EXECUTIVE COMMITTEE MEETING

FRIDAY, DECEMBER 11, 1987

U.S. Senate

Committee on Finance

Washington, D.C.

The meeting was convened, pursuant to notice, at 10:06 a.m. in room SD-215, Direksen Senate Office Building, the Honorable Lloyd Bentsen (chairman) presiding.

Present: Senators Bentsen, Matsunaga, Baucus, Bradley, Mitchell, Pryor, Rockefeller, Daschle, Packwood, Danforth, and Durenberger.

Also present: Daniel Michels, Director, Office of Compliance, Center for Drug Evaluation and Research, FDA/DHHS; John M. Taylor, Associate Commissioner for Regulatory Affairs, FDA/DHHS.

Also present: Bill Wilkins, Staff Director and Chief Counsel; Mary McAuliffe, Chief of Staff, Minority; Jeff Lang, Trade Chief Counsel; Mike Mabile, Trade Counsel; Ed Mihalski, Deputy Chief of Staff, Minority; and Brad Figel, Professional Staff Member, Minority.

(The press release announcing the meeting follows:)

The Chairman. The meeting will come to order.

We have before us for markup H.R. 1207, which is the Prescription Drug Marketing Act.

Mr. Mabile, would you give us the status of that and take us through the piece of legislation?

Mr. Mabile. Yes, sir.

This is the Prescription Drug Marketing Act. It is the House version of a bill that was introduced in the Senate by Senator Matsunaga this year. H.R. 1207 has been passed by the House of Representatives. The Finance Committee earlier this year held a hearing--I believe it was June 15th--on the Senate version, S. 368.

The purpose of this bill is to trade and restrictions on a national distribution system for prescription drugs in order to curb the perceived problems caused by a diversion market for prescription drugs, a market that operates outside of the normal channels of distribution.

To go through the provisions, Sections 1 and 2 are simply a short title of the bill and a statement of finding. Section 3 bans the re-importation of prescription drugs that have been manufactured in the United States and exported from the United States, except re-importations by the manufacturer or re-importations allowed by the Secretary of Health and Human Services on a case by case basis for emergency medical purposes.

Section 4 of the bill generally prohibits the sale, purchase or trade, or offer to sell, purchase or trade, of drug samples, coupons redeemable for prescription drugs, or generally drugs which were purchased by hospitals or other health care entities, or which were donated or supplied at a discount price to a charitable organization. Certain common sense exceptions are provided for health care entities that are members of group purchasing organizations, transfers among commonly owned health care entities, and transfer for emergency medical purposes.

Section 5 of the bill establishes the conditions under which a manufacturer or a distributor can distribute drug samples to licensed medical practitioners. It permits samples to be distributed either through mail or common carrier, or by use of personal representatives: salesman, or they are often called detailed men.

If mail is chosen, the practitioner must sign a written request specifying his name and the drugs that he wishes to received, the dosages and amounts in advance. And the system of distribution must require the practitioner then to send a written receipt back indicating delivery.

Manufacturers and distributors would be required to maintain the request and the receipt forms for a period of three years.

If distribution is made by personal representatives,

there are requirements that the drug samples be stored in such a way as to maintain their potency and sterility. Also, the companies must conduct a complete inventory at least annually of all drug samples in the possession of their representatives, and maintain lists of the representatives who distribute samples. They are also required to keep these records for a period of three years.

Companies would be required to notify the Secretary of Health and Human Services of any significant losses or any known theft of the samples, and also of any convictions of their representatives for violating the restrictions of this bill against selling, trading or purchasing drug samples.

Section 6 puts certain restrictions on wholesale distributors of prescription drugs.

First, any distributor who is not an authorized distributor of a manufacturer--that is, does not have an ongoing relationship with the manufacturer--must give a statement to any purchaser of prior sales of the drug, thereby certifying where the drug was obtained from.

Also, no person would be allowed to engage in interstate distribution of prescription drugs from any State in which they are not licensed to do so. And the Secretary of Health and Human Services would be required to issue minimum guidelines for licensing wholesale distributors, and also the regulations must prescribe the requirements for storage and

handling of drugs and the maintenance of drug distribution records.

Section 7 sets out the penalties for violation of the Act. The particular interest in this section are the exceptions to manufacturers' and distributors' liability for civil penalty in the event that one of his representatives is found guilty of having violated the provisions of the law against selling or offering to sell prescription samples.

