

STATEMENT OF ROBERT H. FURMAN, M.D., VICE PRESIDENT,
CORPORATE MEDICAL AFFAIRS, ELI LILLY AND COMPANY
(ACCOMPANIED BY: EUGENE STEP, PRESIDENT, PHARMACEUTICAL
DIVISION, ELI LILLY AND COMPANY; AND EDGAR G. DAVIS,
VICE PRESIDENT, CORPORATE AFFAIRS DIVISION, ELI LILLY
AND COMPANY)

Dr. Furman. Mr. Chairman and members of the committee, I
am Robert Furman, Vice President of Corporate Medical Affairs,
Eli Lilly and Company. With me today are Mr. E. L. Step,
President of the company's Pharmaceutical Division, and Mr.
E. G. Davis, Vice President of Corporate Affairs. In
addition, I would like to introduce Dr. Arthur Scherbel, head
of the Department of Rheumatology, Cleveland Clinic; Dr.
Bryan Finkle, Director of the Institute for Human Toxicology,
University of Utah; and Mr. Frank Osgood, President, IMS
America whose company provides the information to DEA on
which the DAWN report is based and also has done the script
audit on which assessments of educational programs and
detailing successes has been carried out. These people have
volunteered their services. They represent a very valuable
resource and I hope you and the members of your committee
will feel free to call on them.

Mr. Waxman. We appreciate all of them coming to our
hearing so that we might be able to direct questions to them
in the fields in which they are qualified to give us their

expert answers.

Dr. Furman. We appreciate the committee's invitation to testify. In our statement we will provide information on the significant decline in the misuse of propoxyphene, the elements in the Lilly and FDA programs that have contributed to this result, and reassurance to the committee that propoxyphene, when used as recommended, is a safe and effective analgesic agent.

In 1975 the state toxicologist of North Carolina, Dr. Arthur McBay, provided information based on a systematic analysis of drug deaths throughout coroners' offices in that state which indicated an increasing number of deaths, primarily suicides, involving propoxyphene, either alone or in combination with other drugs. Lilly medical personnel met with Dr. McBay and, in consultation with FDA, requested Dr. Bryan Finkle to undertake a broader evaluation of medical examiner records at various sites throughout the United States. This evaluation was based on the analysis of more than 1,000 medical examiner cases involving propoxyphene, either alone or in combination with other drugs. The results of the evaluation were shared with FDA and DEA and published in 1976.

Lilly, working with FDA, revised the labeling of its Darvon products in 1976 and communicated new information applicable to the use of those products to members of the

medical profession, both in a special brochure and in publication of a synopsis of Dr. Finkle's study in the Journal of the American Medical Association.

After evaluating data from Dr. Finkle's study, the FDA Controlled Substances Advisory Committee recommended that propoxyphene be placed in Schedule IV of the Controlled Substances Act. Subsequently, the Drug Enforcement Administration placed propoxyphene in Schedule IV early in 1977. Lilly did not oppose this action.

As the result of a petition filed by the Health Research Group in late 1978, asking that propoxyphene be banned as an "imminent hazard" or be placed in Schedule II, the Department of HEW and the Drug Enforcement Administration conducted a full and complete review of propoxyphene during the first six months of 1979. The Health Research Group petition contained no new scientific data but was based in large measure on:

1. Information developed by Lilly in 1975 on toxicity associated with the misuse of propoxyphene.
2. Medical examiner reports reflected in drug abuse warning network data, i.e., information comparable to that developed by Lilly in the 1975 Finkle survey.

The 1979 review examined all aspects of propoxyphene: its pharmacology, safety, effectiveness, and dependence liability. The evidence demonstrated that propoxyphene is both safe and effective when used as directed, that the drug

has little potential to produce dependence, and that the principle form of misuse involves suicide or other self-destructive behavior that cannot be dealt with effectively through Schedule II controls.

After extensive review, HEW determined in September of last year that there was insufficient evidence to reschedule the drug to Schedule II of the act as HRG had proposed. Also, it was decided that the type of misuse which was occurring with propoxyphene could be reduced most effectively by providing information on proper use to physicians, pharmacists, and patients. These programs were initiated and are monitored by the Department of Health and Human Services.

The recent UN decision should not have any effect on the careful decision made on the United States last year. We believe the Commission's decision was unwarranted and we are hopeful that the United States and other nations will receive review or reconsideration of it.

