mysteclin-F capsules (250 mg.)	E. R. Squibb & Sons, Inc	6,117.00	Nov. 4, 1965	27,904
Tuberculin PPD tabs (10/20 tests)	MSD	10,872.00	June 9, 1965	21,918
Mandelamine tabs. (1 gm. 1,000)	Warner-Chilcott Labs	54,928.00	Aug. 20, 1965	66,471
Mandelamine tabs. (0.5 gm. 1,000)	do	79,896.00	Prior to 11/18/64	84,394
Mandelamine tabls. (1 gm. 100)	do	31,738.00	Feb. 20, 1963	23,928
Esidrix tablets (50 mg. 1,000s)	Ciba Pharm. Co	30,174.00	June 30, 1967	None
Polaramine repetabs (6 mg. 1,000)	Schering Corp	4,230.00	Prior to 4/10/65	3,142
Travad Desposal enema (4½ oz.)	Travenol Laboratories	30,772.00	July 20, 1964	36,715
Soma tablets (350 mg., 100)	Wallace Laboratories	15,233.00	Nov. 18, 1964	25,780
Synalar Cream (0.25 percent 425 gm.)	Syntex Laboratories	None	Aug. 19, 1968	15,408
Disophrol chronotabs (100)	White Laboratories	None	Feb. 3, 1969	5,913
Pavabid plateau caps. (150 mg. 100)	Marion Laboratories	50,503.00	Apr. 11, 1967	107,917
Gelusil liquid (12 oz.)	Warner-Chilcott Labs	28,841.00	Dec. 16, 1964	30,207
Gelusil liquid (5 oz.)	do	56,421.00	Prior to Dec. 15, 1964.	45,118
Gelusil tablets (1,000s)	do	15,436.00	Prior to Nov. 18, 1964.	13,612
Gelusil tablets (5,000)	do	55,201.00	June 8, 1951	62,938
Daricon tablets (10 mg. 500)	Pfizer Laboratories	15,189.00	May 6, 1966	5,024
Fiorinal tablets (1,000)	Sandoz, Inc	35,198.00	Sept. 19, 1963	44,939
Donnatal tablets (1,000)	A. H. Robins, Co	48,400.00	Prior to Jan. 21, 1965.	55,476
Donnatal extentabs (500)	do	9,474.00	Feb. 12, 1958	10,608
Synalar cream (0.25 percent, 15 gm.)	Syntex Laboratories	37,801.00	Apr. 19, 1963	36,216
Tylenol tablets (325 mg. 1,000)	McNeil Laboratories	65,231.00	Apr. 7, 1964	90,479
Nitrospan capsules (2.5 mg. 100)	USV Pharmaceutical Co	None	Sept. 19, 1968	10,991
Medihaler Iso w/adapter (15)	Riker Laboratories	137,162.00	Nov. 5, 1962	128,045
Metamucil powder (14 oz.)	G. D. Searle	79,453.00	Mar. 3, 1967	87,905
Atarax injection (50 mg./ml. 10 ml.)	J. B. Roerig & Co	53,625.00	Mar. 2, 1966	110,500
Anectine powder (1,000 mg.)	Burroughs-Wellcome & Co	11,136.00	Mar. 11, 1964	10,210
Rela tablets (350 mg. 100)	Schering Corp	41,377.00	May 3, 1961	49,669
Neosporin ointment (½ oz.)	Burroughs-Wellcome & Co	None	August 19, 1968	2,378
Kenalog cream (0.1 percent 5 lbs.)	E. R. Squibb & Sons, Inc	do	April 11, 1968	80,490
Robitussin syrup (4 oz.)	A. H. Robins, Co	19,967.00	October 19, 1967	67,797
Titralac tablets (1,000)	Riker Laboratories	24,495.00	February 13, 1963	25,466
Synalar cream (0.01 percent 45 gm.)	Syntex Laboratories	45,316.00	April 19, 1963	42,699
Robitussin syrup (1 gal.)	A. H. Robins, Co	60,334.00	May 5, 1970	26,234
Chlor-Trimeton repetabs (12 mg. 1,000).	Schering Corp	6,104.00	Prior to October 12, 1964.	12,351
Epitrate ophthalmic sol (2.0 percent 7.5 ml.)	Ayerst Laboratories	2,621.00	February 28, 1968	12,979
Phisohex (gal.)	Winthrop Laboratories	254,160.00	February 20, 1950	239,151
Demerol injection (50 mg./ml. 30 ml.)	do	19,620.00	Prior to April 15, 1957.	15,909
Furacin soluble dressing (lb.)	Eaton Laboratories	8,121.00	September 23, 1965	11,257
Gantrisin tablets (0.5 gm. 1,000)	Roche Laboratories	72,012.00	Prior to January 19, 1965.	89,250

ITEMS OBTAINED SOLE SOURCE DURING FISCAL YEARS 1968 AND 1969 WHERE MORE THAN ONE SUPPLIER EXISTED—Continued

Item	Fiscal years			
	1968		1969	
	Company	Amount	Date standardized	Amount
Pyribenzamine tablets (50 mg. 1,000)	Ciba Pharm. Co	$4,230.00	Prior to July 20, 1965.	$8,412
Isuprel HCl solution (1:200 10 ml.)	Winthrop Laboratories	16,595.00	Prior to January 18, 1965.	21,612
Isuprel HCl solution (1:200 50 ml.)	do	36,158.00	Prior to November 13, 1964.	37,721
Kaopectate (gal.)	Upjohn Co	8,316.00	February 23, 1966	16,253
Polysporin ointment (1 oz.)	Burroughs-Wellcome & Co	22,208.00	March 11, 1964	15,638
Zephiran chloride concentrate (gal.)	Winthrop Laboratories	7,366.00	Prior to December 10, 1964.	5,604
Anusol suppositories (24s)	Warner-Chilcott Labs	29,987.00	Prior to January 18, 1965.	26,584
Benadryl Kapseals (50 mg. 1,000)	Parke-Davis & Co	26,310.00	February 28, 1962	13,830
Colace capsules (100 mg. 250)	Mead Johnson Labs	16,710.00	Prior to November 9, 1964.	32,026
Pyridium tablest (100 mg. 1,000)	Warner-Chilcott Labs	38,978.00	Prior to Oct. 12, 1964	24,313
Pronestyl capsules (250 mg. 1,000s)	E. R. Squibb & Sons, Inc	21,691.00	Mar. 2 1966	48,654
Priscoline tablets (25 mg. 1,000)	Ciba Pharm. Co	4,056.00	Prior to Nov. 12, 1964	8,047
Premarin tablets (1.25 mg. 100)	Ayerst Laboratories	7,904.00	Feb. 28, 1968	2,880
Dilantin kapseals (100 mg. 1,000)	Parke-Davis & Co	36,263.00	Aug. 2, 1967	78,238
Neosporin ointment (1 oz.)	Burroughs-Wellcome & Co	49,680.00	Mar. 11, 1964	29,312
Peritrate SA tablets (80 mg. 1,000s)	Warner-Chilcott Labs	None	Apr. 24, 1969	18,985
Nupercainal ointment (1 lb.)	Ciba Pharm. Co	1,530.00	Prior to Oct. 15, 1964	2,172
Chlor-Trimeton repitals (8 mg. 1,000s)	Schering Corp	5,897.00	Prior to Nov. 13, 1964	6,755
V-Cillin K tablets (250 mg. 100)	Eli Lilly & Co	49,635.00	Mar. 16, 1965	105,408
Furacin solution (0.2 percent, Pt.)	Eaton Laboratories	9,752.00	Sept. 23, 1965	12,302
Pabalate sodium free tablets (500s)	A. H. Robins Co	19,176.00	Prior to Jan. 21, 1965	31,848
Pamine bromide tablets (2.5 mg. 500s)	Upjohn Co	9,606.00	Prior to Nov. 17, 1964	10,788
Lanoxin tablets (0.25 mg. 1,000)	Burroughs-Wellcome & Co	26,957.00	May 14, 1965	31,010
Fleet enema (4½ oz.)	C. B. Fleet Co., Inc	118,023.00	Prior to Jan. 20, 1965	88,561
Kenalog cream (0.1 percent, 15 gm.)	E. R. Squibb & Sons	4,140.00	Aug. 19, 1968	10,640
Apresoline tablets (50 mg. 1,000)	Ciba Pharm. Co	9,254.00	June 23, 1964	20,294
Apresoline tablets (25 mg. 1,000)	do	22,604.00	do	37,226
Barosperse powder (25 lb.)	Mallinckrodt Chemical Works	17,773.00	Nov. 8, 1964	16,894
Meprospan capsules (400 mg. 100)	Wallace Laboratories	7,656.00	Feb. 9, 1967	10,005
Lufyllin tablets (200 mg. 1,000)	Mallinckrodt Chemical Works	None	Oct. 16, 1968	38,607
Barosperse powder (100 lb.)	do	22,690.00	Nov. 8, 1964	32,583
Alpha-Keri (8 oz.)	Westwood Pharm	61,569.00	June 23, 1964	41,651
Senokot tablets (100)	Purdue-Frederick	None	Mar. 18, 1969	1,980
TAO capsules (250 mg., 60)	J. B. Roerig & Co	2,120.00	Mar. 2, 1966	6,270
Pertofrane capsules (25 mg., 1,000s)	Geigy Pharm	23,543.00	Dec. 17, 1965	17,778
Norpramin Tablets (25 mg., 1,000s)	Lakeside Labs	57,142.00	Nov. 4, 1965	32,560
Norpramin Tablets (50 mg., 1,000s)	do	14,760.00	Feb. 14, 1967	28,440

COMBINATION PRODUCTS PURCHASED DURING FISCAL YEAR 1968 AND FISCAL YEAR 1969

	Fiscal Years	
	1968	1969
Aludrox Suspension (8 oz.)	$30,668	----------
Aludrox Tablets (1,000s)	9,485	----------
A-M-T Suspension (8 oz.)	3,529	----------
Desenex Ointment (1 lb.)	7,022	----------
Desenex Powder (1½ oz.)	11,735	----------
Equagesic Tablets (1,000s)	22,438	----------
Prozine Capsules (50s)	5,639	----------
Zactirin Tablets (1,000s)	14,112	----------
Panalba Capsules (250 mg, 100s)	23,979	$25,578.00
Mysteclin F Capsules (250 mg, 100s)	6,117	69,638.00
Darvon Compound-65 Capsules (500s)	572,804	700,543.00
Darvon Compound Capsules (500s)	75,016	75,956.00
Fiorinal Tablets (1,000s)	35,198	44,939.00
Pabalat e Sodium Free Tablets (500s)	19,176	31,848.00
Pabalate Tablets (500s)	24,043	23,998.00
Phenaphen Capsules (1,000s)	8,362	7,865.00
Innovar Injection (5 ml.)	13,004	16,018.00
Innovar Injection (2 ml.)	12,498	12,169.00
Phisohex (1 gal.)	254,160	239,161.00
Neosporin Ointment (1 oz.)	49,680	39,312.00
Polysporin ointment (1 oz.)	22,208	15,638.00
Sebulex (4 oz.)	12,087	12,546.00
Mycolog cream (½ oz.)	----------	21,053.00
Neosporin Ointment (½ oz.)	----------	2,378.00
Keri Lotion (6½ oz.)	7,567	6,683.00
Alpha-Keri (8 oz.)	61,569	41,651.00
Anusol suppositories (24s)	29,987	26,584.00
Lotocreme Lotion (8 oz.)	17,073	19,751.00
Ser-Ap-Es Tablets (1,000s)	5,331	38,869.00
Antivert Tablets (500s)	----------	29,730.96
Quibron Capsules (100s)	----------	10,787.00
Aerolone Compound (1 oz.)	15,738	18,604.00
Tedral Tablets, S.A. (100s)	23,941	30,845.00
Tedral Tablets (1,000s)	44,917	64,579.00
Duo-Medihaler (22.5 ml w/adapter)	33,985	53,222.00
Amesec Capsules (500s)	49,687	66,171.00
Labstix (100s)	----------	101,348.00
Hypaque-M injection (75 percent, 50 ml.)	----------	67,896.00
Renovest injection (50 ml.)	----------	7,906.00
Fleet enema (4½ oz.)	118,023	88,561.00
Travad disposable enema (4½ oz.)	30,772	36,715.00
Triasyn B capsules NF (1,000s)	3,131	8,301.00
Hexavitamin tablets, NF (500s)	11,276	14,458.00
Therapeutic vitamin formula capsules	30,596	50,543.00
Disophrol chronotabs (100s)	----------	5,913.00
Gelusil tablets (1,000s)	15,436	13,612.00
Gelusil tablets (5,000s)	55,201	62,938.00
Gelusil liquid (5 oz.)	56,424	45,418.00
Gelusil liquid (12 oz.)	28,841	30,207.00
Maalox suspension (6 oz.)	121,010	133,773.00
Mucotin tablets (1,000s)	1,889	1,653.00
Mylanta tablets (100s)	11,337	12,768.00
Mylanta suspension (5 oz.)	67,544	91,558.00
Titralac tablets (1,000s)	24,494	25,466.00
Phenobarbital and Belladonna tablets	4,127	4,164.00
Donnatal extentabs (500s)	9,475	10,609.00
Donnatal tablets (1,000s)	48,400	55,476.00
Kaopectate (gal.)	8,316	16,253.00
Deprol tablets, (100s)	24,648	38,603.00
Librax capsules (500s)	31,500	35,790.00
Coly-Mycin-S-Otic drops w/Neomycin and Hydrocortisone (5 ml.)	11,190	17,273.00
Parafon forte tablets (500s)	19,218	77,688.00
Norgesic tablets (500s)	18,949	28,327.00
Robaxisal tablets (500s)	14,990	21,493.00
Soma compound tablets (100s)	4,234	12,583.00
Orenzyme tablets (500s)	7,668	6,390.00
Chymoral tablets (500s)	----------	16,632.00
Entozyme tablets (500s)	19,306	19,838.00
Bronkometer (10 ml.)	6,480	13,608.00
Alevaire (60 ml.)	7,683	7,431.00
Alevaire (500 ml.)	3,910	4,597.00
Metamucil powder (14 oz.)	79,453	87,905.00
Doxidan capsules (1,000s)	24,171	46,158.00
Hexavitamin capsules NF (500s)	18,099	19,461.00