The exceptions are if the manufacturer or distributor itself provides the information leading to the arrest and conviction; if the company maintains an audit and security system which would have led to the reporting of information leading to the arrest and conviction ultimately, or, in rare events, that despite diligent implementation of such a system, this particular violation could not have been discovered by the company under any circumstances.

Those are the substantive provisions. We have left out the effective date.

The Chairman. Do we have a representative from the Administration, from the Department of Health and Human Resources?

Mr. Taylor. Yes.

The Chairman. Would you comment as to the Administration's position on this legislation?

Mr. Taylor. In summary, we oppose H.R. 1207 because insufficient evidence exists to indicate significant health problems have occurred, and, number two, the laws and programs already in place are working to remedy the problems of drug confiscating and diversion; three, implementation of the bill by the Food and Drug Administration and its counterpart, State and local agencies, would be very resource intense, as well as costly for the majority of the industry that is not affected by the activities of this bill.

And, number four, a remedy for an economic problem should not be legislated to a health-oriented base law, such as the Food and Drug Administration, the Food and Drug and Cosmetic Act.

The Chairman. Any questions from the members concerning this piece of legislation?

Senator Matsunaga, I know you have a serious interest in this. Do you care to reply to the Administration's comments?

Senator Matsunaga. Mr. Chairman, I greatly appreciate your scheduling this timely markup session on H.R. 1207, the Prescription Drug Marketing Act of 1987. H.R. 1207, which passed the House in May of this year, is similar to a bill which I introduced with 27 co-sponsors, a total of 28. That is S. 368, which is subject to hearings in the Trade Subcommittee, which I chaired in June.

The Prescription Drug Marketing Act would remedy one of the most pernicious problems facing the American consumer, prescription drug diversion.

Although the American system of testing and manufacturing drugs is one of the safest in the world, consumers purchasing prescription drugs can no longer do so in full confidence that such drugs will be safe and effective. Loopholes in the pharmaceutical distribution system permit prescription drugs to be diverted out of the normal distribution chain into a gray market where they may be mislabeled, improperly stored, and even counterfeited, subsequently resold to unsuspecting wholesalers or retail pharmacists that reach the consumer in that manner.

In addition to protecting consumers from drugs which may be totally ineffective or even harmful, the Prescription Drug Marketing Act would protect reputable business people from the unfair practices of the drug diverters. H.R. 1207 has widespread support among pharmacists, pharmaceutical manufacturers, and wholesale and retail drugists.

The prescription drug diversion problem first came to the attention of the Congress in the early 1980s when G.D. Searle & Company, a U.S. pharmaceutical manufacturer, discovered that one of its products had been counterfeited. The subsequent investigation revealed that a counterfeit had been imported into the United States from Panama marked "U.S. goods

returned," and uncovered many other practices for which American-made drugs were being diverted out of the normal distribution chain, shuttling around the world, in some cases relabeled and re-sold to unsuspecting consumers.

In some cases, such shipments of drugs had been sitting for weeks on a dock in a Third World nation or stored in a diverter's attic without regard to sanitation and necessary refrigeration. In many cases, the product's effective date had expired.

The Oversight Subcommittee of the House Energy and Commerce Committee conducted an intensive investigation of drug diversion between 1984 and 1987. Witnesses told the Subcommittee that sometimes bogus charitable organizations are established to purchase drugs at a charitable discount from manufacturers and then resell them.

Excess pharmaceutical products purchased by hospitals were also being resold to less scrupulous buyers who then resold them to unsuspecting drugists. In some cases, sales personnel of major manufacturers were diverting and reselling drug samples intended for use by physicians.

During our own Senate hearings on S. 368, law enforcement officials testified to similar shocking examples of drug diversion and provided graphic evidence in the form of a whole table full of diverted drugs which had been seized in the State of Georgia. H.R. 1207 is intended to close

loopholes in existing law which permits such practices. The bill would permit the re-importation of American-made drugs intended for sale overseas unless the manufacturers or the Food and Drug Administration needed to recall them in an emergency.

It would, in addition, prohibit hospitals and other health care facilities from reselling drugs which they purchase from the manufacturer.

And, finally, it would prohibit the resale of sample drugs provided by manufacturers to physicians.