The international decision-making process was cursory at best and cannot be compared with the careful consideration given to the scientific and medical issues in this country. The American representatives on the World Health Organization Committee that advised the Commission on narcotic drugs have stated that they understood that a decision to place propoxyphene in Schedule II under the single convention would have no effect on its status in the United States law.

The advice we have received from experts in international law indicates that they are right. The controls applicable to the Schedule IV of the CSA, we are informed, are sufficient to meet the nation's obligation under the single convention. The Commission's decision, therefore, need not require any change in the carefully considered decision already made by government authorities in the United States.

With respect to Dr. Wolfe's comments on the alleged abuse in other countries, I would like to point out that the United Kingdom opposed the Commission on Narcotic Drugs action, so did West Germany, Austria and India. Canada and Finland did not think scheduling was justified. The Commission on Narcotics Drugs Report to the Economic and Social Council, paragraph 118 states as follows: "The representatives of the Federal Republic of Germany stated that there was no need to place it under control. The representatives of India and the United Kingdom and Austria shared that point of view since there was no abuse of substance in their countries. Canada and Finland also did not think that scheduling was justified although they mentioned cases of abuse, especially in combination with alcohol. Measures have been taken at the national level on control substances as a gesture for international solidarity even when abuse was reported in only certain states."

As indicated in the introduction to this statement, we

are pleased to report that misuse of propoxyphene is declining at a substantial rate. Let me point out several items.

First, that the exhaustive HEW/DEA investigation in 1979 reaffirmed the safety and effectiveness of propoxyphene when used as recommended.

Second, the improper use of propoxyphene is generally in association with multiple drug misuse, frequently with alcohol. It is a multiple drug, polydrug problem.

Third, when propoxyphene is misused, such misuse usually occurs with suicidal intent.

Lilly carefully monitors reports of the improper use of propoxyphene. This is done in several ways. Two of the most important sources of data have been the Drug Abuse Warning Network (DAWN), sponsored by the Drug Enforcement Administration, and the data collected directly from medical examiners by Dr. Finkle.

The DAWN system provides a number of measurements of drug abuse. Especially important are data from those medical examiners and coroners' offices which consistently report drug induced deaths to the DAWN system.

From these data it is possible to tabulate the principal drugs mentioned in medical examiner cases, as well as to determine whether or not the death was "drug induced." I should note that it is not necessary for a specific drug to

have been the actual cause of death for it to be "mentioned" in the DAWN reports. As we noted earlier, propoxyphene cases usually involve polydrug abuse, often with alcohol. As Secretary Califano said, "It merely means that the deceased person had the drug in his or her blood."

When the data are examined for propoxyphene for the period 1976 through the third quarter of 1979, two very significant facts are evident.

→ 1. Since the various FDA and Lilly educational efforts for physicians and health professionals were initiated in the spring of 1979, there has been a 30 percent decline in propoxyphene mentions in medical examiner cases.

→ 2. There has been a 55 percent decline in propoxyphene mentions in medical examiner cases since the first quarter of 1977.

The actual number of quarterly propoxyphene mentions from consistently reporting medical examiners is listed below. You will find that in the bar graph on page 9 and I think at a glance at that it will show that since the first quarter in 1977 when the non-medical examiner mentions peak there has been a very gratifying and steady decline.

Dr. Finkle who is with us this morning has also continued an in-depth examination of case data at medical examiner offices throughout the country. He informs me this morning that is not complete. His data base now includes information

from many offices through 1979 and from a larger number through 1978. His commentary on these cases as reported to FDA recently by Lilly is contained in Appendix 1.

This information indicates decreased deaths involving propoxyphene for the period 1977 through 1979 at all sites for which 1979 data have been collected.

The data from Dr. Finkle's tabulation are on page 11. I won't go through this. We will provide the committee the complete tabulation. Suffice it to say, a good many of these medical offices now have a substantial reduction in comparison with 1977.

Although propoxyphene has declined in use in recent months, propoxyphene involvement in drug related deaths is decreasing at a faster rate than the decline in propoxyphene prescriptions. In the bar graph on page 13 all prescriptions for propoxyphene have been compared with DAWN medical examiner propoxyphene mentions. Despite quarterly variations, the trend is clearly down ward downward.

The DAWN system also collects information from emergency rooms. Propoxyphene mentions from DAWN emergency rooms declined 36 percent between the first quarter of 1977 and the fourth quarter of 1979. They declined 27 percent in 1979 alone.