VETERANS' ADMINISTRATION—COMBINATION DRUG PRODUCTS PURCHASED—SOURCE 8

Item number	Item name	Dollar value fiscal year 1968 and 1969
*6505-207087A	Chlorpheniramine Malrate, Codeine Phosphate, Phenylpropanolamine Hydrochloride, Carbetapentane Citrate, Glyceryl Guaiacolate, Sodium Citrate, Citrid Acid, Chloroform and Methylaraben syrup, 473 ml. (16 oz.) (Tussar-2) (3633).	$15,688.00
*6505-213275A	Chymotrypsin, Hydrocortamate Hydrochlorile and Neomycin Palmitate ointment (Chymar), 5 gm. (⅛ oz. No. 2318).	2,175.00
*6505-088-7925A	Chymotrypsin, Hydrocortamate Hydrochlorile and Neomycin Palmitate ointment (Chymar), 15 gm. (½ oz., No. 2314).	6,086.00
*6505-782-0503A	Chymotrypsin, Hydrocortamate Hydrochlorile and Neomycin Palmitate ointment (Chymar), 30 gm. (1 oz., No. 2328).	2,799.00
*6505-782-0478A	Chymotrypsin, Hydrocortamate Hydrochlorile and Neomycin Palmitate ointment (Chymar), 60 gm. (2 oz., No. 2319).	4,712.00
6505-220200A	Cobalamin concentrate tablets 25 mcg. with intrinsic factor, concentrate, 30s (Biopar Forte, No. 2254).	250.80
6505-761-0887A	Cyanocobalamin tablets, 6 mcg., with intrinsic factor concentrate, 30s (Biopar, No. 2258).	447.50
6505-782025A	Pentaerythritol Tetranitrate and Butabarbital sodium capsules, 30 mg., control release, (Pentritol tempules with Butabarbital), 100s (No. 3027).	578.00
6505-782030A	Pentaerythritol Tetranitrate and Butabarbital Sodium Capsules, 30 mg., control release, (Pentritol tempules with Butabarbital) 250s (No. 3012).	578.00
6505-914-6565A	Proteolytic Enzymes with Neomycin ointment, 15 gm. (½ oz, tube, Biozyme, No. 2261).	14,022.00
*6505-892840A	Sodium Secobarbital, Phenobarbital, Sodium Butabarbital, and Sodium Pentobarbital tablets, scored, light green (Nidar) 100s (No. 2870).	832.00
*6505-892843A	Sodium Secobarbital, Phenobarbital, Sodium Butabarbital, and Sodium Pentobarbital tablets, scored, light green (Nidar) 1,000s (No. 2871).	988.50
*6505-893150A	Sodium Sulvacetamide, Trisulfapyrimidine (Deltamile) oral suspension, 0.5 gm. per 5 ml., 480 ml. (16 oz., number 2432).	103.50
*6505-893175A	Sodium Sulfacetamide, Trisulfapyrimidine (Deltamide) tablets, 0.5 gm., 100s (number 2428).	133.60
*6505-064-4154A	Trypsin-Chymotrypsin tablets, in a 6 to 1 ratio, enteric coated, red, Enzyme (Chymoral) 48s (number 2330).	1,053.25
*6505-728-2611A	Trypsin-Chymotrypsin tablets, in a 6 to 1 ratio, enteric coated, red, Enzyme. (Chymoral) 250s (number 2343).	10,212.00
*6505-985-7315A	Influenza virus vaccine, USP, polyvalent, type A and B, 10 ml. (Winvac)	2,775.00
6505-784-6690A	Methiodal Sodium and Neomycin Sulfate solution, 50 ml. (Retropaque)	4,125.00
*6505-903-9996A	Chlorpromazine Hydrochloride and Dextro Amphetamine Sulfate tablets, 10 mg. Chlorpromazine Hydrochloride, USP, and 2 mg. Dextro Amphetamine Sulfate, 50's, sugar coated, aqua colored (Thora-Dex No. 1).	7,600.00
*6505-899-9566A	Chlorpromazine Hydrochloride and Dextro Amphetamine Sulfate tablets, 25 mg. Chlorpromazine Hydrochloride, USP, and 5 mg. Dextro Amphetamine Sulfate, 50's, sugar coated, aqua colored (Thora-Dex No. 2).	5,300.00
6505-045-7790A	Diphtheria and Tetanus toxoids, adsorbed, USP, combined, (Pediatric) alum precipitated, 5 ml. (5 immunizations) tablets number 1799.	1,022.00
6505-780-3523A	Procaine Penicillin and buffered Penicillin for aqueous injection, NF, 10,000,000 units, 10-dose vial (1,000,000 units per dose; 750,000 units Penicillin G Procaine and 250,000 units Penicillin G crystalline-sodium, Duracillin F.A.) 25's.	3,750.00
*6505-890-1902A	Pyrrobutamine compound capsules, yellow opaque body, green opaque capsules 1000's (Co-Pyronil).	1,650.00
6505-685-5411A	Sodium Amobarbital and Sodium Secobarbital capsules Pulv. number 303 1½ gr. (100 mg), blue body, orange capsule 1000's (Tuinal).	722.50
6505-685-5413A	Sodium Amobarbital and Sodium Secobarbital capsules Pulv. number 304, 3 gr. (200 mg.), blue body, orange capsules 1000's (Tuinal).	965.00
6505-059-3457A	Vitamin B Complex and Ascorbic Acid Injection (Betalin Complex F. C.) Ampoule number 620 2 ml. Ampoule 100's.	833.50
6505-901-6671A	Vitamin B complex and Ascorbic Acid injection (Betalin Complex F. C.) Ampoule number 621 10 ml. vial, 25's.	5,484.00
6505-901-6651A	Vitamin B Complex injection (Betalin Complex) Ampoule number 390, 2 ml. ampoule, 100's.	721.50
6505-764-4368A	Vitamin B Complex injection (Betalin Complex) Ampoule number 391, 10 ml. vial, 25's.	1,488.00
6505-766-9589A	Vitamin B Complex and Ascorbic Acid Tablets, coated, cinnamon-brown, 1000's (Becotin-T) tablets number 1810.	1,812.00
*6505-809-2710A	Benzathine Penicillin G and Procaine Penicillin G suspension, sterile, injection, in aqueous suspension, cartridge needle unit, needle size 20 g.x1¼", 300,000 units, 1 ml. (Bicillin CR 600, Tubex) 10's pkg. number 1S405.	8,532.00
*6505-901-6032A	Benzathine Penicillin G and Procaine Pencillin G suspension, sterile, injection, in aqueous suspension, cartridge needle unit, needle size 20 G.x1¼", 300,000 units, 1 ml. (Bicillin CR 600), (Tubex) 50's pkg. number 1U405.	1,777.50
*6505-616-7858A	Benzathine Pencillin G and Procaine Penicillin G suspension, sterile, injection, in aqueous suspension, cartridge needle unit, needle size 20 G.x1¼", 600,000 units, 2 ml. (Bicillin CR 1200 MU, (Tubex) 10's pkg. number W405.	1,035.00
*6505-881-0520A	Benzathine Pencillin G and Procaine Pencillin G suspension, sterile, injection, in aqueous suspension, cartridge needle unit, needle size 20 G.x1¼", 600,000 units, 2 ml. (Bicillin CR 1200 MU), (Tubex) 50's pkg. number 1X405.	2,587.50
6505-984-4052A	Diphtheria and Tetanus toxoids USP, combined, (Pediatric) Aluminum Phosphate, ultrarefined, 0.5 ml. needle size 25 G.x⅝", 10's (Tubex) pkg. number 69E18.	62.40
6505-087-5737B	Diphtheria and Tetanus toxoids and Pertussis vaccine, adsorbed, USP, combined aluminum Phosphate, 0.5 ml. cartridge needle unit, needle size 25 G.x⅝", 10's (triple antigen Tubex) pkg. number 78L9.	385.00

See footnot at end of table, p. 7470.

VETERANS' ADMINISTRATION—COMBINATION DRUG PRODUCTS PURCHASED—SOURCE 8—Continued

Item number	Item name	Dollar value fiscal year 1968 and 1969
6505-299-9541A	Lentopen, 1 ml, needle size 20 G.x1¼", 10's (Tubex). All purpose, 300,000 units Procaine Penicillin G and 100,000 units Potassium Penicillin G in oil, pkg. number 1AB263.	$950.00
*6505-890-1522A	Mepergan injection, 50 mg. Promethazine Hydrochloride and 50 mg. Meperidine Hydrochloride, 2 ml., needle size 22 G.x1¼", 10's (Tubex) pkg. number 1B628.	337.40
6505-809-2707A	Procaine Penicillin G and Streptomycin Sulfate suspension, sterile, 2 ml. cartridge needle unit, needle size 21 G.x1¼", 10's (Wycillin SM Tubex) 400,000 units, pkg. number B652.	3,008.00
6505-089-3068A	Procaine Penicillin G and Streptomycin Sulfate suspension, sterile, 2 ml. cartridge needle unit needle size 21 G. x1½", 10's (Wycillin SM, Tubex) 600,000 units, pkg. number 1A752.	2,680.00
6505-930334A	Tetanus and Diphtheria toxoids, absorbed, USP, combined (adult) Aluminum Phosphate, ultrafined, 0.5 ml., (cartridge needle unit, needle size 25 G.x⅝", 10's (Tubex) pkg. number 69E23.	873.60
6505-835-1123A	Vitamin B Complex injection, 1 ml. cartridge needle unit, needle size 22 G.x1½", 10's (Tubex) pkg. 1A779.	563.20

*Available from one source only.

VETERANS' ADMINISTRATION—COMPETITIVE BIDDING, FISCAL YEAR 1969

Product	Winning bidder	Amount of purchase	Other bidders
Alcohol	Shell	$21,063	5
Alcohol dehydrated	Warner Graham	40,408	1
Alcohol USP	Union Carbide	14,312	2
	USI Chemical	17,861	0
	Warner Graham	7,115	0
	National Distillers	3,993	1
Aminophylline	American Quinine	6,534	2
Aspirin tabs	Dewey	21,349	5
	Kasar	2,718	1
Bacitracin	Premo	6,655	2
Bacitracin ointment	Day Baldwin	10,498	1
	Fougera	1,728	2
	Premo	2,460	2
Chloral Hydrate	Mallinckrodt	1,373	0
Cascara	Lannett	3,096	3
	Halsey Drug	2,660	0
Cascara	Certified Labs	89,112	4
	Halsey	1,939	0
Chlorpheniramine Maleate	Anabolic	1,187	6
Codeine Phosphate	Kirkman	15,561	1
	Lilly	3,678	0
Colchicine tablets	Anabolic	6,485	5
Cyanocobalamin injection	Anabolic	1,269	2
	American Quinine	8,480	3
Ether	Mallinckrodt	6,119	1
Ferrous Sulfate tablets	Zenith	8,294	3
	American Quinine	5,422	4
	Davis Edwards	2,700	1
Glycerin suppositories	G-W Labs	12,236	0
Griseofulvin	McNeil	5,945	4
Hexachlorophene liquid soap	Harley Chemical Co	16,382	0
Hexavitamin tablets	Lannett	5,006	1
Hexavitamin tablets	Gyma	4,633	3
	USV	2,847	1
	Bolar	6,977	5
	American Quinine	6,304	1
Hydrogen peroxide	American Peroxide	2,850	1
	Dewey	20,809	3
Iodine	Mallinckrodt	1,478	1
Isopropyl alcohol	Union Carbide	6,424	2
	Shell Chemical	8,598	3
Isopropyl rubbing alcohol	Dewey	14,402	1
	Halsey Drug	8,372	1
Meprobamate	Gyma	74,400	1
	Wallace	25,000	1
	Halsey Drug	3,733	1
Mineral oil	Dewey	2,011	
	Halsey Drug	4,761	3
	Lannett	5,988	3

VETERANS' ADMINISTRATION—COMPETITIVE BIDDING, FISCAL YEAR 1969—Coninued

Product	Winning bidder	Amount of purchase	Other bidders
Neomycin sulfate	Copanos	$8,442	2
	Premo	26,200	0
	Upjohn	8,136	1
	Premo	26,061	3
Nitroglycerin	Lilly	4,883	0
Papaverine HCl	Merrell	1,309	1
	USV	1,992	5
Penicillin G Injection	Copanos	5,871	1
	Lilly	67,482	1
	Squibb	3,335	0
Phenobarbital	Davis Edwards	900	7
	Kasar	7,569	1
	Massengill	11,071	3
Potassium penicillin G tablets	Copanos	596	4
	Zenith	2,227	0
	Premo	1,078	1
Potassium penicillin G tablets	Zenith	2,795	0
	Pfizer	4,105	1
Prednisone tabs	Zenith	22,579	0
Prednisolone	Lannett	1,016	7
	Zenith	3,425	0
	Massengill	1,161	4
Pyridoxine	Lannett	1,697	5
Pyridoxine HCl	Anabolic	3,112	7
	American Quinine	1,876	4
	Bolar	1,800	9
Quinidine sulfate	Davis Rose Hoyt	18,494	5
	American Quinine	6,278	2
Sodium pentobarbital	Anabolic	1,696	3
	American Quinine	10,616	9
Sodium salicylate	Panray	6,732	1
	Kirkman	13,997	0
Sodium secobarbital	Anabolic	4,141	4
	Davis Edwards	6,168	4
Tetracycline HCl	Rachelle	143,056	5
	Zenith	89,845	2
	Halsey	22,011	1
Therapeutic formula vitamin	American Quinine	19,483	0
	Lannett	19,254	2
Triasyan B tablets	Halsey	2,605	1
	Massengill	3,125	2
Thiamine HCl	Bolar	445	9
	Davis Edwards	3,666	4
	American Quinine	3,631	9

DRUG PROCUREMENTS FROM LARGE COMPANIES BY DSA, GSA, AND VA, FISCAL YEARS 1968 AND 1969

Company	DSA calendar years	GSA fiscal years	VA ficsal years	Total
Abbott	$1,670,201	$114	$502,125	$2,172,440
American Cyanamid	1,934,223	4,000	189,236	2,127,459
American Home	5,124,096	884,516	2,336,373	8,344,984
Bristol	7,638,463	----------	2,490,516	10,128,979
Ciba	400,784	5,000	688,061	1,093,845
Johnson & Johnson	3,349,233	15,345	798,583	4,163,160
Lilly	7,796,491	6,660	9,405,345	17,208,496
Merck Sharpe Dohme	4,214,316	15,129	125,500	4,354,945
Parke Davis	1,882,448	125,842	241,956	2,250,246
Pfizer	2,657,026	5,805	968,248	3,631,071
Richardson-Merrell	1,353,265	----------	41,958	1,395,223
Roche	7,942,776	55,124	7,017,987	15,015,887
Schering	719,086	----------	559,702	1,278,788
Searle	5,038,378	804,874	448,187	6,291,439
Smith Kline & French	5,582,728	----------	4,173,543	9,756,271
Sterling	4,702,992	364,886	2,490,873	7,558,751
Squibb	1,025,349	15,250	622,925	1,663,524
Syntex	873,732	----------	177,444	1,051,176
Upjohn	1,367,936	240	1,010,675	2,378,851
Warner-Lambert	2,611,592	----------	2,443,396	5,054,988
Totals	67,885,115	2,302,785	36,732,633	106,920,523

VETERANS' ADMINISTRATION—SOLE SOURCE PROCUREMENT

We purchase drugs sole source for the following reasons:

1. Only source available.
2. Only one source meets established standards.
3. To satisfy professional requirements.

A number of drugs required for treatment of patients are available from only one source and therefore competition cannot be obtained.

Standards have been established for manufacture, quality control, housekeeping and testing requirements for firms who sell drugs to the VA. These standards are universally applied and must be met by all manufacturers supplying the VA.

We procure drugs sole source when this is necessary to satisfy the prescription as written by the physician. We are responding to requests for filling prescriptions written by over 90,000 non-VA physicians in our service-connected outpatient program alone. These physicians are not on our staff and although efforts are made to contact them by phone to suggest available equivalent medication, it is not always possible to obtain their permission for dispensing a therapeutic equivalent. We are supplying drugs to fill 11 million prescriptions by VA pharmacies at considerable savings over what we would pay to have the same prescription filled in community pharmacies.

Physicians prescribing for VA patients are requested and encouraged to use generic terminology whenever possible to permit more standardization of drug procurement. The two forms used by physicians to order medications for patients, namely, VA Form 10–1158 "Doctors Orders" and VA Form 10–2577d "Prescription Form", contain statements authorizing dispensing of another brand of a generically equivalent product, identical in dosage form and content of active ingredients. If the prescribing physician doesn't agree to use of a generic product he must check in an appropriate place provided on the form. This encourages him to use the generic product but permits him to express his professional right to prescribe a particular item he feels is essential in treatment of the patient.

Senator NELSON. On page 24 in the Task Force on Prescription Drugs, there is a statement by the Task Force on rational prescribing which I ask be printed at this point in the record.

(The material follows:)

[Excerpt, Task Force on Prescription Drugs—Report and Recommendations—Committee Print, 90th Congress, 2d Session—Subcommittee on Monopoly of the Select Committee on Small Business, U.S. Senate—Prepared by the U.S. Department of Health, Education, and Welfare, Aug. 30, 1968, page 24]

* * * * * * *

Rational prescribing

The appropriate selection of a drug—the right drug for the right patient, in the right amounts at the right times—is generally defined as rational prescribing, and any significant deviation is considered to be irrational prescribing.

Rational prescribing is obviously the result of judgments on many points—the safety and efficacy of the drug for the clinical problem at hand, the advantages or disadvantages of alternative forms of therapy, the most appropriate dosage form, the length and intensity of treatment, the possible side effects or adverse reactions, and the possibility of drug interaction.

To these may be added judgments concerning relative costs.

Rational prescribing is clearly a major goal for the welfare of patients. It is likewise a major goal for any drug insurance program. Here, emphasis has been placed not directly on achieving rational prescribing but rather on preventing some of the more serious or costly forms of irrational prescribing. Among the latter are these:

The use of drugs without demonstrated efficacy.

The use of drugs with an inherent hazard not justified by the seriousness of the illness.

The use of drugs in excessive amounts, or for excessive periods of time, or inadequate amounts for inadequate periods.

The use of a costly duplicative or "me-too" product when an equally effective but less expensive drug is available.

The use of a costly combination product when equally effective but less expensive drugs are available individually.

The simultaneous use of two or more drugs without appropriate consideration of their possible interaction.

Multiple prescribing, by one or several physicians for the same patient, of drugs which may be unnecessary, cumulative, interacting, or needlessly expensive.

Senator NELSON. I want to thank you very much for your testimony.

Mr. JOHNSON. Thank you very much, Mr. Chairman. It was a pleasure.

Senator NELSON. And for spending your time here with us this morning.

Thank you.

(The complete prepared statement and supplemental information submitted by Mr. Johnson follows:)

STATEMENT OF HON. DONALD E. JOHNSON, ADMINISTRATOR OF VETERANS' AFFAIRS

Mr. Chairman and Members of the Committee, I welcome the opportunity to appear before this Subcommittee to describe to you the policies and practices of the Veterans Administration in the selection and procurement of drugs and to acquaint you with the role we play within the Federal Government in this important field of medicine.