It is important to note that the Prescription Drug Marketing Act does not prohibit physicians from obtaining sample drugs from manufacturers and giving them to their patients, nor does it prohibit a manufacturer's sales representative from delivering sample drugs personally. It does not prohibit hospitals and reputable charitable organizations from purchasing prescription drugs from a manufacturer, just as they do under existing law. It will require that physicians request samples in writing and provide a receipt when samples are delivered either by the manufacturer's representative or by mail, and it would require the manufacturer to keep such request and receipt on file for three years, and subject to Food and Drug Administration.

It would require manufacturers to keep track of sample

drugs in the possession of sales personnel.

Mr. Chairman, the language has been included in the Senate's draft report which would clarify Congress' intent that small businesses should not be disproportionately affected by the audit provisions and civil penalties contained in H.R. 1207.

The report language would also clarify our intent that prescription drugs may be returned to the manufacturer for credit when the manufacturer recalls an ineffective or dangerous drug, and such returns would not constitute a resale of the drug.

With these clarifications, I am pleased to say that the legislation has the vigorous support of the National Association of Chain Drugstores, the National Association of Retail Drugists, the National Wholesale Drugist Association, the American Asssociation of Hospital Pharmacists, the American Pharmaceutical Association, the Pharmaceutical Manufacturers Association, the National Pharmaceutical Association, and the American Hospital Association.

I strongly urge the Committee, Mr. Chairman, to favorably report H.R. 1207 so that we can call a halt to the most shocking examples of drug diversion.

The Chairman. Thank you, Senator.

We have 10 members here and, hopefully, we will be able to get 11.

I am also advised that some of the committees are using what might be called a rolling quorum, meaning that if at any point you get the 11, and if they leave, that they leave their proxies; that you can go ahead and vote out a measure, and that that, up to this point, has not been objected to on the floor.

Would there be objection by members of the committee if we did that?

Senator Packwood. Mr. Chairman?

The Chairman. Yes.

Senator Packwood. I think it is a very good idea.

You will recall last year in the last Congress when I was Chairman we just did it without a quorum. And nobody objected, I realize. And then I think one or two people began to object to requiring quorums all the time for the most routine reporting out uncontested nominations. And I think it is much better to just, clearly, when you have got a very major bill, you are going to have a quorum. So I think it is an excellent idea for most of our routine matters.

The Chairman. Thank you, Senator Packwood.

Are there any other comments? Any objections to that procedure? And we will try to limit that to those things that we deem to be noncontroversial.

(No response)

The Chairman. All right.

Are there other comments concerning thise piece of legislation?

Senator Pryor. Mr. Chairman.

The Chairman. Senator Pryor.

Senator Pryor. If I might, I want to say thanks to you, as Chairman, for holding this hearing. I mean it is just a very good piece of legislation as it is now drafted and I would like to thank Senator Matsunaga.

We had some original concerns with the report language, Mr. Chairman, in this legislation. One of those was addressed just a moment ago by Senator Matsunaga, and that is the disproportionate penalty that might fall on small companies.

I have a very, very small generic company in the State of Arkansas. And we think that the language relative to the disproportionate nature of big versus small drug companies is very good.

The second area that we were concerned with was the physical auditing procedures. I understand that there again has been, I don't want to say an exception, but at least a sensitivity expressed in the language relative to the very small companies versus the large companies.

Mercke, for example, I understand has 2,000 of what they call detail personnel. The company in my State has four.

And I understand that this language is acceptable now. And I wanted to say how much I do express my gratitude for the cooperation of the staff and other members of this committee in working this matter along.

The Chairman. Thank you.

Any further comments?

Senator Durenberger. Mr. Chairman.

The Chairman. Senator Durenberger.

Senator Durenberger. Just as a co-sponsor to the legislation, I compliment Senator Matsunaga and the other co-sponsors and recommend its adoption.

Senator Matsunaga. I would like to point out, Mr. Chairman, the following members are co-sponsors: Boren, Breaux, Burdick, Cochran, DeConcini, Durenberger, Exon, Glenn, Gore, Grassley, Hecht, Heflin, Heinz, Inouye, Johnston, McConnell, Melcher, Mitchell, Moynihan, Roth, Sanford, Sasser, Shelby, Simon, Stennis, Wilson, and Wood.

Senator Pryor. Could I be a co-sponsor, Mr. Chairman?

(Laughter)

Senator Pryor. I thought I was on there. Pardon me. I ask unanimous consent that I be an original co-sponsor.