During the proceedings last year the DEA polled drug abuse officials in all states about propoxyphene. Responses

were received from only 27 states. Only five said there was any evidence of abuse, only three state officials endorsed placing propoxyphene in Schedule II.

Analysis of DEA Drug Abuse Warning Network data showed that propoxyphene was rarely abused for psychic effects or dependence. There has never been any evidence of illicit traffic from legitimate channels of distribution.

Recently Lilly conducted a study of more than 2,500 patients who received propoxyphene -- even to be statistically representative of 1.8 million persons who received prescriptions administered by the prescription data services corporation. The study showed almost no evidence of persons who obtained propoxyphene in quantities greater than those needed for legitimate medical purposes. In fact, over 99 percent of the persons in the sample received only the amount of propoxyphene needed for dosages recommended in the improved labeling for the drug. In short, the leading indicators provide reassurance that the FDA and Lilly information programs have been effective in that propoxyphene misuse is steadily decreasing.

Recently, as you heard Dr. Crout say, we wrote Lilly and questioned several aspects of the propoxyphene information program. Since the receipt of that letter, Mr. Step, Mr. Davis and I have met with Dr. Crout and his staff and discussed their concerns. We assured them that the Lilly

program was not a "promotional campaign." The information program developed by Lilly and the FDA involved the distribution of vast quantities of letters, brochures, package literature, patient information sheets, and "Management of Overdosage" booklets. Thousands of interviews were held and physicians awareness of the precaution is applicable to the use of propoxyphene was sharpened.

The Food and Drug Administration, as noted in Dr. Crout's letter, relied upon data from the national detailing audit, an IMS service, as an indicator of physician awareness. Mr. Frank Osgood, who is here with us this morning, the President of IMS, participated in the recent FDA/Lilly conference. He advised that the national detailing audit does not provide an appropriate data base on which to evaluate the effectiveness of the Lilly program.

A survey designed to reflect accurately physicians' increased knowledge regarding propoxyphene has been conducted by IMS and the results have been provided to FDA. In that survey 88 percent of the physicians involved indicated an awareness of the precaution is applicable to prescribing propoxyphene. A summary of that survey has been provided to you.

In his letter to Lilly, Dr. Crout expressed concern regarding Darvon sampling. On receiving a physician's signed request, Lilly sales personnel did leave samples of Darvon

products during some physician calls. Such sampling is conducted in accordance with strict company accountability rules and in compliance with federal regulations applicable to the distribution of controlled substances. A precise examination of company records indicates that during the educational effort sampling was at one-half the level reported to the FDA by the National Detailing Audit.

Lilly sales representatives are not, as stated in the FDA letter, paid on a "commission sales" basis. They are not paid bonuses in relation to physicians utilization or rejection of any specific Lilly product. They share with other employees in an annual contingent compensation plan based on overall company performance. More than 75 percent of the men and women who are Lilly sales representatives are pharmacists, and many of the remaining 25 percent have degrees in science and/or advanced degrees. All are college graduates.

The Department of Health, Education and Welfare disseminated information in February 1979 on Secretary Califano's decision not to remove propoxyphene from the market and his announcement of the pending evaluation of the safety, effectiveness and abuse liability of propoxyphene.

The FDA Drug Bulletin, under the caption "Fatalities Due to Propoxyphene," was distributed in March 1979 to nearly a million health professionals.

Lilly proposed in April of 1979 to voluntarily disseminate to patients and to health professionals, including physicians and pharmacists, information on the proper and appropriate use of propoxyphene. The elements in that information program were developed jointly by Lilly and the FDA.

Information on the content of this program is provided below and included:

- revised package literature providing additional information and emphasis on proper use

- a special brochure for distribution to physicians with summary warning information and revised package literature

- information sheets for distribution by pharmacists and physicians directly to patients, containing information to limit improper use of Darvon and a display of the various product forms

- a revised "Management of Overdosage" booklet for physicians and emergency room personnel

- drug warning letters for physicians and pharmacists

- prescription vial warning stickers for use by pharmacists on Darvon prescriptions

- destruction of all obsolete labeling and package literature

- distribution of appropriate quantities of the

foregoing items (with business reply cards to provide for reordering):

a. To more than 120,000 physicians identified by Lilly as significant prescribers of Darvon products (75,000 physicians by personal contact and the remainder by mail.)

b. To an additional 100 45,000 physicians

c. To 25,000 psychiatrists

d. To 60,000 community and hospital pharmacist.