As the Administrator of Veterans Affairs I am directing an agency which is the largest Federal consumer of drugs and medicine outside the military. In fact, except in times of war or major military action, we are the largest Federal consumer. In addition, by delegation and assignment under the Federal Property and Administrative Services Act of 1949, as amended, we are the commodity manager for all non-military Federal users. Our procurement and contracting for this commodity thus provides logistical support for many Federal programs as well as for the Veterans Administration medical and clinical programs. I will describe in some detail the operations of our program, which may serve to amplify the meaning of the data already provided this Subcommittee.

As a small businessman myself for a number of years, I personally as well as officially wholeheartedly subscribe to the principles of the Small Business Act (15 USC 631), particularly Section 2a which provides that a fair proportion of Federal Procurement shall be from small business. The data furnished to this Subcommittee might lead to the conclusion that a rather small proportion of the Veterans Administration drug procurement is from small business. I would like to supplement that data with the information that of all our drug purchases from both central procurement and individual hospital procurement 16% of our dollars are spent directly with small contractors; an additional 5% is for prescriptions purchased from local private pharmacies, almost all of which are small businesses; and a significant proportion of the remaining 79%, although the product of large manufacturers, may be procured from small business distributors and drug wholesalers. This is not the optimum situation for the Veterans Administration, and I shall see that strong and sincere efforts are extended to improve our posture in support of small business.

Unfortunately, as the Chairman and Members of this Subcommittee well know, the procurement of drugs is considerably more complex and complicated than almost any product purchased both for Federal and private programs. It has been fraught with controversy and is not free from strongly held divergent opinions. It is an area in which those of opposing views can find competent expert opinions in support of any particular viewpoint as to the safety, efficacy, relative therapeutic merits or (to use a term not often related to human life and health) the cost effectiveness of any given drug, drug manufacturer or therapeutic drug category. It is an area which, as the Administrator of this large drug-consuming agency, I am convinced does not offer "pat" or unequivocal answers. It is within this framework that the policies on the selection and procurement of drugs evolve within the Veterans Administration.

The administrative process does not dictate the selection of drugs which will be prescribed and dispensed in our Veterans Administration hospitals and clinics. We consider that the judgment of the physician is paramount to all other considerations in the drug selection process. In this agency his judgment is not made as a matter of unenlightened preference in an information vacuum. Supplementing his own knowledge and sources of information is the approval process at both the local hospital and national agency level. He is also supported by technical and scientific data provided by our Pharmacy Service and cost and market data provided by our Supply Service.

I would like to digress slightly to call the Subcommittee's attention to the unique and extensive affiliation program between the Nation's medical schools and the Veterans Administration. This affiliation program provides us with a vast body of fresh information on both laboratory and clinical research, pharmacological studies, new drug developments, in a more comprehensive and timely manner than otherwise might be available. We make full use of this information and do not, as some have charged of private physicians, rely primarily upon promotional and advertising sources for knowledge of drug products.

The process of drug selection begins at the individual Veterans Administration hospital. When one of our physicians proposes to add a new drug product to those approved for use, he presents his proposal to a Therapeutic Agents and Pharmacy Review Committee. This Committee, consisting of representative members of the professional, technical and administrative staff meets at least monthly to review the drug selection process. Before approving a new product, the Committee considers available data on the item's safety, efficacy, known side-effects, adverse reactions, extensiveness of use in the medical community, and valuates these factors together with data on duplication of drugs already approved for local use, the cost of therapeutically equivalent drugs, the ready availability of sources for both routine and emergency deliveries. After considering all these factors, the Committee in approving the drug, will direct a period of clinical evaluation followed by its inclusion in the station's drug formulary, which is available to all physicians on the staff, at every nursing station, and is provided to non-Veterans Administration physicians prescribing for eligible veteran beneficiaries both in and out of our hospitals. If the Committee does not concur in the proposal, the drug may be approved for use by the physician for a specific patient, but it would not be used for additional patients without subsequent review by the Committee for each such patient and it would not be described or listed in the station's drug formulary.

The results of each station's local committee proceedings are reported in detail to the Central Office Executive Committee on Therapeutic Agents. This central committee provides an overview of the agency operations, provides guidance and assistance to individual hospital committees, and digests and disseminates data to Veterans Administration personnel through a variety of media.

In considering the selectian process of drugs procured by the Veterans Administration, a little-known fact must be borne in mind. The historical picture of drug usage by this agency is one of providing drugs and medicine to hospitalized veteran patients. We formerly provided a limited amount of drugs from our own pharmacies or through financial reimbursement to private pharmacies for outpatients. Several recent legislative actions have extensively increased the number of veterans who are to receive drugs and medicines at government expense. In Fiscal Year 1968, for the first time in this agency's history, the total expenditure for drugs provided outpatients exceeded that provided inpatients. This trend has steadily increased in Fiscal Years 1969 and 1970 and is projected to continue upward. Many of the prescriptions for these drugs are written by private physicians. Although we provide these physicians with data on our drug selections and our formularies, we cannot and do not attempt to control their professional practice by administrative direction. This growing outpatient workload has increased the number and kinds and brands of drugs purchased by the Veterans Administration to fill these prescriptions.

This Subcommittee has in the past expressed the view that the purchase of drugs on a "generic" basis should be increased. We interpret this to mean the procurement on a competitive basis of drugs formulated of the same primary chemicals. It is the official policy of this agency to request and encourage

physicians prescribing for our inpatients and outpatients to use generic terminology or nonproprietary nomenclature whenever possible. The two forms used by physicians to order medications for patients, VA Form 10–1158 "Doctors Orders" and VA Form 10–2577d "Prescription Form", contain statements authorizing dispensing of another brand of a generically equivalent product, identical in dosage form and content of active ingredients. If the prescribing physician does not agree to the use of a generic product he must check in the appropriate place provided on the form. This encourages him to use the generic product but permits him to express his professional right to prescribe a particular item if he feels he can justify the request.

When we can be assured of effective safeguards to adequately assure that chemically equivalent drugs are also biologically and therapeutically equivalent, we promote actively the use of generically procured drugs. At this time in the critical review and challenge of our historical methods of assuring the safety and efficacy of drug products, we are proceeding with greater caution. There is increasing evidence that many of the drugs marketed for some years as chemically equivalent drugs meeting USP or NF standards will not produce the same clinical response in patients. I am certain this Subcommittee is aware of the National Academy of Sciences/National Research Council "white paper" which recommended that manufacturers of generic drugs available on the market for some years be required to prove that their products have the same therapeutic effectiveness as the original drugs they seek to imitate. As I stated earlier this entire area is one in which there are divergent views. The promotion of generic equivalent procurement and the criticism of marketing of so-called "me too" drugs is an example of the dichotomy of views. Generically equivalent drugs almost universally enter the market as "me too" drugs. We will continue to develop the program of generic procurement when this will produce lower drug costs to us. However, we will not sacrifice the assurance of optimum patient care by use of questionable therapeutic agents merely to obtain the lowest price available. Until increased scientific knowledge and more precise standards are available to us, we must continue to exercise our own best judgment in the selection of therapeutically equivalent drugs.

Your staff has expressed interest in our policy toward the use of combination drugs. It is our policy to discourage the use of these drugs. We do not prohibit their use when the prescribing physician determines that a combination drug is required for his patient. It is noteworthy that over 86% of the expenditures in our central drug program were for single entity drugs during a period when the combination drugs were enjoying an increasing share of the national market.

We, of course, continually monitor our drug program to guard against use of drugs producing previously unsuspected adverse reactions. We participate in the Food and Drug Administration's adverse reaction reporting system, both providing and receiving data from them on a regular basis. Information on adverse reactions is promptly disseminated to our hospitals and clinics and drug recalls handled through a system of double safeguards. In addition to the notifications provided through the FDA drug recall system, we also inform our stations on those items which are standardized for our use. There have been several instances lately where either the safety or effectiveness of specific drugs have been called into question prior to actual suspension or recall. We alert our hospitals and clinics to these by special announcements, telegrams, or other prompt notifications. If these items are procured through our central procurement program, we either discontinue procurement or purchase minimum quantities to meet only immediate needs pending resolution of the controversy. The decision as to continued use of a product under special review is left to the prescribing physician, but with the assurance that he is fully informed of any findings about the possible continued marketing of the drug.

There is widespread evaluation under organized and controlled studies in the Veterans Administration into the uses of and efficacy and safety of drug products. In addition to these organized individual and cooperative studies, there is continuing evaluation in the everyday practice of medicine by our staff of 5,000 physicians. The dissemination of the knowledge from these sources has continually contributed to the improved health care not only of veterans but the entire nation. Several major medical breakthroughs, such as the chemo-therapy used in treatment of tuberculosis, either originated in our Veterans Administration medical research or were possible because of our

cooperative ventures with medical and pharmacological inquiries initiated by others.

Turning to our procurement practices, I would like to again emphasize that the question of selection of which specific drugs will be procured is a professional and not an administrative decision. The responsibility of our procurement staff located within the supply organization is to purchase the drugs selected for use at the lowest cost, to assure their distribution to our pharmacies in an efficient and timely manner and to provide quality control and inspection processes during manufacture needed to insure that drugs meet the Veterans Administration specifications and quality requirements. Approximately one half our annual drug requirements are provided by purchase from our Veterans Administration Marketing Center in Hines, Illinois and distribution through our three supply distribution centers at Somerville, New Jersey; Hines, Illinois; and Bell, California. Thirty five percent are purchased by our individual hospitals and clinics from Federal Supply Schedules, executed by the Veterans Administration Marketing Center for use of all Federal agencies. The remainder are purchased by special negotiation or from local sources by our hospitals and clinics.

The data furnished your Committee related to those drug items purchased by our Marketing Division for Drugs and Chemicals located at our Veterans Administration Marketing Center. In determining which items will be supplied through our central purchase and distribution program we apply the following criteria: (1) volume purchases are necessary to secure timely delivery and advantageous prices; (2) price advantages through bulk buying is sufficient to assure greatest economy through central distribution; (3) items are physically adaptable to storage and distribution; (4) the frequency of issue, repetitive use, physical characteristics, and stability of requirements justify central purchase and distribution.

Items which do not meet these criteria are provided through the Federal Supply Schedule for Federal Supply Groups 6505 and 6810, Drugs, medical chemicals and reagents. A reporting system on frequency of drug use permits the periodic reevaluation of our methods of supply. This reporting system does not produce data your Subcommittee desired on individual items procured locally, since it did not contain names of suppliers, or bidder information. It does provide us with usage trends to permit movement of items from one method of supply to another.

Our quality control process consists of the following elements: (1) professionally developed specifications, including USP or NF requirements, and any other additional descriptive or performance requirements considered necessary; (2) inspection of manufacturers' facilities before inclusion on the Veterans Administration bidders' list; (3) laboratory analysis by the Food and Drug Administration of random samples selected by Veterans Administration personnel from various lots before acceptance by our central distribution points; (4) physical inspection of random samples by professional personnel either at our supply depots or our hospital and clinic pharmacies; (5) a reporting system which we call Quality Improvement Reports to be submitted by using activities in case of dissatisfaction with products or need for improvement; (6) periodic reinspection of our suppliers' facilities and suspension from participation in Veterans Administration procurement of those not meeting our standards. We work in close cooperation with the Defense Supply Agency in exchanging information on bidder performance, inspection reports, product suitability, etc. We accept the quality control findings and vendor inspection reports of the Defense Supply Agency as an integral part of our own quality control program. We also interchange quality control information with the Food and Drug Administration and other elements of the Department of Health, Education and Welfare.

I previously mentioned that we procure or contract for drugs for other Federal users. In 1961 the Administrator of General Services Administration, as provided in the Federal Property and Administrative Services Act, assigned to the Veterans Administration the responsibility and authority for the procurement and distribution of drugs, biologicals, medical chemicals and reagents required by Federal agencies. Since that time we have contracted for and administered the Federal Supply Schedules for these items. We have also provided them from our central depot stocks to those agencies who have placed requisitions upon us. During the Fiscal Year 1970, we estimate that other Fed-

eral agencies acquired $37.5 million worth of drugs and chemicals and reagents through or from us, broken down as follows: $33,500,000 ordered from Federal Supply Schedules executed by the Veterans Administration; $3,500,000 ordered from our supply depot stocks; $500,000 ordered from stocks at our hospitals. We also procure from time to time items made available to us from the Defense Supply Agency when that agency is able to acquire them at a lower cost than our own direct procurement.

In closing, I would like to assure this Subcommittee that we are interested in effective control of drug purchasing, and in the greatest economy consistent with our needs and the effective and safe treatment of our veteran patients. We do strive to bring competitive conditions into the drug market and to economize wherever possible. I would like to mention a couple of examples of this. The largest recovery in the history of this nation for overcharges on drugs sold at prices in restraint of trade involved the antibiotic tetracycline hydrochloride. Recognizing that competition was apparently not being developed despite availability of this item from several manufacturers, Veterans Administration reported information suggesting restraint of trade or price regulation to the Federal Trade Commission and the Department of Justice in 1955. In the widespread publicity attendant upon the Federal Trade Commission and court actions which resulted in the ordered refund of millions of dollars, the fact that the Veterans Administration initiated this action has been largely overlooked. We have taken action where we felt there was supporting evidence and alternative courses to exert the pressure of the Federal process in promoting competitive procurement for drugs.

Another example of our cost awareness is our action in procurement of rubella measles vaccine for the immunization programs sponsored by Health, Education and Welfare. When we were first requested to procure this item, the cost was $1.41 per unit dose. As the result of our efforts to obtain a better price and our encouragement to several firms to manufacture this product, we have negotiated the unit price down to 72¢. The savings to the government for this product was approximately $2,900,000 during this last fiscal year alone.

I assure this Subcommittee that we will be constantly alert to improve the quality, safety and therapeutic effectiveness of drug products and to expend the Federal dollars entrusted to the Veterans Administration in a prudent and thrifty manner.

Mr. Chairman, this concludes my statement. I have members of my staff here with me and we will be happy to answer questions or provide additional information which will aid you in your hearings.

(Subsequently, the Veterans' Administration submitted the following literature upon the general subject. In addition to the article, "Treatment of the Acute Alcohol Withdrawal State: A Comparison of Four Drugs," two exhibits on "Drug Treatment of Schizophrenic Reactions" and "Treatment of the Acute Alcohol Withdrawal State," and a bibliography of some other studies are included.)

Treatment of the Acute Alcohol Withdrawal State: A Comparison of Four Drugs

BY S. C. KAIM, M.D., C. J. KLETT, PH.D., AND BENJAMIN ROTHFELD, M.D.

Amer. J. Psychiat. 125: 12, June 1969

Treatment of the Acute Alcohol Withdrawal State: A Comparison of Four Drugs

BY S. C. KAIM, M.D., C. J. KLETT, PH.D., AND BENJAMIN ROTHFELD, M.D.

A double-blind study of 537 patients evaluated the relative efficacy of four drugs—chlordiazepoxide, chlorpromazine, hydroxyzine, and thiamine—commonly used in treating alcohol withdrawal symptoms, specifically to prevent delirium tremens and convulsions. Of the 55 patients who developed these symptoms, two percent were in the chlordiazepoxide group; the incidence ranged from ten to 16 percent in the other treatment groups. The authors conclude that chlordiazepoxide appears to be the drug of choice among those tested.

IN THEIR CLASSICAL STUDY Isbell and associates(8) conducted an experiment in which ten former morphine addicts consumed large amounts of alcohol for prolonged periods, following which alcohol was abruptly withdrawn. Four of the subjects withdrew from the study before abstinence symptoms appeared. The six volunteers who consumed alcohol for 48 days or more exhibited significant symptoms on withdrawal: tremor, weakness, perspiration, nausea, vomiting, diarrhea, hyperreflexia, fever, elevated blood pressure, and insomnia. Seizures occurred in two of the subjects, delirium tremens in two others, and hallucinations without impairment of sensorium in two (one of whom also suffered convulsions).

Because these subjects consumed an excellent diet liberally supplemented with vitamins, it did not seem likely that their symptoms were due to a nutritional deficiency. The report by Isbell and associates strongly supported the thesis that withdrawal of alcohol is responsible for this syndrome.

In a more naturalistic setting Victor and Adams(18) studied 266 patients who were consecutively hospitalized for alcoholism. After the intake of alcohol was stopped, 32 (12 percent) of the patients suffered seizures, 14 (five percent) had delirium tremens, and 47 (18 percent) exhibited atypical hallucinatory states. These authors also considered the syndromes related to cessation of drinking.

Fraser(5) produced an abstinence syndrome in chronically intoxicated dogs (tremulousness, seizures, and a "canine delirium") when alcohol was abruptly withdrawn from them. The Lexington group (Isbell and associates) stated that complete cessation of drinking was not necessary to provoke abstinence symptoms, for they found that a 25 percent reduction in the average daily alcohol intake could result in a fall of blood alcohol values to zero.