The Chairman. All right. Without objection. All of which approved you are a persuasive proponent, Senator.

Are there further comments concerning the legislation or questions concerning it?

(No response)

The Chairman. Does staff have any further comments on it?

Mr. Mabile. No, Mr. Chairman.

The Chairman. Now on this, we need one more for a quorum. And rather than hold you--I don't believe we have a problem here--let's put this as a part of that to try to protect any one person on the committee; that if we get one of those situations in the judgment of the chair that it is not particularly controversial that we will use a rolling quorum of people, but they will have to leave their proxies unless any one member tells us ahead of time that he does not want us to do it. Then we will not do it, if he tells us ahead of time. Fair enough?

Senator Packwood. Fair enough.

The Chairman. All right.

Then will someone put the motion here?

Senator Packwood. I make a motion that we report the bill.

Senator Matsunaga. I second.

The Chairman. The motion has been made and seconded. All in favor of the motion to report the bill make it known by saying "aye."

(Chorus of "ayes")

The Chairman. Opposed by a similar sign.

(No response)

The Chairman. Now, gentlemen, leave me your proxies. And I will await that eleventh member.

(Whereupon, at 10:28 a.m., the meeting was recessed.)

AFTER RECESS

(10:44 a.m.)

The Chairman. How does the Senator from New Jersey vote?

Senator Bradley. Aye.

The Chairman. All right. That is enough. Passed.

Senator Matsunaga. Well thank you a lot. I appreciate your patience.

(Whereupon, at 10:45 a.m., the meeting was concluded.)

C E R T I F I C A T E

This is to certify that the foregoing proceedings of an Executive Committee Meeting of the United States Senate Finance Committee, held on December 11, 1987, were transcribed as herein a-pears and that this is the original transcript thereof.

William J. Moffitt

WILLIAM J. MOFFITT
Official Court Reporter

My Commission expires April 14, 1989.

AGENDA

UNITED STATES SENATE
COMMITTEE ON FINANCE

Friday, December 11, 1987

H.R. 1207, the Prescription Drug Marketing Act (see attached staff document).

December 11, 1987

DESCRIPTION OF H.R. 1207
PRESCRIPTION DRUG MARKETING ACT

(Prepared by the Staff of the Senate Committee on Finance)

H.R. 1207 amends the Federal Food, Drug, and Cosmetic Act to tighten restrictions on the national distribution system for prescription drugs. Among other things, it prohibits the reimportation of prescription drugs except by the manufacturer or for emergency use; bans the sale, trade or purchase of drug samples; prohibits with certain exceptions the resale of prescription drugs purchased by health care entities for their own use; mandates storage, handling and accounting requirements for drug samples; prohibits the wholesale distribution of drugs in interstate commerce from States that do not license wholesalers or whose licensing requirements do not meet minimum standards; and establishes a range of criminal and civil penalties for violations.

The purpose of the legislation is to control the so-called "diversion market" for prescription drugs that operates outside of normal channels of distribution and makes it difficult to prevent the marketing of mislabeled, adulterated, subpotent, expired, or counterfeit pharmaceuticals.

H.R. 1207 was reported by the House Committee on Energy and Commerce on April 30, 1987. It was passed by the House on May 4, 1987, under suspension of the rules, with no Member speaking in opposition during debate and without a roll call vote.

A similar Senate bill, S. 368, was introduced this year by Senator Matsunaga and referred to the Finance Committee. The International Trade Subcommittee of the Finance Committee held a hearing on S. 368 on June 15, 1987.

In a brief statement of policy issued April 30, 1987, the Administration stated opposition to H.R. 1207, and gave the following reasons: (1) There is insufficient evidence that significant health problems have resulted from drug diversion; (2) there are existing laws to remedy problems relating to drug counterfeiting and diversion; (3) certain types of legitimate and beneficial drug distribution will be unnecessarily curtailed; and (4) the bill cannot be administered in a cost effective manner and will be costly for the industry. We have been led to expect a further position paper from the Administration prior to the markup, and will distribute it to Members when it is available. In addition, representatives of the Department of Health and Human Services (HHS) will be present at the meeting to answer any questions that Members may have regarding the Administration's position.

Summary of Provisions

Ban on reimportation.--Section 3 bans the importation into the United States of any drug that was manufactured in the United States and previously exported, unless imported by the manufacturer. The Secretary of HHS is authorized to allow importation that would otherwise be barred if necessary for emergency medical care.