-- preparation and distribution of a film incorporating the views of three prominent psychiatrists on the identification and treatment of depressed and potentially suicidal patients:

a. Approximately 150 copies are available in various company offices throughout the country for use by health groups.

b. All medical and pharmacy schools in the United States have been provided copies.

-- Surveys have been conducted

a. To determine physician awareness of the revised warnings applicable to propoxyphene

b. To determine pharmacy use of patient information sheets.

A survey is currently in progress to determine patient's understanding of instructions for the proper use of propoxyphene.

Lilly continues to analyze DAWN medical examiner and emergency room data.

Dr. Finkle's study of medical examiner data is going forward under Lilly sponsorship.

Dr. Robert Litman, of the Suicide Prevention Center of Los Angeles, is conducting an one year study of all codeine and propoxyphene related deaths.

Prescription Data Services information on drug use, both with respect to propoxyphene and other agents, has been, and is continuing to be, reviewed.

Reports to the company of toxicity and dependence are investigated and tabulated.

Darvon patient information sheets have been developed in Spanish and Yiddish.

Available crime laboratory information (Wisconsin) is scanned -- propoxyphene reports are negligible.

Periodic reports on all of the foregoing activities are submitted to and reviewed with the Food and Drug Administration. FDA and other agencies within the Department of Health and Human Services are continuing to evaluate propoxyphene. With surveillance both by the appropriate federal agencies and the company, we anticipate that any significant change in public health statistics related to propoxyphene will be promptly reported and acted upon.

In summary, Mr. Chairman, an extensive information

program has been conducted, and physicians are aware of the precautions applicable to the use of propoxyphene. All available data indicate that propoxyphene involvement in medical examiner cases and emergency room situations has decreased and is continuing to decrease sharply. Both Lilly and the Department of Health and Human Services are monitoring this situation on a continuing basis, and Lilly is committed to programs for the safe and effective use of Darvon products.

Thank you for this opportunity, Mr. Chairman, to present our views to you and the members of your committee. We will be glad to respond to questions.

Mr. Waxman. Thank you, very much, Dr. Furman, for your statement.

You have patient information sheets in Spanish and Yiddish. The Spanish, of course, is probably the most widely used second language in this country. Why Yiddish?

Dr. Furman. You will have to ask some of my marketing friends for that answer.

Mr. Waxman. You didn't bring them with you?

Dr. Furman. Mr. Step, who knows all the answers, can answer that. We will be happy to find that out.

Mr. Waxman. One alternative to reclassification would be to have physicians write on the prescription "do not refill". This would give the physician the ability to check to be sure

that the patient is not abusing Darvon. Do you think that that would be a good idea, for physicians to write "do not refill"?

Dr. Furman. In certain cases I certainly do and that is recommended by the psychiatrists on our film. If a patient is known to be one who has attempted suicide in the past, obviously its refillability should be limited. The psychiatrists in the film also suggest that a member of the family be advised of the prescription, what it contains and what it is for in order to have a sort of a built-in monitor. I think, however, rather than to insist on imposing a regulation, physicians should make this decision and I think they are increasingly making this decision.

Mr. Waxman. If Darvon were reclassified into Schedule II, one of the major differences would be that there would be that requirement of a physician to review it. Since there is so much abuse of Darvon, would it not be a mild inconvenience to have physicians regularly review the prescription before renewing it as opposed to allowing this refill five times within six months without a physician?

Dr. Furman. First, 60 to 80 percent of the deaths in association with Darvon are suicides. Furthermore, there are upwards of 30 to 50 million people in the United States who suffer from chronic pain disorders, varicose veins, arthritis and rheumatism. To arbitrarily impose on these disabled

patients, in many instances, the requirement and expense and time required to go back to the physician and have a new prescription written I think imposes an unnecessary burden both on the patient and the physician. I think the answer to the problem is not the arbitrary imposition of these kinds of restrictions but to increasingly make the physician aware of this kind of thing when he perceives in his patient the potential for abuse.

Mr. Waxman. Do you believe the abuse of Darvon is in any way related to the ability of patients to obtain refills of the prescription?

Dr. Furman. I cannot say that it is not. To the extent that it is, I would hesitate to say. Perhaps Dr. Scherbel could comment on that.

Mr. Waxman. I would prefer to do this, if I might. We are going to have to respond to a vote on the floor. If there is additional information you think would be helpful to us, I will keep the record open and we would be pleased to receive it.

Dr. Furman. Thank you. I am sure there is.