Fraser(5) likens alcohol withdrawal to withdrawal from barbiturates, and he advises (in both cases) substitution of a drug with equivalent effects in order to avert delirium, seizures, or both. Isbell and associates(8) advise against alcohol for this purpose because its calories lack proteins, vitamins, and minerals, and it is difficult to adjust dosage to avoid intoxication. They

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Read at the 124th annual meeting of the American Psychiatric Association, Boston, Mass., May 13-17, 1968.

Dr. Kaim is director, staff for alcoholism and related disorders, Veterans Administration Central Office, Washington, D. C. 20420. Drs. Klett and Rothfeld are with the Veterans Administration Hospital, Perry Point, Md., where Dr. Klett is chief, Central Neuropsychiatric Research Laboratory, and Dr. Rothfeld is associate chief of staff.

This study is project 16 of the Veterans Administration Cooperative Studies in Psychiatry. Preliminary reports were presented at the 12th and 13th annual conferences of the Veterans Administration Cooperative Studies in Psychiatry, Denver, Colo., 1967 and 1968 and at the Second International Symposium on Action Mechanisms and Metabolism of Psychoactive Drugs, Paris, France, October 1967.

cite the traditional use of paraldehyde and the lesser use of barbiturates and chloral hydrate in the treatment of delirium tremens. Although sedation had been regarded as symptomatic treatment, the Lexington group postulates that it may represent specific treatment in the sense that the sedatives used may be adequate pharmacologic substitutes for alcohol.

Since the advent of the newer psychopharmacologic agents—reserpine, the phenothiazines, meprobamate, the benzodiazepines, etc.—many of these drugs have been employed in the treatment of the acute alcohol withdrawal state. The early reports on the use of these agents tended to be optimistic. Postel and Cossa(13) cited a decrease in delirium tremens mortality from 65 percent in 1952 to 25 percent in 1955 following treatment with 25 percent alcohol, chlorpromazine, and vitamin B complex intravenously. Figurelli(4) reported a decrease in delirium tremens mortality from ten percent to 0.6 percent after changing treatment from paraldehyde to promazine.

More recent studies have been reported in a more sober vein. In a study comparing promazine and paraldehyde, Thomas and Freedman(15) found that in the milder alcohol withdrawal states more patients were symptom free after two days of treatment with promazine than were those treated with paraldehyde. However, if patients treated with promazine did not respond in two days the symptoms tended to become more severe, with a prolonged course ensuing. In four such patients (of a total of 34) severe delirium developed, one terminating fatally. All of the 33 patients treated with paraldehyde were free of symptoms by the fourth day. Of 39 other patients admitted in delirium tremens, 17 were treated with promazine and 22 with paraldehyde. There were six deaths in the promazine group (35 percent) but only one in the paraldehyde group (4.5 percent).

In another recent study Golbert and associates(6) treated 49 patients for alcohol withdrawal syndromes (agitated and tremulous states, including two patients with acute hallucinosis) with either promazine, chlordiazepoxide, alcohol, or a combination of paraldehyde and chloral hydrate. In the alcohol group (12 patients), five developed delirium tremens, and one of them also had convulsions. In the promazine group (13 patients), seven developed delirium, one with convulsions; the only deaths (two) occurred in this group. In the chlordiazepoxide group of 12 patients, six developed delirium. In the paraldehyde-chloral group (12 patients), only one developed delirium.

Golbert and associates(6) treated 23 patients in delirium tremens with either promazine or the paraldehyde-chloral combination. In the promazine group of 12 patients, one developed convulsions and two died. There were no convulsions or deaths in the paraldehyde-chloral group. Thus in both promazine-treated groups there was a mortality rate of 16 percent, compared to no deaths in the other groups.

The literature is replete with reports on the clinical use of other psychoactive agents. Laties and associates(12) found promazine and chlorpromazine "essentially indistinguishable in performance" in the treatment of delirium tremens. Kaim and Rosenstein (11) reported that:

> In the alcoholic with frank or impending delirium tremens and associated convulsive seizures, Librium [chlordiazepoxide], in higher dosage of 200 to 300 mg. daily, brings prompt and gratifying control of both the psychotic and the convulsive phenomena without the toxicity experienced with the use of phenothiazines, reserpine, or even the barbiturates.

Weiner(19) advocates the routine use of hydroxyzine parenterally as "the recommended drug" for treatment of the acute alcoholic states, with sodium amytal intravenously for "the few that do not respond." He advises against paraldehyde (danger of sudden death) and phenothiazines (hypotensive risk). Victor(17) stresses that the newer psychoactive drugs "have proved of value only in the milder forms of the withdrawal syndrome. However, there are no adequate data to show that any of them is effective in preventing delirium tremens."

In spite of the high incidence of alcoholism, there have indeed been very few large-scale studies evaluating the relative effectiveness of different drugs used in the treatment of the alcoholic during the acute withdrawal period.

Treatment Program

Because of the serious nature of this condition and its widespread occurrence in the 166 Veterans Administration hospitals, a large-scale cooperative study was initiated to evaluate the relative efficacy and safety of four drugs commonly used in treating the withdrawal symptoms of the alcoholic. Chlordiazepoxide, chlorpromazine, hydroxyzine, and thiamine were evaluated against a matching placebo control in 23 VA hospitals using a common protocol.

All newly admitted patients who had been drinking heavily for a period of at least two weeks immediately preceding hospitalization were considered for the study, as well as patients who were originally admitted for relatively minor medical or surgical conditions and who developed alcohol withdrawal symptoms during the early part of hospitalization.

Patients selected for the study had to show at least four of the following eight symptoms of withdrawal: gastrointestinal distress (anorexia, nausea, or vomiting), sweatiness or flushing, insomnia, tremulousness, irritability, apprehension, depression, and clouded sensorium or confusion.

Patients were excluded from the study for any of the following reasons: over 55 years of age, frank schizophrenia or obvious chronic brain syndrome, complications requiring primarily medical or surgical attention, delirium tremens at the time of hospitalization, and known epilepsy or diabetes.

Procedure

Successive patients who fulfilled the selection criteria were assigned by random code to one of the five treatment groups. On the first day all patients received, every six hours, either: 50 mg. of chlordiazepoxide intramuscularly, 100 mg. of chlorpromazine orally, 100 mg. of hydroxyzine intramuscularly, 100 mg. of thiamine intramuscularly, or placebo.

On the second through tenth days a flexible dosage schedule was employed within decreasing limits. During the last four days of the ten-day treatment period half of each treatment group was changed to placebo. All treatment was oral after the first day. During the first day patients on intramuscular medication also received placebo capsules; patients on oral medication also received intramuscular placebo injections.

During the ten days of the study no other psychoactive drugs, conventional sedatives, or hormone or vitamin preparations could be prescribed. Fluids were prescribed orally or intravenously as needed in accordance with good medical care. Other supportive treatment (counseling, psychotherapy) was also provided as seemed indicated.

The principal investigator at each participating hospital was responsible for the coordination of the research team and for the collection of the laboratory and scale data. The research team consisted of an evaluation group (nurse and nursing assistant) from each shift and the treatment physician. The ward evaluation team was responsible for completing the following items: Nurses' Alcohol Symptom Scale (at the end of each eight-hour shift), medication record (during each shift), Lorr and McNair Mood Scale (once daily), and alcadd test (during the sixth treatment day). The treatment physician was responsible for completing the Symptom Check List daily and the Global Rating on the first, sixth, and tenth days.

Patients could be dropped from the study because of refusal to take oral medication, inadequate control of symptomatology, development of delirium tremens or other serious complications, or intercurrent illness. In such cases the patient was promptly rated and the reasons given for the termination on the Early Terminator Record.

When a patient completed or was dropped from the study, all his forms were forwarded for processing to the Central Neuropsychiatric Research Laboratory, VA Hospital, Perry Point, Md.

Results

Significant results are found in the group of patients who had to be terminated early, which numbered 106 of the 537 patient population studied. As seen in table 1, 39 patients were lost from the study because they left the hospital against medical advice or without leave or were allowed to leave

TABLE 1
Reasons for Early Termination from the Study

REASON	DRUG GROUP					
	CHLORDIAZEPOXIDE (N = 103)	HYDROXYZINE (N = 103)	CHLORPROMAZINE (N = 98)	THIAMINE (N = 103)	PLACEBO (N = 130)	TOTAL (N = 537)
Left hospital against medical advice or without leave	10	2	9	9	7	37
Delirium tremens	1	2	4	4	7	18
Convulsions		3	6	2	5	16
Delirium tremens and convulsions		2	3		1	6
Behavioral worsening	1	3	2	6	3	15
Vomiting, intractable				1	1	2
Hypertension				1		1
Pneumonia		1	1	1		3
Tuberculosis		1				1
Severe cold	1					1
Skin eruption					1	1
Requested discharge	1				1	2
Requested change of medication		1				1
Died [1]		1				1
Inadequate therapy		1				1
Total	14	17	25	24	26	106

[1] Another patient, dropped from the chlorpromazine group because of delirium tremens and convulsions, subsequently died.

before the tenth day of treatment. The early terminators were fairly evenly distributed among the five groups, with the exception of the hydroxyzine group, which lost only two patients compared with eight to 11 lost in each of the other groups. It is difficult to account for this one significant difference, as these patients discharged themselves from the hospital for a variety of reasons. One may speculate that alcoholics feel more comfortable with hydroxyzine than with the other drugs studied.

Fifteen patients were terminated because of behavioral worsening, ranging from one in the chlordiazepoxide group to six in the thiamine group. This was the only significant difference.

Twelve patients were dropped from the study because of nine miscellaneous reasons. No more than one patient in a treatment group was terminated for any one of these causes.

The clinically important findings concern those patients who developed delirium tremens or seizures (or both). The incidence of delirium for the entire population of 537 was 24, or 4.5 percent. The incidence by drug group follows:

Chlordiazepoxide	1	(1 percent)
Chlorpromazine	7	(7 percent)
Hydroxyzine	4	(4 percent)
Placebo	8	(6 percent)
Thiamine	4	(4 percent)

Chlordiazepoxide thus is seen to have resulted in a significantly lower incidence of delirium than either chlorpromazine or placebo.

Several patients who suffered isolated seizures were not dropped from the study. Adding these to the cases terminated because of convulsions, the over-all incidence of seizures among the 537 patients was 37, or seven percent. The seizure incidence according to drug group follows:

Chlordiazepoxide	1	(1 percent)
Chlorpromazine	12	(12 percent)
Hydroxyzine	8	(8 percent)
Placebo	9	(7 percent)
Thiamine	7	(7 percent)

It is apparent that chlordiazepoxide was significantly better than any of the other treatments. An important additional factor should be mentioned here. Only one of the patients receiving thiamine, one receiving hydroxyzine, and three receiving the placebo

TABLE 2
Incidence of Delirium Tremens and Convulsions

DISTURBANCE	DRUG GROUP					TOTAL (N = 537)
	CHLORDIAZEPOXIDE (N = 103)	CHLORPROMAZINE (N = 98)	HYDROXYZINE (N = 103)	THIAMINE (N = 103)	PLACEBO (N = 130)	
Delirium tremens	1	4	2	4	7	18
Convulsions	1	9	6	7	8	31
Delirium tremens and convulsions	0	3	2	0	1	6
Total (percent in parentheses)	2 (2)	16 (16)	10 (10)	11 (11)	16 (12)	55 (10)

suffered convulsions after the first day of treatment. In eight of the 12 chlorpromazine patients who had seizures, the seizures occurred after the first day and as late as the sixth day of treatment.

The total incidence of delirium tremens and convulsions in the patient population is shown in table 2, which includes those patients with convulsions who were not terminated early.

What about the approximately 400 patients who stayed the course? In general, the scales employed indicated that all five treatment groups improved rapidly, the larger changes occurring in the first two days. Individual symptoms appeared to respond more readily to one or another of the treatments, but no treatment method had an over-all consistent superiority. In fact, the placebo group appeared to fare (symptomatically) as well as any of the others.

Discussion

The state resulting from acute withdrawal from prolonged use of excessive amounts of alcohol is attended by an appreciable risk of serious symptoms, the development of delirium tremens, and a moderately high mortality rate. The world literature abounds with conflicting reports on the effectiveness of numerous treatment regimens. The advent of the phenothiazines led to their extensive use in this condition. Early reports were extremely favorable, as is usual in the case of new agents. More recent reports, however, have been quite guarded as to both the efficacy and safety of the phenothiazines in this regard.

The opinion has recently been expressed that no adequate data have yet been reported to prove that any of the newer psychoactive agents is effective in preventing the development of delirium tremens during the withdrawal state.

With these issues in mind the VA embarked on a double-blind comparative evaluation of four of the commonly employed treatments of the alcohol withdrawal syndrome. As in other studies of this state, most patients in all five treatment groups (including placebo) improved rapidly, the rate of change appearing greatest in the first two days of treatment. The success or failure rates in this study must be keyed to the rates of occurrence of the two most common and serious developments in this syndrome: convulsions and delirium tremens. Chlordiazepoxide was associated with the best outcome in both these disturbances; chlorpromazine, with the worst.

With respect to seizures, our finding confirms the early report of Kaim and Rosenstein(10) of the anticonvulsant action of chlordiazepoxide. The finding that patients receiving chlorpromazine incurred the most seizures confirms the reports of Bonafede(2), Fabisch(3), Sainz(14), Barrett(1), and Ticktin and Schultz(16).

Chlordiazepoxide also appeared to offer substantial protection against the development of delirium tremens during alcohol withdrawal. In a recent study Greenberg and Pearlman(7) reported that dreaming was suppressed during periods of increasing blood levels of alcohol. Withdrawal led to an increase in stage 1 rapid eye movement sleep, with 100 percent stage 1 found just before the development of delirium tremens.

Barbiturates and some of the newer psychoactive agents also suppress dreaming. The authors postulate that with chlordiazepoxide, which does not suppress dreaming during its short-term use, the dream deficit can be made up during sleep rather than delirium. The findings in the present study lend support to this speculation.

Jaffe(9) has aptly cited the very low degree of cross-dependence with alcohol shown by the phenothiazines, contrasted with the high degree of cross-dependence with alcohol shown by chlordiazepoxide. From the results of this study we would agree with him that "since the development of delirium tremens always carries with it a . . . risk of a fatal outcome, it seems appropriate to treat all but the mildest cases of alcoholic withdrawal with agents that show cross-dependence with alcohol."

Conclusion

A double-blind controlled comparison was made in 23 Veterans Administration hospitals of chlordiazepoxide, chlorpromazine, hydroxyzine, thiamine, and a placebo in 537 patients suffering acute alcohol withdrawal symptoms. Treatments were compared with regard to symptom change and the development of delirium tremens and seizures.

Symptomatic improvement occurred in the great majority of patients in all five treatment groups, the greater changes occurring during the first two days of treatment. Individual symptoms appeared to respond more readily to one or another of the treatments (including placebo), but there was no consistent over-all superiority of any one treatment.

Convulsions developed in one percent of the patients who received chlordiazepoxide, in 12 percent of the chlorpromazine group, eight percent of the hydroxyzine group, seven percent of the placebo group, and seven percent of the thiamine group. Delirium tremens developed in one percent of the chlordiazepoxide group, seven percent of the chlorpromazine group, four percent of the hydroxyzine group, six percent of the placebo group, and four percent of the thiamine group.

It is concluded that chlordiazepoxide appears to be the drug of choice (among those tested) in the prevention of delirium tremens and convulsions during the acute alcohol withdrawal state. Chlorpromazine was associated with the highest incidence of both delirium and seizures. The differences between these two drugs were highly significant in the development of both delirium tremens and convulsions.

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DRUG TREATMENT OF SCHIZOPHRENIC REACTIONS

VA Cooperative Studies of Chemotherapy in Psychiatry

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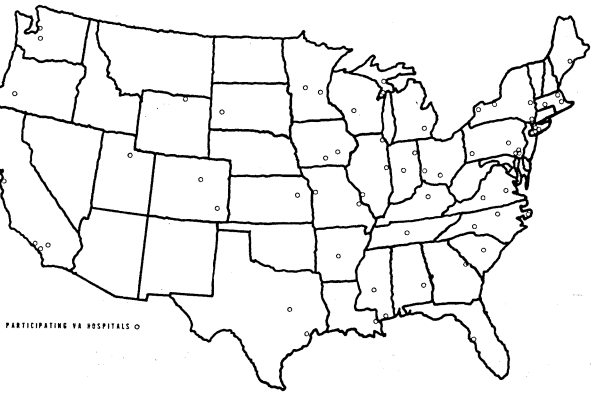
The exhibitors wish to make clear that the work being summarized has resulted from the efforts of literall hundreds of people. They have been fortunate in having small parts to play in this monumental effort.

EXHIBIT PREPARED BY MEDICAL ILLUSTRATION SERVICE
VA HOSPITAL, PALO ALTO, CALIFORNIA

ALBERT RENDES, WILL RENNER, ROBERT BLAINE
PROVIDED THE ART AND PHOTOGRAPHIC WORK.