Sales restrictions.--Section 4 prohibits the sale, purchase, or trade, or the offer to sell, purchase or trade, of any drug sample, any discount or cost-free coupon redeemable for prescription drugs, or any drug which was purchased by a hospital or other health care entity or which was donated or supplied at a discount price to a charitable organization. Exceptions are provided for acquisitions by a health care entity that is a member of a group purchasing organizations and transfers among members of such organizations; transfers among entities that are under common control; transfers by charitable institutions to nonprofit affiliates; dispensing of drugs by health care entities pursuant to valid prescriptions; and transfers for emergency medical purposes.

Distribution of drug samples.--Section 5 establishes conditions with which a manufacturer or distributor of prescription drugs must comply in order to be qualified to distribute samples to medical practitioners. It permits samples to be distributed by either of two means -- (1) by mail or common carrier or (2) by company representatives. To receive samples, practitioners must sign a written request form identifying the practitioner and the drug sample requested. If distribution is made by mail or common carrier, the recipient of the sample must execute a written receipt upon delivery to be returned to the manufacturer or distributor. Manufacturers and distributors would be required to maintain the request and receipt forms for a period of three years and to make the forms available to State and Federal regulatory and enforcement officials.

Distribution by means of company representatives also may be made only upon request of the recipient practitioner. Manufacturers and distributors choosing to distribute through representatives would be required to store drug samples in such manner as to maintain their effectiveness and guard against contamination and adulteration. They must also conduct, at least annually, a complete inventory of all drug samples in the possession of their representatives, and to maintain lists of all representatives who distribute samples and of all sites where samples are stored. They are further required to keep records for at least three years of all samples distributed, destroyed, or returned, of all inventories, of all thefts and significant losses, and of all requests for samples. Manufacturers and distributors would also be responsible for notifying the

Secretary of HHS of any significant losses and known thefts of samples and of convictions of any representatives for selling, purchasing, or trading drug samples.

Wholesale distributors.--Section 6 of the bill requires all persons engaged in the wholesale distribution of prescription drugs who are not authorized distributors (an authorized distributor is one with an ongoing relationship with the manufacturer) to provide to wholesale distributors a statement identifying each prior sale of a drug, thus certifying where they obtained it. Manufacturers would be required to maintain lists of authorized distributors.

No person would be allowed to engage in wholesale distribution in any State in which he is not licensed. In addition, the Secretary of HHS would be required to issue regulations establishing minimum standards for licensing of wholesale distributors, and the regulations must prescribe requirements for storage and handling of drugs and the maintenance of drug distribution records.

Penalties.--Section 7 of the bill establishes the following schedule of penalties for violations:

(1) Reimportation of a drug; sale, purchase, or trade of a drug or drug sample; sale, purchase, trade or counterfeiting of a coupon; or wholesale distribution of drugs by an unlicensed distributor -- imprisonment for not more than 10 years or a fine of not more than $250,000, or both.

(2) Manufacturer or distributor, upon conviction of its representative for buying, selling, trading or offering to buy, sell or trade drug samples in violation of this legislation or any similar State law --

(a) A civil penalty of not more than $50,000 for the first two violations in any 10-year period.

(b) A civil penalty of not more than $1,000,000 for each violation after the second conviction in a 10-year period.

(3) Failure of a manufacturer or distributor to report to the Secretary the conviction of a representative -- a civil penalty of not more than $100,000.

The bill provides certain exceptions to a manufacturer's or distributor's liability for a civil penalty --

(1) If a manufacturer or distributor provides information leading to the arrest and conviction of its representative for buying, selling, or trading samples.

(2) If, in an action against a manufacturer or distributor relating to the conviction of its representative, the firm shows by clear and convincing evidence that it conducted an investigation that would have led to the reporting of information leading to the arrest and conviction of the representative or that despite diligent implementation of an independent audit and security system, the manufacturer or distributor could not reasonably have been expected to detect the violation.

Effective dates.--Ninety days after the date of enactment, except that the requirement that the Secretary issue guidelines to establish minimum standards for licensing and the requirements for distribution of samples established in section 5 do not take effect until 180 days after enactment. The requirement that wholesale distributors be licensed by a State in accordance with the Secretary's minimum standards does not take effect until two years after issuance of the Secretary's regulations setting the standards.