(The material to be furnished follows):

Mr. Waxman. Mr. _____ says that Lilly's informational complaints would be meaningful if the intent of every visit by sales representatives must be to emphasize the precautions necessary for the judicious prescribing the safe use of these products. He went on to add this message should be conveyed in qualifying information in 100 percent of the visits made. Has Lilly's informational campaign adhered to this standard?

Dr. Furman. Well, I think that is a highly idealized situation and I dare say Dr. Crout on reflecting might agree. The sales representative is allowed an opportunity to discuss matters with the physician at the pleasure of the physician. The physician is a busy man and if he feels that he is sufficiently aware of the proper prescribing and use of propoxyphene, he is not going to allow a detail man to occupy the 5 or 10 minutes which would otherwise be required for such communication and will insist on talking about something else and in an area where he is not so well informed. So I think it is really unrealistic to expect an interview to be limited solely to Darvon, its production and uses, when the physician says, "Look, Mr. Lilly, I am well aware of those things, I want to talk about something else."

Mr. Waxman. Do you agree that part of the problem of the physicians' ignorance of the dangers from the abuse has been the fact that in the past the information they received

through the merchandising techniques in the company has been deficient in giving that information to them?

Dr. Furman. I would not agree that it is deficiency in merchandising techniques but I think you have to realize that this drug has been available for more than 20 years, literally billions of doses have been administered, it is highly useful for physicians who have practices such as Dr. Scherbel. I think there has grown a tremendous experience on the efficacy of Darvon and the practice of the physician has been thoroughly engaged by this past satisfactory performance.

Mr. Waxman. We have heard testimony that perhaps it was 20 years ago the thought that Darvon was perfectly safe and non-narcotic, et cetera, was represented to the physicians and then subsequent to that information has come about where there is now the clear understanding that there are dangers involved. This was Dr. Goyan's testimony.

Dr. Furman. Anything that has been said about the propoxyphene products must, of course, conform to FDA approved labeling. The idea that it was non-narcotic arose understandably enough from the decision of the WHO-UN apparatus that it did not need to be classified in the UN convention Schedule II. The studies in subhuman primates and in human as well as in animals indicated that the dependence liability of propoxyphene was not only substantially less than that of morphine but less than that of codeine and as

the years went by after the propoxyphene products were introduced to the market by Lilly -- and there is certainly a possibility for many years of no evidence of any dependence liability or any dependence creation -- the notion gained precedent that this was a safe drug, that it had very little, if any, dependence liability and the fact that it was a narcotic was more or less a legal issue.

Now we have heard this morning several times that it is closely related to methadone. Chemically it is, but estrogens and androgens make the difference between men and women. If you take propoxyphene and take the levorotatory form rather than the dextrorotatory form, chemically identical, otherwise the dextrorotatory form has no dependence liability potential whatsoever and is not analgesic.

Mr. Waxman. We have to respond to a vote on the Floor. We will recess for such time as it will take us to get to the Floor and come right back.

Dr. Furman. Thank you.

(Whereupon, a short recess was taken.)

Mr. Waxman. Your interpretation of the UN action is that it has no regulatory impact on the United States, is that correct?

Dr. Furman. That is correct.

Mr. Waxman. What was the United States vote on that

issue in the UN?

Dr. Furman. Affirmative.

Mr. Waxman. For the scheduling?

Dr. Furman. Yes.

Mr. Waxman. Article 21 of the Treaty on Limitation of Manufacturer and Importation states that, " the total of the quantities of each drug manufacturer imported in any country or territory in any one year shall not exceed the sum of the following," and they go through a listing. Have you had an opportunity for your lawyers to read that Article 21 to see what impact it would have?

Dr. Furman. May I ask Mr. Davis to respond to that, my colleague?

Mr. Waxman. Yes.

Mr. Davis. Thank you, Mr. Chairman.

Yes, we have asked most international legal experts, including the State Department under Secretary Vance, and we have also spoken with the senior officials of the United Nations Commission on Narcotic Drugs and the International Narcotic Control Board with respect to the question you asked. The essential answer is that the intention of the Treaty is to put production curves on any illicit manufacture of a drug but not to restrict the production of a drug for legitimate medical use under prescription or any other dispensing by the physician. Since it is well known that in the United States

there is no illicit manufacture of consequence, the advice of that council is that it is quite possible for the government to comply administratively with the requirements of the Treaty by simply providing the United Nations with the annual reports of total production of propoxyphene since all of it is for legitimate medical use in the United States.