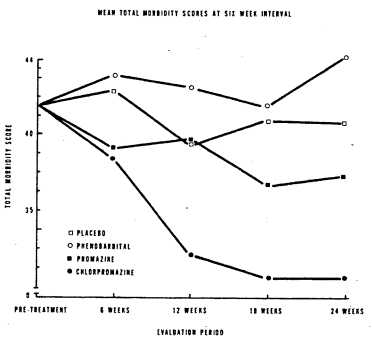
BASIC PRINCIPLES OF THE COOPERATIVE STUDIES



1 LARGE, HOMOGENEOUS SAMPLES OF PATIENTS
2 RANDOM ASSIGNMENT OF TREATMENTS
3 BLIND CONTROLS
4 OBJECTIVE ASSESSMENT OF PATIENT CHANGES
5 STATISTICAL ANALYSIS OF DATA

hese studies have evolved a series of logical questions about drug therapy of schizophrenia have been proposed.

TRANQUILIZING DRUGS REALLY WORK IN SCHIZOPHRENICS ?



Yes, beyond any doubt. The question was answered in a controlled study of the relative effectiveness of chlorpromazine, promazine, phenobarbital and placebo (1957).

805 CHRONIC PATIENTS

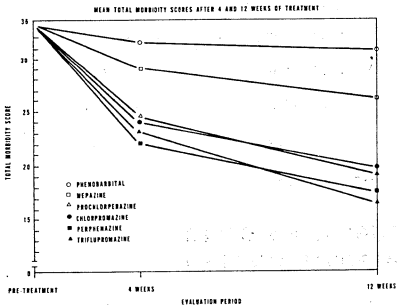
37 HOSPITALS

24 WEEKS OF TREATMENT

Chlorpromazine and promazine better than phenobarbital or placebo; chlorpromazine better than promazine.

ARE SOME DRUGS BETTER THAN OTHERS ?

Yes, but it's hard to find significant differences between many like drugs. Two studies have indicated these findings: the first, a comparative study of chlorpromazine, triflupromazine, mepazine, prochlorperazine, perphenazine and phenobarbital (1958 the second, a comparative evaluation of chlorpromazine, chlorprothixine, fluphenazine, reserpine, thioridazine and triflupromazine. (1960

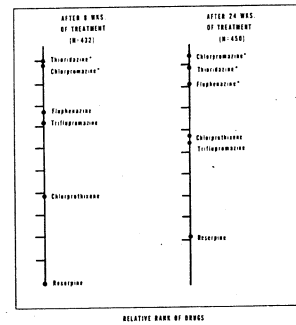


640 NEWLY ADMITTED PATIENTS

35 HOSPITALS

12 -WEEK TREATMENT

All five phenothiazine tranquilizers better than phenobarbital; four best better than mepazine, but no difference between these four.



512 NEWLY ADMITTED PATIENTS

32 HOSPITALS

24 WEEKS OF TREATMENT

Drugs marked by asterisks were significantly better than reserpine; top five drugs not significantly different.

ARE SIDE EFFECTS AND COMPLICATIONS A MAJOR PROBLEM IN USING PSYCHOTHERAPEUTIC DRUGS?

No, not even in double-blind trials. We've treated approximately 3000 patients in various blind controlled studies with:

NO fatalities from treatment NO cases of agranulocytosis NO cases of drug-induced jaundice

About 4% drop-outs for medical reasons

Here is the prevalence of certain side effects in 1000 patients:

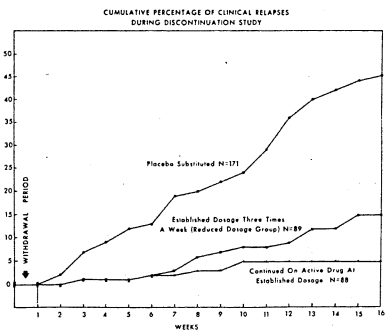
AKATHISIA	16%	NAUSEA, VOMITING	9%
DYSTONIA	3%	CONSTIPATION	10%
SEIZURES	1%	EOSINOPHILIA	16%
DERMATITIS	4%	LEUCOPENIA	7%
DRY MOUTH	15%	ABN. HEPATIC TESTS	15%
WEAKNESS, FATIGUE	20%	WEIGHT GAIN > 25 LBS.	6%

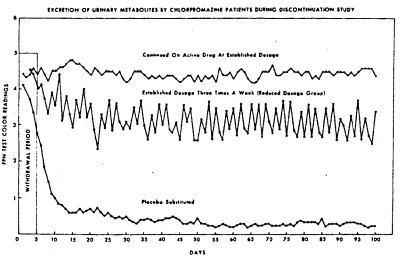
EXTRAPYRAMIDAL SYNDROMES 10%

WHAT HAPPENS WHEN DRUGS ARE STOPPED IN PATIENTS WHO HAVE IMPROVED ON THEM?

Many relapse. Three-hundred-forty-eight patients who had been treated with either chlorpromazine or thioridazine were either continued on full doses, reduced to taking drug only 3 days a week (3/7 dose), or switched to placebos. (1961)

Here are the results in terms of relapses and urine tests:



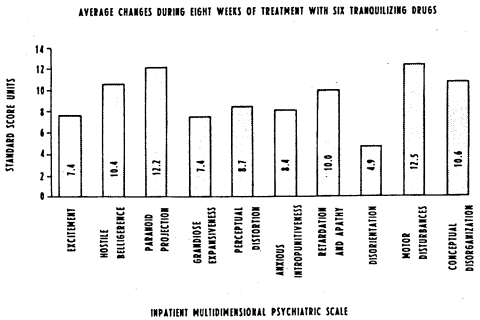


hile it is clear that many patients may be withdrawn from drugs for substantial periods of time without relapsing, we simply don't how to identify such patients. Possibly a number of patients might require less drug for maintenance therapy than is commonly used.

HOW ARE PATIENTS CHANGED BY THESE DRUGS ?

Primary symptoms of schizophrenia are improved. In many studies now the principal areas of change have been found to be in such important symptoms as emotional withdrawal, hallucinations, delusions and other disturbed thinking, and paranoid projection.

An example of the types of changes observed in one such study is shown below:



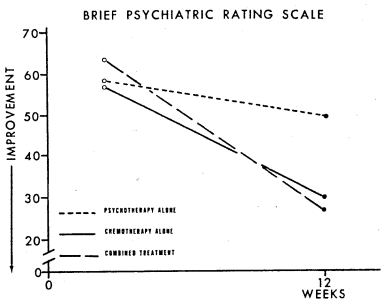
These drugs are more than 'tranquilizers' . They should be appropriately termed 'antipsychotics'.

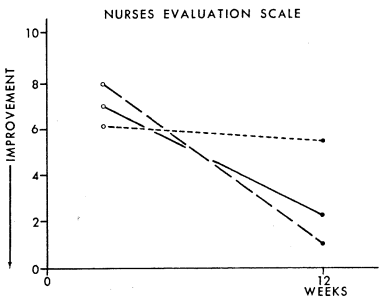
DOES PSYCHOTHERAPY ADD TO CHEMOTHERAPY?

Not in schizophrenics seen in group psychotherapy three times a week for twelve weeks. Patients were randomly assigned to drug treatment alone (thioridazine), group psychotherapy alone or both treatments together.

Chemotherapy alone or combined with psychotherapy was superior to psychotherapy alone in reducing psychotic symptoms.

MEAN SCORES OF IMPROVEMENT ON TWO RATING SCALES

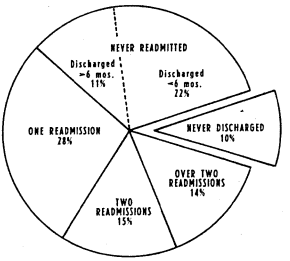




WHAT HAPPENS TO SCHIZOPHRENIC PATIENTS?

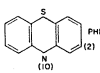
Nearly 600 of our patients from one study were followed for three years. Two out of three admitted to the study were released within nine months; almost a third were released in four months.

Ten percent are clearly therapeutic failures as they remained hospitalized continually over the three-year period.



THE MAJOR ANTIPSYCHOTIC DRUG CLASSES

PHENOTHIAZINE DERIVATIVES

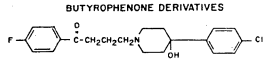


Chlorpromazine (Thorazine) (2) Cl (10) $CH_2-CH_2-CH_2-N-(CH_3)_2$

Thioridazine (Mellaril) (2) SCH_3 (10) CH_2-CH_2 N CH_3

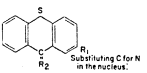
Fluphenazine (Prolixin) (2) CF_3 (10) $CH_2-CH_2-CH_2-N$ $N-CH_2-CH_2-OH$

BUTYROPHENONE DERIVATIVES



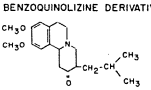
Haloperidol

THIOXANTHENE DERIVATIVE



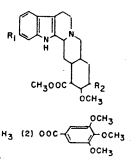
Chlorprothixene (Taractan) (1) Cl (2) $CHCH_2CH_2N(CH_3)_2$

BENZOQUINOLIZINE DERIVATIVE



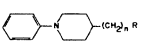
Tetrabenazine (Nitoman)

RAUWOLFIA ALKALOIDS



Reserpine (Serpasil)

PHENYLPIPERAZINE



Model Structure

The six drug groups represented may be called major tranquilizers because they are useful in major emotional disorders. Only three of many phenothiazine derivatives have been shown. Most of these drug classes have antipsychotic effects and produce extrapyramidal syndromes but have little else in common.

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TREATMENT OF THE ACUTE ALCOHOL WITHDRAWAL STATE:

DEVELOPMENT OF DELIRIUM TREMENS AND CONVULSIONS

A comparison of four drugs

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INTRODUCTION

An acute withdrawal state develops in alcoholic subjects within hours to days after cessation (or diminution) of a prolonged period of heavy drinking. Symptoms may include, in various combinations, anorexia, nausea, vomiting, sweating, flushing, insomnia, tremulousness, tachycardia, agitation, irritability, apprehension, depression, weakness, fever, clouded sensorium and confusion. If untreated, this syndrome may progress to hallucinosis or delirium tremens, and may be complicated by grand mal seizures.

Most symptoms of acute alcohol withdrawal will resolve spontaneously in several days. The two feared developments in this syndrome are delirium tremens and convulsions, either of which may terminate fatally.

Despite the high incidence of alcoholism, there have been very few large scale studies evaluating the relative effectiveness of different drugs used in the treatment of the alcoholic during the acute withdrawal period.

Because of the serious nature of this condition and its widespread occurrence in the 166 Veterans Administration hospitals, a large scale cooperative study was initiated to evaluate the relative efficacy and safety of four drugs commonly used in treating the withdrawal symptoms of the alcoholic. Chlordiazepoxide, chlorpromazine, hydroxyzine, and thiamine were evaluated against matching placebo controls in 23 Veterans Administration hospitals using a common protocol.

MATERIALS AND METHODS

All newly admitted patients who had been drinking heavily for a period of at least two weeks immediately preceding hospitalization were considered for the study, as well as patients originally admitted for relatively minor medical or surgical conditions who developed alcohol withdrawal symptoms during the early part of hospitalization.

Patients selected for the study had to show at least four of the following eight symptoms of withdrawal:

1. Gastro-intestinal distress: anorexia, nausea or vomiting
2. Sweatiness and/or flushing
3. Insomnia
4. Tremulousness
5. Irritability
6. Apprehension
7. Depression
8. Clouded sensorium or confusion

Patients were excluded from the study for any of the following reasons:

1. Over 55 years of age
2. Frank schizophrenia, or obvious chronic brain syndrome
3. Complications requiring primarily medical or surgical attention.
4. Delirium tremens at the time of hospitalization
5. Known epilepsy or diabetes.

Successive patients who fulfilled the selection criteria were assigned by random code to one of the five treatment groups. On the first day all patients received every six hours, either:

1. 50 mg. of chlordiazepoxide intramuscularly
2. 100 mg. of chlorpromazine orally
3. 100 mg. of hydroxyzine intramuscularly
4. 100 mg. of thiamine intramuscularly, or
5. Placebo

On the second through tenth days, a flexible dosage schedule was employed within decreasing limits. During the last 4 days of the 10-day treatment period half of each treatment group was changed to placebo. All treatment was oral after the first day. During the first day patients on intramuscular medication also received placebo capsules; patients on oral medication also received intramuscular placebo injections.

During the ten days of the study, no other psycho-active drugs, conventional sedatives, or hormone or vitamin preparations could be prescribed. Fluids were prescribed orally or intravenously as needed in accordance with good medical care. Other supportive treatment was also provided as seemed indicated.

Chlordiazepoxide—LIBRIUM Chlorpromazine—THORAZINE

Hydroxyzine—ATARAX, VISTARIL

RESULTS

In general, all 5 treatment groups improved rapidly, the larger changes occurring on the first 2 days. The clinically important findings concern those patients who developed delirium tremens or seizures (or both).

The total incidence of delirium tremens for the entire population of 537 was 24, or 4.5%. The total incidence of convulsions was 37, or 7%. The breakdown by treatment group is shown in the following table:

INCIDENCE OF DELIRIUM TREMENS AND CONVULSIONS

	Delirium Tremens (alone)	Convulsions (alone)	DT and Convulsions	Total	
Chlordiazepoxide N—103	1	1	0	2	(2%)
Chlorpromazine N— 98	4	9	3	16	(16%)
Hydroxyzine N—103	2	6	2	10	(10%)
Thiamine N—103	4	7	0	11	(11%)
Placebo N—130	7	8	1	16	(12%)
Total N—537	18	31	6	55	(10%)

CONCLUSION

The state resulting from acute withdrawal from prolonged use of excessive amounts of alcohol is attended by an appreciable risk of the development of serious complications, delirium tremens and convulsions, and a respectable mortality rate.

The view has been expressed that no adequate data have yet been reported to prove that any of the newer psychoactive agents are effective in preventing the development of delirium tremens during the withdrawal state.

With these issues in mind the Veterans Administration embarked on this double-blind comparative evaluation of four of the commonly employed treatments of the alcohol withdrawal syndrome.

The success (or failure) rate in this study was keyed to the rates of occurrence of the two most common and serious developments in this syndrome: convulsions and delirium tremens. In this study, chlordiazepoxide was associated with the best outcome on both these scores.

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Drug Therapy in Schizophrenia

A Controlled Study of the Relative Effectiveness of Chlorpromazine, Promazine, Phenobarbital, and Placebo

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Despite the vast number of clinical investigations of tranquilizing agents which followed their introduction, relatively few studies have used adequate controls. Such controlled studies as were done often were based on small numbers of patients, involved differing control techniques, or led to contradictory conclusions.[1-6]

Because of the difficulty in obtaining controlled drug studies of sufficient scope to be clinically meaningful, a cooperative study was planned to include psychiatric hospitals in the Veterans Administration nation-wide system. Such a study had the advantage of including a large and well-defined sample of patients treated in multiple hospital settings. Difficulties, anticipated in establishing a commonly understood research protocol and obtaining evaluations of treatment sufficiently similar to permit pooling of the data, did not prove to be insurmountable.

At the time this study was planned, two trends were already evident in regard to tranquilizing drugs.[7] One was that reserpine and Rauwolfia alkaloids were diminishing in popularity for psychiatric use. The other was that interest in the phenothiazine derivatives, based on the successes with chlorpromazine, was mounting. Although preliminary clinical studies had indicated effectiveness of a dechlorinated analogue, promazine, this drug had not been tested under conditions of a "double-blind" control. Thus, these two phenothiazine derivatives, chlorpromazine and promazine, were selected for study. For comparison, an active agent, phenobarbital, and an inert placebo (lactose) were chosen. The purpose of the study was to determine whether these treatments differed in efficacy for specified

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Smith, Kline & French Laboratories and Wyeth, Laboratories, generously prepared and furnished the medications.

From the Veterans Administration Cooperative Studies of Chemotherapy in Psychiatry. The presented authorship indicates only major roles in coordinating the study and preparing this report. Other major contributors to this study were Thomas G. Andrews, Ph.D.; Eugene Caffey Jr., M.D.; S. T. Ginsberg, M.D.; Joseph Cameron, M.A., Amedeo S. Marrazzi, M.D., and Marcus P. Rosenblum, M.D. Additional participants, numbering several hundred, have been acknowledged in the *Transactions of the First (1956), Second (1957),* and *Third (1958) Research Conferences on Chemotherapy in Psychiatry,* published by the U.S. Veterans Administration Department of Medicine and Surgery, Washington 25, D.C.

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schizophrenic patients under controlled conditions.

Procedure *

Population.—The study population was made up of men under 51 years of age who were hospitalized for schizophrenic reactions. Patients with organic brain disease, previous leukotomy, or active systemic disease were specifically excluded.