In fact, just very briefly, conversations with those senior officials of the United Nations has indicated that the single convention they stressed does not mandate or impose any particular method of control within a given country nor is it intended to curb drug production for legitimate uses. Its purpose is to assure that the production and distribution of scheduled drugs correspond generally to the amounts required by physicians and for other legitimate medicinal uses. So with respect to dextral propoxyphene the UN officials observed that it is a well known fact that it is not a drug of significant diversion or illicit manufacturer and that there is no intention in the UN action to curb production which is being used to fulfill legitimate medical needs. Therefore, it is quite possible for the United States to comply with the requirements of the Treaty without having to impose production curves on legitimate production.

Mr. Waxman. Mr. Leland.

Mr. Leland. Thank you, Mr. Chairman.

Dr. Furman, you were saying that 75 percent of your

detailed personnel were registered pharmacists, is that correct?

Dr. Furman. Yes, sir.

Mr. Leland. And 25 percent or the large portion of your other sales, your detailed personnel, were science oriented people, people who had backgrounds in science?

Dr. Furman. That is correct, Mr. Leland.

Mr. Leland. You stated also in light of that that the detailed personnel have not really had the opportunity to communicate with the doctors specifically to any great length about the adversities of Darvon, the question of dangers of Darvon.

Dr. Furman. If I said that, I didn't mean to say that.

Mr. Leland. If you will clear that up.

Dr. Furman. The sales representative, the detail man sees the physician at the pleasure of the physician. If he begins a discourse which the physician feels is redundant and is not telling him anything he does not know, he is going to say, all right, Mr. Lilly or Mr. Leland or whoever it happens to be, I am aware of those things, there are some things I would like to know, and he is the one that controls what is discussed, within reason.

What I am saying is that when Dr. Crout suggested or requested that the sole purpose of the visit be to detail the physician on the proper use and hazards of propoxyphene that

this is not always something that can be accomplished because a large number of physicians are abundantly aware of the precautions that must be exercised for the use of propoxyphene as a result of great coverage of the propoxyphene problem by various media, including the FDA publications and our own efforts. So I think it is an unrealistic goal although theoretically an ideal one. It is unrealistic to expect that a physician is going to sit still for a discourse for which he is already familiar. That is what I had in mind.

Mr. Leland. However small or great that discourse is, do your detail personnel ask the physicians to exercise their right to write on this prescription "do not refill"?

Dr. Furman. I can't speak to that precisely. So many prescription blanks have a place for the physician to indicate no refills or one or so many so that option has always been available to the physician.

Mr. Leland. But I mean in terms of the danger that we have discovered to be prominent surrounding Darvon -- you are saying that you really don't encourage the doctors to use that particular phrase.

Dr. Furman. I think it would be a bit presumptuous of us, Mr. Leland, because I think that is a decision the physician has to know, based on the patient, whether he has a psychiatric history, whether he has abused drugs in the past,

whether there is any history of suicidal attempts. On the other hand, the average patients that Dr. Scherbel sees who is accustomed to using Darvon and other analgesics, such a restriction would be undesirable so I think it is a matter of the physician's judgment.

Mr. Leland. The doctor you refer to is obviously very prominent and has limited more attention to this matter than probably the average physician. I realize that you are using him possibly as an example of the American doctor or a physician who uses this product, but what about the dangers to the people in your whole educational program and that kind of stuff that many times more often than not the doctors need the encouragement and advice and consent of people who know more about the drug's usage and the drugs themselves. Doctors are not that well versed in pharmacology and in a lot of instances pharmacists are much more able to do this.

As I understand it, the physicians in medical school learn something like -- one year they take a course or in some places a semester of pharmacology whereas the pharmacists, 75 percent of your detail personnel, have gone to school five years and three years spent in that and related subjects. Do you not feel that your sales task force or your detail personnel would be more adequate in delivering that kind of information?

What I am saying is in my opinion I don't think it is a

presumption on your part. I think it is an obligation that you have.

Dr. Furman. Well, to the extent that the physician and pharmacist should be retained to assure the proper prescription and use of any drug, propoxyphene or any other, I could not agree with you more, I think you are exactly right. We have always felt that the physician and the pharmacist should act as a team. When it comes, however, to a decision regarding the appropriateness for a drug for a given patient, I think that is a decision that is quite apart from knowledge of the pharmacology or the metabolism of the drug. Now granted the physician can prescribe and use the drug much more intelligently and appropriately if he is aware of the kind of information that our sales people and pharmacy trained people can provide him, but the decision as to whether to use the drug, how much to give, what dosage and to what extent it can be refilled is more a clinical judgment than a pharmacologic one.