Sampling. — Thirty-seven hospitals contributed 805 patients to the study. Patients were selected from four main categories: acute disturbed, acute nondisturbed, chronic disturbed, and chronic nondisturbed. Chronic patients greatly outnumbered the acute (81% to 19%); the number of nondisturbed patients was greater than the number of disturbed patients (73% to 27%). Chronic nondisturbed patients made up about two-thirds of the sample because a sufficient number of acute disturbed patients was not available.

Patients selected within each of the four categories of chronicity and disturbance were randomly distributed among four treatment groups. The number of patients dropped during the course of the study because of serious side-reactions, inadequate evaluation, or other reasons was distributed evenly among the categories. The final sample available for analysis consisted of 692 patients.

Treatment.—"Double-blind" controls were used in applying the four treatments: chlorpromazine, promazine, phenobarbital, and placebo. Patients nominated for the study were assigned medication in random order. Neither the patients nor their physicians knew which of the four agents was assigned. As a safeguard, the manager of the hospital was provided with this information for release only if the welfare of the patients so dictated. As pharmacologic and side-effects might impair "double-blind" conditions, using two tranquilizers reduced the chances of identifying the drugs. The commonest side-effect, drowsiness, was duplicated by phenobarbital.

Decisions regarding dosage and duration of treatment were made only after considerable discussion. The issue of flexible doses as opposed to fixed doses was decided in favor of the latter, it being recognized that an arbitrarily selected dose of a drug might not be optimal for all patients. A daily dose of 400 mg. of chlorpromazine was considered enough to demonstrate any therapeutic effect of this agent. An equal dose of promazine was recommended by the manufacturer. The dose of phenobarbital was 200 mg. daily. All medications were packaged in capsules containing one-fourth the total daily dose of drug, that is, 100 mg. of chlorpromazine or promazine or 50 mg. of phenobarbital in each capsule. Each patient's supply of medication was labeled only with his name and the code number. All medications were odorless and identical in appearance and taste. No previous tranquilizing medication had been given for at least two months prior to the study to chronic patients and one month to acute patients. Initiation of medication was gradual, beginning with 1 capsule on the first day of the study, 2 on the second, 3 on the third, and the full dose, of 4 capsules, daily thereafter. All medication was given orally, divided into 2 or 3 daily doses given at least eight hours apart.

The duration of treatment was arbitrarily determined at 12 weeks, a period of sufficient length to demonstrate therapeutic effects. At the end of this time, a "blind cross-over" was effected for another 12 weeks, as diagramed in Figure 1. Thus some patients were allowed to continue on the same treatment for 24 weeks; others had a control medication replaced by a tranquilizer or vice versa. Of the 692 patients completing the first 12 weeks of treatment, 489 (from 26 hospitals) completed the second 12-week treatment period.

The only treatment activities restricted were individual and group psychotherapy, shock therapy, and interward transfer. All other treatment activities available in the hospital were continued during the study. Supplemental conventional hypnotics, not barbiturates, were permitted when deemed essential.

Method of Evaluation of Treatment.—Clinical changes in patients were measured by three rating devices: (1) The Multi-Dimensional Scale for Rating Psychiatric Patients (MSRPP),[11] (2) a Clinical Estimate of Psychiatric Status,[12] and (3) the Manifest Anxiety Scale.[13]

The MSRPP consists of 62 items, 40 of which require a clinical psychiatric interview for rating. The deviations of a patient's item scores from the norm yield a "total morbidity score." Subgroupings of items also provide scores for 11 factors of psychopathology: activity level, withdrawal, conceptual disorganization, perceptual distortion, mannerisms, paranoid projection, retarded depression, melancholy agitation, self-depreciation, resistiveness, and belligerence. In this study, a team of observers at each hospital gave a consensus rating for each patient with this scale. Data for this

* Detailed statements about the population, the sampling procedure (randomization procedure, homogeneity of groups, etc.), treatment procedure (precautions, laboratory methods, etc.), and method of evaluation (training of raters, arriving at team consensus rating, recording observations, nature of scales, etc.) are available elsewhere.[8-10] Detailed statistical tables of the complete data may be obtained from the Central Neuropsychiatric Research Laboratory, Veterans Administration, Perry Point, Md.

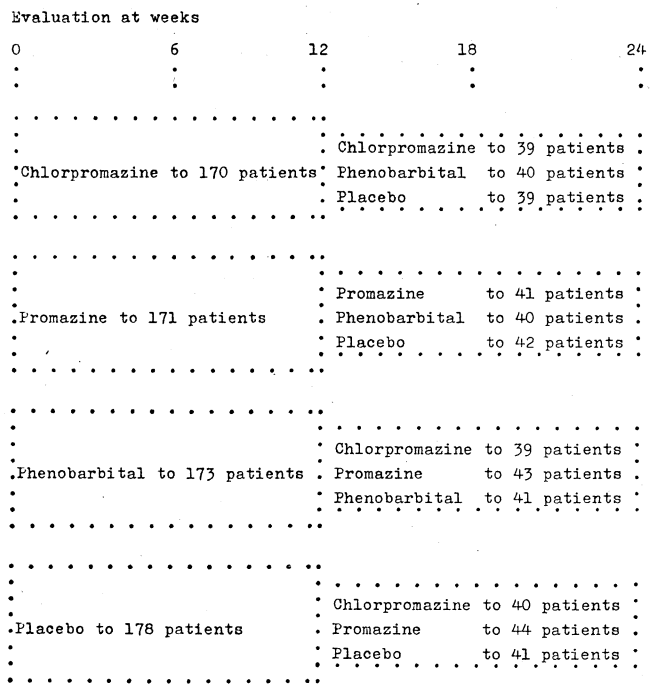

Fig. 1. — Diagram of study plan.

scale were complete for the entire sample of patients.

The Clinical Estimate of Psychiatric Status required judgments by psychiatrists for 11 items of psychopathology and prognosis: severity of illness, recent change in mental condition, severity of symptoms, risk of leaving hospital without permission, participation in activities and self-care, probable time of release, probable level of required care if released, probable level of economic productivity if released, probability of return to hospital if released, risk of violence to self, risk of violence to others. This device was inadequate for evaluating patient change but was somewhat useful in describing the sample of patients as a whole.

The Manifest Anxiety Scale required the active participation of patients for answering questions. The scale could be completed by only about half the sample, with answers of doubtful reliability, and therefore was not considered appropriate for evaluating these patients.

These measures were obtained at the beginning of the study, at the midpoint and end-point of the of the study, at the mid-point and end-point of the initial 12-week treatment course, and at the mid-point and end-point of the second 12-week cross-over study. As drugs were changed only at the 12-week interval, for the sake of brevity most consideration will be given these ratings.

Statistical Analysis.[14-18]—Data were analyzed by multiple covariance, providing linear adjustment of group means to estimated equal starting levels of age, length of hospitalization, duration of illness, total morbidity, weight, and, in the initial 12-week study, chronicity and disturbance (the last two variates were not retained in the cross-over study because very few of the 489 patients in its sample were classified as other than chronic and non-disturbed). Treatment group means on all measurements were compared relative to the estimated variability among individuals in the population from which the sample was assumed to have been drawn at random. The difference in means at the end of the 24th week, adjusted to equal starting levels, was used to test the difference in change over 24 weeks; the difference between means at the end of the 24th week, adjusted to equal levels at start and end of 6th and 12th weeks, was used to test the difference in change over the second 12 weeks. Contrasts were tested for significance at the 5% level and against critical values based on the ranges of ranks of sets of means. This level was halved in those very few instances in which initial dispersions varied significantly among groups.

Results

Characteristics of the Sample at Start of Study.—The patients assigned to each of the four treatment groups were quite similar as to means and variances of background variables at the start of the study. The sampling technique apparently succeeded in eliminating biasing factors among the groups.

The sample for the 12-week course consisted of 20% classified as chronic disturbed, 61% as chronic nondisturbed, 7% as acute disturbed, and 12% as acute nondisturbed; for the 24-week course, 23% as chronic disturbed, 74% as chronic nondisturbed, 2% as acute disturbed, and 1% as acute nondisturbed. In all other respects, the two samples were essentially alike at start of treatment. The average patient was 36 years old, had been ill about 10 years, and had been hospitalized for over 7 years. On the MSRPP, relative to a sample of Veterans Administration psychiatric hospital patients,[11] he scored at levels of markedly more total morbidity, resistiveness, perceptual distortion, mannerisms, withdrawal, self-depreciation, and conceptual disorganization; considerably more paranoid projection and belligerence, and very slightly more retarded depression, hyperactivity, and melancholy agitation.

A further description of the average patient, based on psychiatrists' judgments, follows: The patient was more severely ill than the average patient in the hospital. His mental condition had not changed substantially for the two weeks preceding the study. While there was some risk, it was rather unlikely that he would harm himself or others. He might possibly try to leave the hospital unofficially, but, again, this was somewhat unlikely. In terms of the most realistic treatment goals, he would require a minimal degree of nursing care and would participate, though not very much, in ward activities. If he were able to be released from the hospital, it would be in the care of his family, and the probability of his return would be high. He would be either unproductive economically or only partially self-supporting.

Drop-Outs and Side-Reactions.—The number of patients who were dropped from the study or reported to have developed untoward symptoms during it did not vary significantly among the four groups in the initial 12-week course or the 12 groups in the cross-over study.

Of the 805 subjects selected for the study and placed on medication, 67 (8%) had to be withdrawn in the first 12 weeks for the following reasons: increased disturbance, 18, of whom 10 received a tranquilizer; medication refused, 12, of whom 9 were in the tranquilizer groups; side-effects, 8, and an unrelated physical illness, 4. In 9 the patient selection was incorrect (overage, lobotomy); 14 were discharged from the hospital before the study was completed (5, absent without leave; 1, transferred; 1, trial visit; 7, no reason given). In two cases the reason for withdrawal was not stated.

Of 528 patients who started on the second 12 weeks, 39 (7.4%) were withdrawn before treatment was completed. Administrative reasons accounted for dropping all these patients but one.

Only 27 (3%) patients of the total original sample were reported to have developed side-effects in the first 12 weeks: extrapyramidal syndrome, 6 (1 with phenobarbital); excessive drowsiness, 9 (1 with phenobarbital and 2 with placebo); dermatitis, 6 (3 with phenobarbital); vertigo, 2 (1 with phenobarbital); leukopenia, 3 (2 with phenobarbital), and jaundice (1 with phenobarbital). Side-effects were severe enough in eight patients for them to be dropped from the study; seven had been receiving a tranquilizer. One of these seven developed leukopenia; five, extrapyramidal syndrome; one, dermatitis; and another, who received phenobarbital, a rash. Two cases of excessive drowsiness were the only instances of side-effects reported from the placebo group. Nine (4.5%) of the phenobarbital patients had noticeable side-effects. In the promazine group there were 5 (2.5%), and in the chlorpromazine group, 11 (5%).

Of the 489 patients who completed the 24-week course, 15 (3.1%) developed, in the second 12 weeks, untoward symptoms, most as the result of intercurrent illness. Side-effects attributable to treatment occurred as follows: One patient had leukopenia, and one, convulsive seizures, while receiving promazine after 12 weeks of phenobarbital; one had edema of the hands and eyes while receiving chlorpromazine after 12 weeks of placebo.

One side-effect which was peculiar to the tranquilizing drugs was weight gain during treatment. In each case in which chlorpromazine or promazine was compared with the control medications, weight gain was significantly greater (statistically) with the tranquilizer drugs. This relationship occurred when the drugs were used continually or only during one or the other period of treatment.

Changes in Total Morbidity and Specific Symptoms During Treatment.—In assessing the effects of the drugs, either when given alone or in sequence, comparisons were made on the basis of the MSRPP total morbidity score and in regard to specific symptoms of psychopathology, aberrant behavior, or prognostic estimates gathered from the MSRPP and the Clinical Estimate of Psychiatric Status. Only results statistically significant at the 5% level will be presented. Of the 600 contrasts herein considered, 110 were found significant.

The experimental design permitted comparisons to be made between the four treatments administered for 12 weeks to fairly large groups of patients and between 12 treatment groups of smaller size after 24 weeks of consecutive treatment. Figure 2 shows changes which occurred in the total morbidity scores of patients treated for 12 weeks. Chlorpromazine was more effective in reducing morbidity than promazine, phenobarbital, or placebo. Promazine was superior to each of the two control medications. The latter two did not differ from each other.

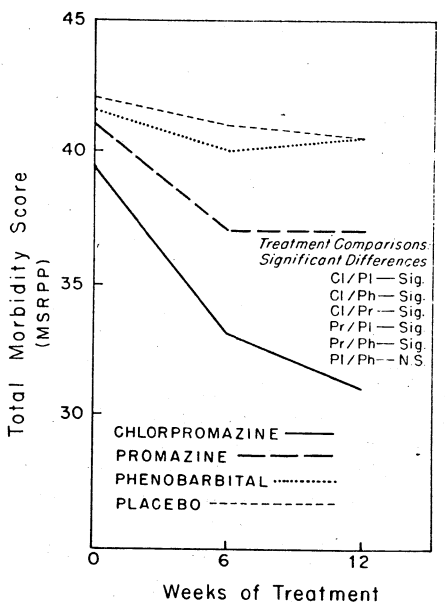

Fig. 2.—Changes in total morbidity scores during initial 12-week period of drug therapy.

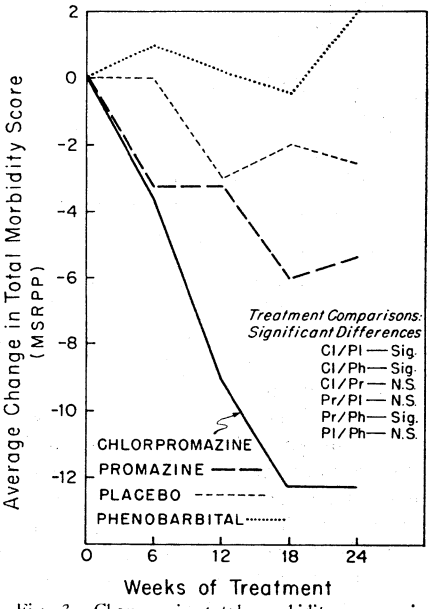

Fig. 3.—Changes in total morbidity scores in patients treated consecutively for 24 weeks with a single drug.

Changes in total morbidity which occurred in the smaller groups of patients treated for 24 weeks with a single treatment are shown in Figure 3. Chlorpromazine produced striking improvement in being greatest in the initial 12-week period. Over 24 weeks, improvement from chlorpromazine was not significantly greater than that from promazine but greater than from the control drugs. Improvement from promazine was significantly more than from phenobarbital but not from placebo. The difference between placebo and phenobarbital was not significant.

The first 12-week treatment period was considered to be most important for assessing changes in specific symptoms as the patients were newly treated. After the cross-over of treatments occurred, the situation became more complex, with the possibility of some carry-over effects from the earlier treatment. Table 1 describes the relationships of the various treatments to one another in regard to reduction of symptoms during this initial period of treatment. Chlorpromazine was superior to any of the other three treatment drugs in reduction of certain symptoms. Promazine surpassed phenobarbital and placebo in a more limited range of symptomatic improvement. The differences between phenobarbital and placebo were slight.

TABLE 1.—*Differences in Reduction of Symptoms Between Drug-Treated Groups During Initial Twelve-Week Treatment Period* *

Cl surpassed Pr in reducing symptoms of total morbidity, severity of illness, unimproving mental condition, risk of leaving hospital without permission, withdrawal, conceptual disorganization, perceptual distortion, mannerisms, self-depreciation, resistiveness, belligerence, risk of violence to others.
Cl surpassed Ph in the same respects plus participation in activities and self-care.
Cl surpassed Pl in the same respects with the exception of risk of leaving the hospital without permission and participation in activities and self-care.
Pr surpassed Ph in reducing symptoms of total morbidity, conceptual disorganization, perceptual distortion, mannerisms, resistiveness, and belligerence.
Pr surpassed Pl in reducing symptoms of total morbidity, conceptual disorganization, and perceptual distortion.
Ph surpassed Pl in reducing symptoms of retarded depression.
Pl surpassed Ph in reducing symptoms of belligerence.

* Cl, chlorpromazine; Pr, promazine; Ph, phenobarbital; Pl, placebo.
All differences are beyond the 5% level of statistical significance; only comparisons showing such differences are noted.

TABLE 2.—*Differences in Reduction of Symptoms Between Drug-Treated Groups over Twenty-Four-Week Period: Same Drug Used Continually* *

ClCl surpassed PrPr in reducing symptoms of withdrawal, conceptual disorganization, mannerisms, and belligerence; surpassed PhPh in reducing the same symptoms plus total morbidity, unimproving mental condition, and resistiveness: surpassed PlPl in reducing symptoms of total morbidity, conceptual disorganization, paranoid projection, and belligerence.
PrPr surpassed PhPh in reducing symptoms of total morbidity and resistiveness; reduced no symptoms significantly more than ClCl or PlPl.
PhPh reduced no symptoms significantly more than ClCl, PrPr, or PlPl.
PlPl surpassed ClCl, PrPr, and PhPh in reducing the symptom of self-depreciation; surpassed PhPh in reducing the symptom of resistiveness.