Mr. Leland. Of course, but the problems we are realizing today, it seems to me that an encouragement on the part of the detail person should be exercised in order that we can somewhat limit the problems that we are having, particularly in light for lobbying in my estimation against changing the schedule. Am I presumptuous to say that you are --

Dr. Furman. No.

Mr. Leland. It just seems to me that should be the case and I am not discouraging discourse on that point.

Let me ask you one other thing which it probably will be considered terribly crass of me because we have been talking about the therapeutic value and the importance of the health of human beings but let me ask you what would be the economic impact of rescheduling Darvon from Schedule IV to Schedule II?

Dr. Furman. Well, I cannot answer that with any precision. I think it is a foregone conclusion that the number of prescriptions written would go down that it would be incumbents upon the patients to return to the physician for a visit for renewal and, as I said before and as Dr. Scherbel has pointed out in his testimony last year, this imposes a really cumbersome and unnecessary burden on that really vast majority of patients who use the drug properly and effectively.

Mr. Leland. Dr. Furman, it is our responsibility to look after the safety and welfare of the people of our country by way of legislation and the responsibilities imposed on us by our elections and our service in this Congress. It seems to me that when you deal with priorities that the saving of one life, the lessening of ill health proposed by abuse of drugs or otherwise is a whole lot more important to the American people than imposing an economic burden on the people. Would you not agree with that?

Dr. Furman. I agree with that. I think we both have the same end in mind but are embracing different approaches to the accomplishment of that end. I think the way to handle the problem is to bring the physician awareness and knowledge to a point where this problem is in essence solved not by imposing an arbitrary restriction on his use of the drug because we cannot legislate morality, we cannot eliminate suicide in this country by banning a drug at one time or another that happens to be a very popular item for suicide. Suicide is a psychiatric societal problem whether we are talking about the use of a Saturday night special or a car in a garage with a motor running and the door down or anatripalene or propoxyphene or codeine or what have you. I don't think the way to get the solution to this problem is evident by imposing restriction on the number of refills.

Mr. Leland. Do you think we ought to legalize cocaine?

Dr. Furman. Why are you asking that?

Mr. Leland. I ask you that because if cocaine was allowed to be accessible to the general public, then the abuse of cocaine would not necessarily be restricted.

Well, let me put it another way. I am trying to bring a parallel with what your example was. If we make Darvon more restrictive, it is not going to decrease the incidence of suicide which is the conclusion I draw from you.

Dr. Furman. I think it would decrease it a little. I

think it would have a negligible impact on the suicide rate. It would decrease the number of suicides from Darvon but it would not decrease the suicide number in the United States, they would move to another drug, they already are.  *Novid*

Mr. Leland. Is that what you are saying?

Dr. Furman. All the evidence indicates that. Anatripalene has displaced propoxyphene in the prescription for drugs and the number of medical examination cases of anatripalene is going up sharply while that for Darvon is going down.

Mr. Leland. Then maybe we should further restrict that drug.

Dr. Furman. At the moment --

Mr. Leland. Let me ask you one final question because I understand what you are saying.

I am truly concerned about this. I learned as a pharmacist that all drugs were potential poisons and that drugs were merely substitutes for lack of the kinds of substances in our bodies that were necessary in order to affect the health of the person and that when we can avoid using drugs we should as much as possible, whether that is by restriction in law or policy or by the total elimination of the production of those drugs altogether. I realize that in a free enterprise system we have to exercise some kind of concern about the competitiveness in terms of Darvon as

opposed to some other drug, aspirin or otherwise, in terms of trying to avail the public of means to healthy body but we have determined that in contemporary times that the increasing problem of drug abuse and drug usage, we are going to have to do something -- something that is significant and probably something that is much different than what we are used to, even violating sometimes the integrity of the free enterprise system.

If, in fact, you had determined that Darvon is tremendously dangerous to the public, would you be willing to advise your company to take Darvon off the market? Provocation on the part of the FDA?

Dr. Furman. If it suddenly should become aware that people were dying suddenly, heretofore for an unknown reason but now known to be known to be due to some previously known effect of Darvon or propoxyphene, the Lilly Company would say this is a dangerous drug and it should be controlled but that is not the situation with Darvon.

Mr. Leland. I won't go into that.

Dr. Furman. I am entirely in sympathy with your aims and I would hope that you and I and other members might after this session at some convenient time continue this dialogue because I think you are touching upon a terribly important aspect of a societal problem.

Mr. Leland. I am just reminded of my attempt to try to

ban the sale of amphetamines in Texas. Amphetamines have no real therapeutic use but hurt a lot of people. Your organization, the Pharmaceutical Manufacturers Association, all came down to Austin, Texas, and they whipped my behind quite frankly. You just banned together and overwhelmed me with your political influence and no one could say that amphetamines served any real therapeutic purpose. Some psychiatrists say we ought to reserve the right of psychiatrists to use amphetamines in some extreme instances but in terms of the prominence of the sale of amphetamines on the market was unjustifiable and that is not just my opinion, it was the opinion of the law enforcement officers, the opinion of pharmacists, the opinion, off the record, of one or two of the manufacturing company representatives.

Mr. Waxman. Would the gentleman yield?

Mr. Leland. I will.

Mr. Waxman. I think we have to be concluding the hearing soon but just to respond to the statement just made from a personal experience that the gentleman from Texas has had, I would not want him to engage in stereotyping all people in industry or all companies in the industry. I would be the first one to feel that stereotyping would be an unfair way to treat people.

Mr. Leland. I yield to the wisdom of my Chairman and the only reason I had an iota of stereotyping was because I was

amazed at the information specification that they were using the translation of Spanish and Yiddish.

Mr. Waxman. I won't even comment on that.

Mr. Leland. I am just trying to figure out whether or not the Jewish community in this country are inclined more to the abuse of Darvon than anybody else.

Mr. Waxman. We are both interested in that question.

We have here, unlike what Mr. Leland maintains for amphetamines and drugs does have a legitimate purpose, a therapeutic purpose. I have not heard that disputed but I hear from everyone concerned that this is a drug that has a danger to it in its abuse. How best we can limit the abuse of that drug is a question that we have to think through together. As I understand what you are saying, Dr. Furman, it is that you think the limiting of that abuse can best be brought about by an educational campaign by informing physicians that there are dangers with certain kinds of patients who are likely to abuse it and they have to be aware of that fact.

Dr. Furman. And the patients, too, Mr. Chairman.

Mr. Waxman. And the patients, too.

Another approach to the limiting the approach would be rescheduling the drug, assuming that rescheduling process meant that the burden of establishing the criteria for rescheduling has been established by the Veterans

Administration. I am wondering in my mind whether that rescheduling is a substitute to the exclusion of the education of the physician and the patient. We have that much to do with limiting the abuse of the drug because it seems to me that without the educational campaign even a rescheduling would not accomplish the results that all of us would like to see accomplished.

Dr. Furman. I cannot help but agree that the informational and educational aspects of what you are saying represent the way to get the job done. To me placing these arbitrary restrictions on the availability of the drug will not address the basic problem of drug abuse and suicide with drugs in the United States.

Mr. Waxman. On the other hand, a rescheduling which would make the drug less available would by its nature mean that less people would be abusing the drug.

Dr. Furman. Is there any advantage that if the Saturday night special is used the use of propoxyphene is sharply curtailed?

Mr. Waxman. I think our concern ought to be not for those who are intentionally out to commit suicide, whether they use propoxyphene or Darvon or the Saturday night special or some other method to accomplish the suicidal intent. It is still something beyond our control but I think we ought to be concerned about those who are not aware who will be using

the drug thinking that it is not going to do them the type of harm.

I am trying to figure out a summary of where we are. I think the summary is that we all share the basic goal of trying to protect the abuse of this drug and after this examination we will have to look to see if there is any legislative role for us to play, and whether there is or not this was a use of our oversight role here from the FDA, the Health Research Group which has taken such an active part in addressing the concerns about this one drug and those of you who represent the industry. I think it has been very helpful to us who have your testimony and for you to be with us today.

We will leave the record open to receive any additional information that we did not have included through this morning's hearing and that additional information will be made a part of the record.

Dr. Furman. Thank you, Mr. Chairman. I would just like to leave with the hope that something is working. The death rates and abuse are plummeting and I would hope that we would maintain a posture of careful scrutiny and watchful waiting to see what the ensuing months bring in the way of accomplishment of our goals which we share mutually.

Thank you very much.

Mr. Waxman. Thank you very much.

That concludes our meeting.