*ClCl, PrPr, PhPh, and PlPl indicate successive 12-week courses of each agent.
All differences beyond the 5% level of statistical significance; only comparisons showing such differences are noted.

Comparisons between the smaller groups treated for 24 weeks consecutively with a single treatment yielded essentially similar results (Table 2). Continued treatment with chlorpromazine produced more symptomatic improvement than continued treatment with the other three agents. Twenty-four weeks of promazine therapy reduced total morbidity and resistiveness more than phenobarbital only. Phenobarbital produced no significant symptom reduction as compared with the other three agents. Placebo for 24 weeks reduced the symptom of self-depreciation significantly more than any one of the other agents.

The cross-over design permitted various sequence of drugs (chlorpromazine and promazine) and control medications (phenobarbital and placebo) to be evaluated. Figure 4 shows the changes in total morbidity which occurred when the drugs were preceded by placebo or followed by it. When placebo was administered during the initial 12-week period, slight changes toward improvement were seen. The addition of chlorpromazine for the second 12-week period produced strikingly more reduction in morbidity. The effect of promazine in this regard was slight. When the drugs were

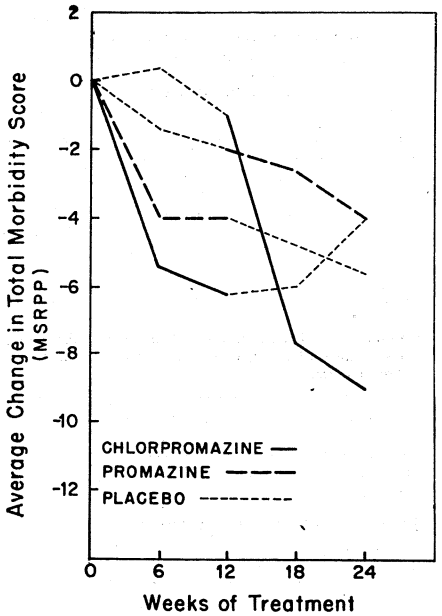

Fig. 4.—Changes in total morbidity scores in patients treated with placebo either before or after promazine or chlorpromazine.

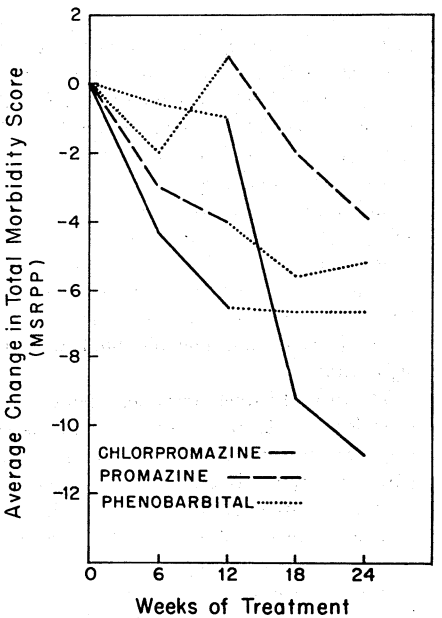

Fig. 5.—Changes in total morbidity score in patients treated with phenobarbital either before or after promazine or chlorpromazine.

administered first, both produced improvement (chlorpromazine more than promazine). Somewhat surprisingly, placebo following drug therapy maintained much of the improvement obtained initially from chlorpromazine and actually enhanced that obtained from promazine. This finding suggests that some carry-over effect may be obtained from treatment with these drugs, the improvement persisting as long as three months.

When phenobarbital preceded or followed treatment with the tranquilizing drugs, similar results were obtained (Fig. 5). Initial treatment with phenobarbital produced negligible effects. When chlorpromazine was added, improvement was rapid and marked; with promazine, less so. Initial treatment with the tranquilizers produced improvement (more so with chlorpromazine). When phenobarbital followed the tranquilizers, improvement from chlorpromazine was maintained and that from promazine enhanced.

TABLE 3.—*Differences in Reduction of Symptoms When Drugs Followed Control Medications or Vice Versa: Twenty-Four-Week Treatment* *

Cl surpassed Pr
ClPh surpassed PrPl in reducing symptoms of severity of illness; ClPl surpassed PrPl in reducing symptoms of risk of violence to others.
Cl surpassed Ph
ClPh surpassed PhPh in reducing total morbidity and symptoms of conceptual disorganization, mannerisms, resistiveness and belligerence.
Cl surpassed Pl
ClPl surpassed PlPl in reducing symptoms of paranoid projection.
Pr surpassed Ph
PrPh surpassed PhPh in reducing total morbidity and symptoms of unimproving mental condition, conceptual disorganization, mannerisms, and resistiveness.
Pr surpassed Pl
PrPl surpassed PlCl in reducing symptoms of paranoid projection.
Pl surpassed Cl and Pr
PlPl surpassed ClPl; PlCl surpassed ClCl, and PlPl surpassed PrPl, in reducing symptoms of self-depreciation.

* ClPh, PrPh, PlPr, etc., refer to successive 12-week courses of the medications in the order indicated.
All differences beyond the 5% level of statistical significance only comparisons showing such differences are noted

Comparisons of symptom reduction when drugs followed control medications or vice versa are shown in Table 3. In general, the presence of a tranquilizing agent in the sequence increased symptomatic relief, as compared with the control agents. Furthermore, chlorpromazine was generally better than promazine. Phenobarbital was never superior to the tranquilizing drugs in improving any specific symptom. Placebo excelled each of the other three agents in reducing self-depreciation.

Comment

Sampling and Statistical Considerations. The intent of this study was to determine the relative effectiveness of these drugs with schizophrenic patients classified as acute, disturbed and nondisturbed, and as chronic, disturbed and nondisturbed. However, the available sample proved to be composed mainly of chronic nondisturbed patients. Accordingly, the results of this study are most applicable to such patients. One should expect that therapeutic effects of the tranquilizing agents might have been more easily demonstrable in the other three groups of schizophrenics. In the cross-over study, the preponderance of chronic nondisturbed patients was even greater. In addition, the fragmentation of the original sample produced rather small samples for each treatment sequence. Both these factors might be expected to increase the difficulty in demonstrating clear-cut therapeutic differences.

Every effort was made to assure that differences among patient groups following treatment were in fact due to the treatment.

In the statistical analysis, it was assumed that the samples had been randomly selected, that each treatment group resembled the other in most pertinent characteristics, and that the design of the experiment eliminated other biasing factors. As far as could be determined, all these assumptions were tenable in this study.

Tools for Evaluation of Patient Change. The two rating devices utilized consisted of one which was extensively tested and one completely new. The MSRPP has been well validated and very widely used.[11,19,20] As no scale is more accurate than the raters, it is important to note that this scale was used in this study by a team, consisting in all cases of a pyschiatrist and a psychologist, which made a consensus rating. Later evaluation of this technique suggested that it has a high degree of interrater reliability.[21] Each team was specially trained in the use of the scale prior to the initiation of the study. Consequently, it was felt that the results of these ratings were acceptably reliable.

Although the Clinical Estimate of Psychiatric Status required only "global" intuitive judgments, it was felt that such material might prove to be useful. Without previous trial, one could not be sure of the degree of the relevance or interrater consistency of the scale. In most cases significant improvement of patient groups in regard to "severity of illness" measured by this device was consistent with similar improvement in the total morbidity score of the MSRPP. However, what some of the measures in this scale were relevant to had not been established and could not be clearly interpreted.

Drop-Outs and Side-Effects.—The number of drop-outs and side-effects was comparatively small. However, these findings could not be generalized beyond the present sample, since 65% of patients had received tranquilizing drugs before. Presumably, such patients may have had an opportunity before the study to become "desensitized" to some of the side-effects of these agents.

Clinical Findings.—A number of factors in this study tended to introduce a "negative bias." The chronicity of the patients and their previous refractoriness to tranquilizing drugs did not afford the most sensitive group for demonstrating therapeutic effects of these agents. The use of a single fixed dose, while considered necessary in the experimental design, may have limited the effects of treatment. Equivalence of dosage between drugs was determined from clinical

experience and advice of drug manufacturers, with possible unknown bias in favor of one treatment over another. The relatively brief duration of treatment may have tended to minimize changes.

Despite these handicaps, the results obtained were consonant with most clinical experience. When chlorpromazine was used, either preceding or following another treatment, the effect of the drug was clearly superior to that of the others. As chlorpromazine is generally considered to be the "standard" against which all other tranquilizers should be measured, the results obtained here bear out this high opinion of the drug. Promazine, while showing definite therapeutic effects, produced changes of less degree and in fewer instances. Here, too, clinical opinion is that this drug is less effective than chlorpromazine at the same dose levels, especially in chronic schizophrenics.[22] Had a higher or a flexible dose of this drug been used, differences between promazine and chlorpromazine might have been less striking, and the superiority of the former drug over phenobarbital and placebo more evident.

The fact that placebo and phenobarbital produced little therapeutic benefit in chronic schizophrenics came as no surprise to clinicians with extensive experience in treating such patients. The placebo effect is contingent upon a high degree of spontaneous remission and a high level of suggestibility of the patient, neither situation obtaining in chronic schizophrenics. On the other hand, the retention of therapeutic gains from tranquilizers for as long as three months following the cross-over to placebos or phenobarbital was surprising. Although it is a common clinical experience that some patients may stay in remission for a long time after discontinuation of medication, it is equally common for patients to relapse within days or weeks. The process of group averaging of morbidity might tend to mask a frequency of relapse that would be intolerable clinically, but relapse of individual patients in this study could not have been very frequent, else the changes in averages would have been greater. Another controlled study has indicated that carry-over effect from chlorpromazine may last as long as three months after patients have been switched to placebos.[23] While tending to support this idea, the present study does not constitute definitive proof because of the comparatively small sample (39 to 42 patients) in each of these treatment groups.

Another interesting aspect of the use of placebos in this study was the apparent amelioration of a symptom of mental depression (self-depreciation) by placebo when given continually for 24 weeks, as compared with the other three agents given in the same fashion. Here the effect may be negative rather than positive; the drugs may have aggravated this particular symptom. Clinical evidence suggests that, at least with the phenothiazine derivatives, some patients may have depressive symptoms aggravated.

Summary

A large cooperative study involving 692 men with schizophrenic reactions hospitalized in 37 Veterans Administration neuropsychiatric hospitals was undertaken to determine the relative effectiveness of chlorpromazine, promazine, phenobarbital, and placebo. Controls included random assignment of treatments, use of the double-blind technique for drug administration, and provision for similar conditions of treatment. Chlorpromazine and promazine were administered in daily doses of 400 mg., and phenobarbital, in doses of 200 mg. After 12 weeks of treatment, some patients continued for 12 more weeks on the drug initially assigned, and some were switched to control medications following the tranquilizing drugs, or vice versa.

Chlorpromazine was found to be significantly better in reducing total morbidity of patient groups treated with this drug over a 12-week period than were any of the other three agents. Over the 24-week period chlorpromazine was significantly more effective than either control medication. Promazine was significantly more effective than either control medication over the 12-week period,

but superior only to phenobarbital after 24 weeks of treatment. No significant differences in clinical effects were noted between phenobarbital and placebo when the drug was given for 12 or 24 weeks. When chlorpromazine or promazine followed control medications, clinical improvement was increased, especially with the former drug. However, the substitution of control medication following tranquilizing drugs maintained the gains from the latter surprisingly well for an additional 12-week period. Reduction of specific symptoms of illness was greatest with chlorpromazine, less with promazine, and little with the control medications. Placebo was more effective than all drugs in reducing the symptom of self-depreciation, a symptom of mental depression. Side-effects from treatment with all four agents were minimal, and none was severe.

The value of chlorpromazine in treating schizophrenic patients was confirmed by this study. Promazine did not appear to be so effective, possibly owing to inadequate dosage. Phenobarbital and placebo were comparatively ineffective, as might be expected in a sample composed largely of chronic schizophrenic patients.

The feasibility of carrying out such large-scale cooperative studies of drugs reported useful in psychiatry was confirmed. Results obtained from this study provide definitive support for previously held clinical opinions regarding the efficacy of tranquilizing drugs in treating schizophrenic reactions.

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TREATMENT OF SCHIZOPHRENIC REACTIONS WITH PHENOTHIAZINE DERIVATIVES

A Comparative Study of Chlorpromazine, Trifluprom azine, Mepazine, Prochlorperazine, Perphenazine, and Phenobarbital [1]

JESSE F. CASEY, M.D.,[2] JULIAN J. LASKY, PH.D.,
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JESSE F. CASEY, M.D.,[2] JULIAN J. LASKY, PH.D., C. JAMES KLETT, PH.D.,[3] AND LEO E. HOLLISTER, M.D.[4]

Since chlorpromazine[5] has been proved useful in treating chronic hospitalized schizophrenics(1, 2, 3, 4), newer phenothiazine derivatives have appeared with claims of higher potency, greater therapeutic effectiveness, and fewer side effects or complications. After reviewing the voluminous literature, the harried clinician might still wonder whether any of the newer compounds were superior in any way. The reports on mepazine, for example, have ranged from enthusiastic endorsement to unqualified rejection(5, 6, 7, 8, 9) : Bowes concluded that mepazine was twice as strong as, interchangeable and synergistic with chlorpromazine ; Denber's sober title, "Ineffectiveness of mepazine . . ." completed the spectrum of opinion.

Recently more definitive studies of the newer phenothiazine derivatives have appeared(10, 11). Although these studies still contain contradictions, the differences are more understandable. In Freyhan's study of 10 phenothiazine compounds and reserpine, chlorpromazine was more effective than mepazine, reserpine, and promazine. It is inferred from his data that perphenazine, prochlorperazine, trifluoperazine and trifluprómazine were not more effective than chlorpromazine, although he makes it clear that they caused more extrapyramidal reactions. Goldman differed with Freyhan, stating that perphenazine, prochlorperazine, and trifluprómazine were more effective than chlorpromazine, caused fewer side effects and practically no complications. He could not differentiate therapeutically between perphenazine and prochlorperazine but found that trifluprómazine produced fewer side effects than either. Some of these contradictions appear to be due to the use of different dosage schedules, criteria of improvement, treatment goals, and population samples.

With this and its own experience as a background(12, 13), the Veterans Administration began, in May 1958, a large-scale cooperative study of the relative therapeutic

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[1] Project 3 of the Veterans Administration Cooperative Studies of Chemotherapy in Psychiatry. Preliminary results were presented at the Fourth Annual Research Conference on Chemotherapy in Psychiatry, VA Hospital, Memphis, Tenn., May 20, 1959. The indicated authorship connotes roles in planning or coordinating the study and preparing this report. Others who made major contributions were : T. G. Andrews, Ph.D., J. L. Bennett, M.D., E. M. Caffey, Jr., M.D., H. M. Houtchens, Ph.D., C. J. Lindley, M.A., M. Lorr, Ph.D., A. S. Marrazzi, M.D., A. Pokorney, M.D., and M. Rosenblum, M.D. The 35 VA hospitals which participated in this study are located at : Albany, N. Y., American Lake, Wash., Ann Arbor, Mich., Augusta, Ga., Battle Creek, Mich., Bay Pines, Fla., Biloxi, Miss., Brockton, Mass., Bronx, N. Y., Buffalo, N. Y., Coatesville, Pa., Danville, Ill., Denver, Colo., Downey, Ill., Fort Meade, S. Dak., Houston, Tex., Jefferson Barracks, Mo., Los Angeles, Calif., Lyons, N. J., Montrose, N. Y., Murfreesboro, Tenn., New York, N. Y., Northampton, Mass., North Little Rock, Ark., Northport, N. Y., Palo Alto, Calif., Perry Point, Md., Roseburg, Ore., Salt Lake City, Utah, Sepulveda, Calif., Togus, Me., Tomah, Wis., Topeka, Kan., Tuskegee, Ala., and Waco, Tex. Without the generous cooperation of staff personnel from these hospitals, this study would not have been possible.

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[5] The generic and trade names of the drugs used in this study are : chlorpromazine—Thorazine (donated by Smith, Kline and French Laboratories), mepazine—Pacatal (Warner-Chilcott Laboratories), perphenazine—Trilafon (Schering Corporation), prochlorperazine—Compazine (Smith Kline and French), trifluprómazine—Vesprin (E. R. Squibb and Sons).

effectiveness and toxicity of chlorpromazine, trifluprom azine, mepazine, prochlorperazine, and perphenazine. Phenobarbital was used as a control medication.

PROCEDURE [6]

Patient Sample: Six hundred forty newly admitted schizophrenic men were studied in 35 VA hospitals. The average patient was 34 years old (the median was also 34), and the range was 18-54 years. He weighed 161 pounds, had finished 10½ grades, had been a semi-skilled worker, and was first treated for mental illness 7¼ years before his current admission. About half the patients were single, 30% were married, and the rest were divorced (10%) or separated (8%). The number of previous hospitalizations were as follows: none-18%, one-23%, two or three-27%, four or five-21%, six or more-11%. Forty-four percent had never received tranquilizers previously. All were in good physical health.

As measured by the Multidimensional Scale for Rating Psychiatric Patients-MSRPP(14), the average study patient before treatment was a little sicker, in general, but as active and no more depressed than the general population of schizophrenic men hospitalized in VA hospitals. He was somewhat more resistive, belligerent, withdrawn, and conceptually disorganized than the usual hospitalized schizophrenic veteran and markedly more paranoid, self-depreciatory, mentally agitated, active, and perceptually confused.

The attrition in the sample by the end of the study was 26%. One hundred fifty patients were dropped from the study. An additional 18 could not be included because of incomplete data. During the study period 85 patients left the hospital: 43 without medical approval, 24 on trial visits, and 18 by approved discharge. Also eliminated were 23 patients who were worse or had shown no improvement, 16 who refused medication, 4 who became seriously depressed, and 1 who was transferred. Finally, 21 patients were dropped; 12 because of side effects and 9 due to deviant laboratory findings.

Drugs, Dosage, Duration of Treatment: Identical-appearing coded medications were supplied to the hospitals from a central point in the following strength capsules: chlorpromazine, 50 and 200 mg.; triflupromazine and mepazine, 25 and 50 mg.; prochlorperazine, 10 and 25 mg.; perphenazine, 8 and 16 mg.; phenobarbital, 32 mg. These doses were chosen as equivalent on the basis of the manufacturer's recommendations. During the first 4 weeks of treatment, a fixed progressive dosage schedule was followed in all treatment groups: day 1, one low strength capsule; day 2, two low strength; day 3, three low strength; day 4, one high strength; days 5 through 14, two high strength; days 15 through 28, three high strength. During the remaining 8 weeks of the study, a flexible schedule was used in which the physician adjusted the dose, within limits of 1 to 6 high strength capsules daily, to produce optimal therapeutic effects in his individual patients.

Figure 1 shows the average number of capsules prescribed per week during the fifth through the twelfth weeks for patients in each of the 6 treatment groups. The average daily dose of each drug during the flexible dosage period was as follows: chlorpromazine, 635 mg.; trifluprom azine, 175 mg.; mepazine, 190 mg.; prochlorperazine, 90 mg.; and perphenazine, 50 mg.

After the fifth week there were reliable [7] variations among the treatment groups in number of capsules prescribed. Fewer capsules were prescribed for chlorpromazine patients than for any other group during the sixth week. In the eighth week and for the remainder of the study, significantly fewer capsules were prescribed for chlorpromazine and perphenazine patients than for mepazine or phenobarbital patients. Physicians used the full range of 1 to 6 capsules daily for each medication.

METHODS OF EVALUATING TREATMENT

Clinical Status: Clinical changes in patients were measured by two rating de-

[6] The study protocol, reproduced in its entirety in the Transactions of the Third Annual Research Conference in Chemotherapy in Psychiatry, contains considerable detail concerning selection of patients, the randomization procedures, precautions, restrictions, laboratory controls and forms.

[7] All differences discussed are statistically significant at or beyond the .05 level.

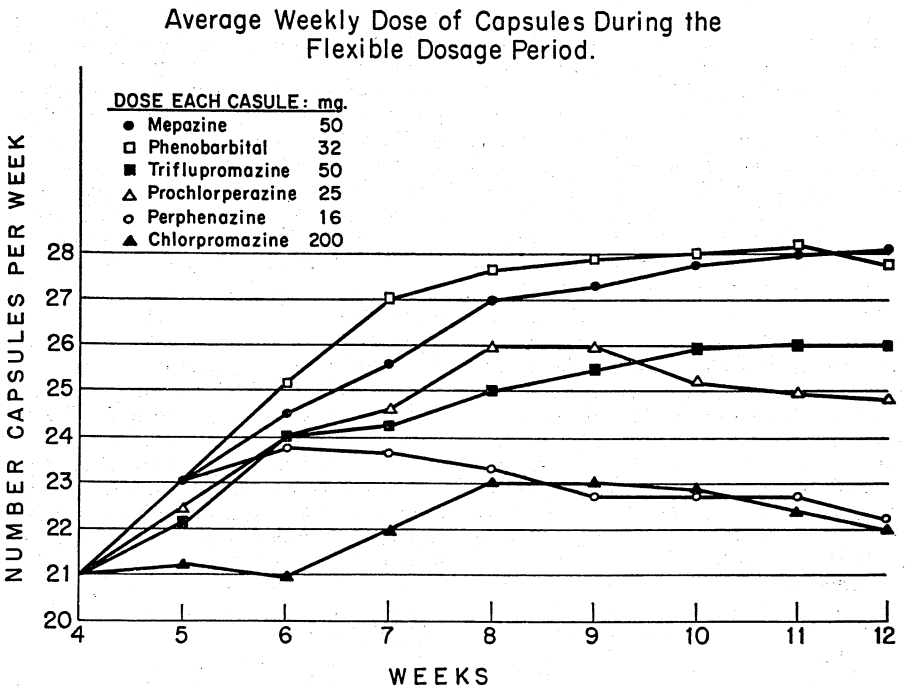

FIGURE 1

vices: the MSRPP and the Clinical Estimate of Psychiatric Status scale-CEPS(15). The MSRPP consists of two parts, the clinical interview section completed by a 2- or 3-man team of psychologists and psychiatrists, and a ward behavior section based on the observations of a 2- or 3-person team of nurses and nursing assistants. The MSRPP yields a total morbidity score which is an overall index of psychopathology and 11 additional scores which represent symptom clusters. The reliability of the MSRPP was estimated by having each member of the clinical and ward teams make their pretreatment judgments independently before arriving at team consensus evaluations(16). The CEPS required judgments from psychiatrists on 12 items of psychopathology and prognosis. Patients were evaluated by both rating devices before and after 4 and 12 weeks of treatment.

Untoward Symptoms: The presence or absence of 18 specific symptoms and signs were checked and recorded weekly by the physician. These included adverse behavioral effects, disturbances of the central and autonomic nervous systems and allergic reactions, chosen on the basis of known side effects of the phenothiazines.

Laboratory Measures: Hematologic tests included differential and total leucocyte counts obtained just before treatment and each week during treatment. Serum glutamic oxalacetic-transaminase (SGO-T) or serum alkaline phosphatase determinations were used as screening hepatic tests. Either of these tests was requested before treatment and then weekly for the first 5 weeks. If either was abnormal, a battery of additional hepatic tests was to be ordered. Pulse rate and blood pressure were recorded daily for the first weeks of treatment and morning temperatures were recorded daily for the first 8 weeks.

STATISTICAL ANALYSIS

The statistical model for evaluating the relative therapeutic effectiveness of the

study drugs was analysis of multiple covariance (simple randomized design). Each of the 24 criterion measures derived from the MSRPP and CEPS was analyzed for relative changes in clinical status during the first 4 weeks, the following 8 weeks, and over the entire 12-week study period. Final criterion mean scores in each analysis were adjusted for initial status on the criterion being analyzed as well as for the net effect of 11 control variables: age, education, occupational level, marital status, number of previous hospitalizations, nature of onset of first and current illness, months since condition first required medical attention, initial weight, history of previous tranquilizers and morbidity. In addition to adjusting the criterion means of the 6 treatment groups for whatever differences existed prior to treatment despite random assignment, this technique statistically eliminated that portion of the variability of the criterion associated with the covariates. The net effect of the adjustment was to provide statistical equality of the treatment groups prior to treatment and to reduce the error term used in evaluating mean differences.

One thousand and eighty comparisons were carried out; each of 6 treatment groups being compared with each other, yielding 15 comparisons for each of 24 criteria over each of three time periods. The effect of making so many comparisons is to increase the likelihood of deciding there is a significant difference when in fact there is not. The findings were subjected to a multiple range test(17, 18) for protection against this kind of error.

RESULTS

Criteria of Clinical Effectiveness: Adjusted mean morbidity scores (MSRPP) for each of the 6 treatment groups are shown in Figure 2. The pretreatment mean is based upon the entire sample of patients. Even at the end of 4 weeks of treatment, a significant reduction in total morbidity had been produced by chlorpromazine, triflupromazine, prochlorperazine, and perphenazine as compared with phenobarbital. The differ-

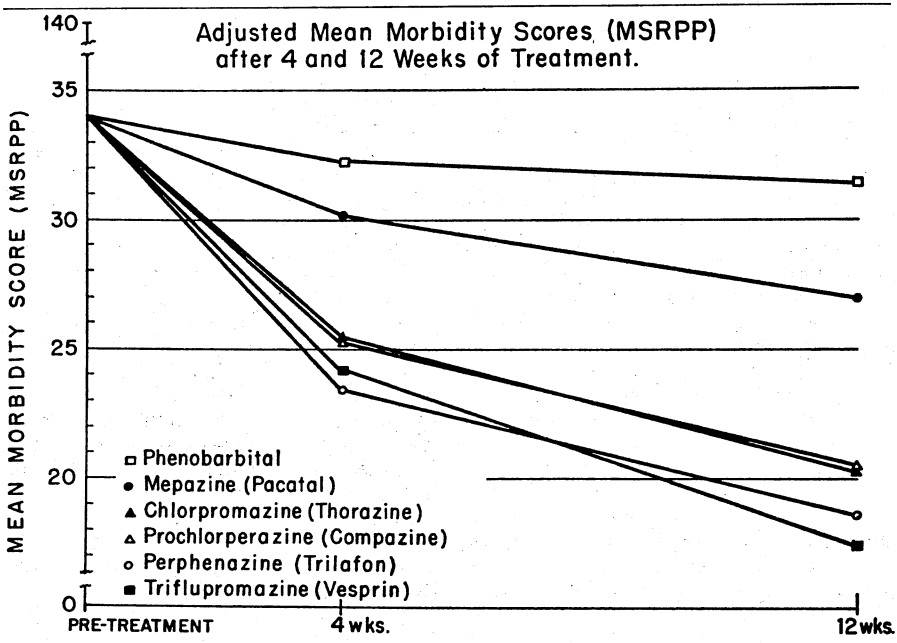

FIGURE 2

ence between mepazine and phenobarbital was not significant at this time. When 12 weeks of treatment had been completed, all 5 phenothiazines had reduced morbidity significantly more than phenobarbital. Four of the phenothiazines were superior to mepazine at both the 4th and 12th week evaluations. There were no significant differences among the 4 more effective drugs. Even though the differences shown in Figure 2 between prochlorperazine and trifluprazine may appear to approach significance, this difference has a p value $> .20$.

The results of the analyses of relative change in the remaining 23 criteria of clinical effectiveness have been organized in Table 1 to emphasize the 3 main findings which occurred during two time periods.[8]

1. *All five phenothiazine derivatives were therapeutically effective, i.e.,* they were superior to phenobarbital, the control drug, in respect to some important criteria of improvement. There were no instances in which the phenobarbital group showed reliably greater improvement than the phenothiazine groups. The ways in which all phenothiazines were superior to phenobarbital are shown in the upper portion of Table 1.

2. *One of the phenothiazine derivatives was less effective than the other four.* In every instance that mepazine surpassed phenobarbital, all other phenothiazines also did so. In the middle portion of Table 1 are listed those criteria of clinical effectiveness on which all phenothiazines except mepazine exceeded phenobarbital. In the lower third of Figure 1 are presented those cri-

[8] Detailed statistical tables containing the adjusted means, F ratios, and results of the multiple range test for *all* criteria at the *three* evaluation periods may be found as a supplement in the Appendix of the Transactions of the Fourth Annual Research Conference on Chemotherapy in Psychiatry. Inquiries concerning additional statistical or procedural details may be directed to the Central NP Research Laboratory, Perry Point, Md.

TABLE 1

CLINICAL DIFFERENCES BETWEEN VARIOUS PHENOTHIAZINE DERIVATIVES AND PHENOBARBITAL OR MEPAZINE IN NEWLY ADMITTED SCHIZOPHRENIC MEN

Patients receiving chlorpromazine, mepazine, perphenazine, prochlorperazine and triflupromazine were more improved than those receiving phenobarbital in the following ways:

After 4 Weeks	*After 12 Weeks*
Less: resistive; belligerent; thinking disturbance; nursing care required.	Same gains as after 4 weeks plus: less likely to injure others; greater chance for early discharge; greater chance for independence and self-support following discharge; illness less severe; condition improving; decrease in symptoms.

Patients receiving chlorpromazine, perphenazine, prochlorperazine and triflupromazine were noted more improved than those receiving phenobarbital in the following additional ways:

After 4 Weeks	*After 12 Weeks*
Less: motor disturbance; likely to injure self. Decrease in symptoms, illness less severe, condition improving.	Less: motor disturbance; likely to injure self; paranoid projection; perceptual distortion; AWOL potential. More participation in activities.

Patients receiving chlorpromazine, perphenazine, proclorperazine and triflupromazine were more improved than those receiving mepazine as follows:

After 4 Weeks	*After 12 Weeks*
Less: paranoid projection; motor disturbance.	Less: motor disturbance; perceptual distortion; belligerence; thinking disturbance; likely to injure others; melancholy agitation. Decreased symptoms and greater chance for discharge. Condition improving.

teria with respect to which chlorpromazine, trifluprom azine, prochlorperazine, and perphenazine were better than mepazine. There were no instances in which any of these phenothiazines was reliably worse than mepazine.

3. *The remaining four phenothiazine derivatives were not differentiated from one another in therapeutic effectiveness.* Over the entire 3-month period there were no significant differences among these 4 treatment groups on any of the 24 criteria.

SIDE EFFECTS AND LABORATORY FINDINGS

Only 21 patients (3%) were discontinued from treatment because of side reactions or deviant laboratory tests, this number being fairly evenly distributed among the 6 treatment groups. Five patients were dropped because of leucopenia. Four had deviant hepatic tests. Other reasons for termination included: 3 cases of Parkinsonism, 1 epigastric pain, 1 photophobia, 1 dermatitis, 2 deviant temperature or blood pressure, and 4 patients who became pale, nauseated, weak or hypotensive.

A detailed report of the abnormal symptoms, signs and laboratory tests has been published elsewhere(19). The piperazinyl-phenothiazines, perphenazine and prochlorperazine, produced most of the side effects followed by the aliphatic phenothiazines, chlorpromazine and trifluprom azine. Mepazine and phenobarbital produced the fewest side effects. Although the extrapyramidal syndrome was unique for the phenothiazines (and most pronounced with the piperazinyl derivatives), most of the other side effects measured, including adverse behavioral reactions and autonomic nervous system effects, were also reported in some measure for phenobarbital. Hematologic changes (leucopenia, eosinophilia, and leucocytosis) were encountered with all drugs without significant differences in frequency. The same was true of abnormal hepatic tests, none of the patients having a definite clinical picture of jaundice.

DISCUSSION

Since this study was designed as a comparative evaluation of 4 newer phenothiazines with chlorpromazine serving as a standard or reference treatment, emphasis was placed upon the *relative* effectiveness and toxicity of these 5 agents rather than the evaluation of any one considered independently. Phenobarbital, mimicking some of the properties of the phenothiazines, was included as an active placebo. To be considered an effective agent, any phenothiazine derivative should be superior, at least, to a conventional sedative.

The fact that all the phenothiazines studied were effective in reducing some aspects of psychopathology is evident from their comparison with phenobarbital and is consistent with most published reports. Of greater interest are the symptoms affected. After one month of treatment with these drugs, patients were less resistive, belligerent, and disturbed in their thinking than patients receiving phenobarbital. These changes were accompanied by a decrease in the amount of physical nursing care required. Further gains were made during the last two months of the study. Psychiatric judgments indicated that patients receiving the phenothiazine derivatives had better prospects for early discharge and were more likely to be independent and self-supporting after discharge than patients receiving phenobarbital.

In short, any of the 5 phenothiazine derivatives produced clinical effects superior to phenobarbital. It is inferred that these 5 agents would be superior to an inert placebo group or to a group that had received no capsules at all. The reduction in morbidity of the phenobarbital group during treatment was slight and did not reach significance. A previous VA cooperative study based on a large sample of chronic schizophrenic patients demonstrated that neither a placebo nor phenobarbital had therapeutic value nor was either more effective than the other(1).

Although all the phenothiazines were more effective than phenobarbital, mepazine was less effective than the other four. This finding may be related to differences in chemical structure as discussed by Himwich(20). One explanation of mepazine's apparent inferiority might be that it had been used at too low a dose. During most of the first month of treatment, mepazine patients received 150 mgs./day, the lower limit of the range of maximal therapeutic