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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

FDA PART 15 HEARING

PRESCRIPTION DRUG MARKETING ACT

Friday, October 27, 2000

8:30 a.m.

Room 1061
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Mr. Seth Ray
Ms. Toni Stifano
Mr. John Taylor

SPEAKERS:

Ms. Winckler
Mr. Young
Mr. Ricciardi
Mr. O'Connor
Mr. Kelley
Mr. Goldhammer
Dr. Franz
Mr. Sasich
Ms. Capps
Mr. Devine
Mr. Shirley
Mr. Simms

C O N T E N T S

Welcome and Introduction of Panelists
Jane Axelrad, Associate Director for Policy, CDER 4

Diane Maloney, Associate Director for Policy, CBER 14

Speakers:

Susan Winckler, Group Director, Policy and Advocacy, American Pharmaceutical Association 17

Anthony L. Young, General Counsel, Pharmaceutical Distributors Association 36

Salvatore Ricciardi, President and CEO, Purity Wholesaler 66

Patrick C. O'Connor, Washington Representative, International Warehouse Logistics Association 93

Ty Kelley, Director of Government Relations, International Marketing Institute 101

Alan Goldhammer, Associate Vice President, Domestic Regulatory Affairs, Pharmaceutical Research and Manufacturers of America 112

Charles F. Franz, President, American Veterinary Distributors Association 128

Larry Sasich, Public Citizen Health Research Group 135

Shelly Capps, International Academy of Compounding Pharmacists 146

Paul Devine, Truxton Incorporated 166

Chris Lamb, Vice President, Plasma Services, American Red Cross 186

Dr. Celso Bianco, CEO, America's Blood Centers 196

Laura McDonald, Program Manager, Blood Centers of America 207

Steve Shirley, President, R&S Sales 217

Steve Simms 240

Derek Robertson, Representative of Hemophilia Centers 250

1 P R O C E E D I N G S

2 MS. AXELRAD: Good morning to everyone. On behalf
3 of the Food and Drug Administration, I want to welcome you
4 to this public hearing on the Prescription Drug Marketing
5 Act.

6 As most of you know, the purpose of this hearing
7 is to elicit comments from the public on the potential
8 impact of certain requirements in the final regulation
9 implementing the act relating to wholesale distribution of
10 prescription drugs and the distribution of blood
11 derivatives. The agency plans to use the information
12 obtained from this hearing and from comments on the meeting
13 notice to determine what steps, if any, should be taken to
14 modify the requirements in the final regulation or to seek
15 legislative changes. We will be accepting comments related
16 to this hearing and the issues that are discussed here
17 today, that is, written comments, until November 20th, 2000.

18 Before we start, I want to introduce myself and
19 members of the panel. I am Jane Axelrad, the Associate
20 Director for Policy in the Center for Drug Evaluation and
21 Research. I will start with Diane.

22 MS. MALONEY: Diane Maloney, Associate Director
23 for Policy in the Center for Biologics.

24 MS. MCCONAGHA: Bill McConagha, Associate Chief
25 Counsel, Office of Chief Counsel, Food and Drug

1 Administration.

2 MR. RAY: Seth Ray, Associate Chief Counsel for

3 Drugs in the Chief Counsel's Office, FDA.

4 MR. TAYLOR: I am John Taylor, Director, Office of

5 Enforcement, Office of Regulatory Affairs.

6 MS. OGRAM: Lana Ogram, Division Director,

7 Prescription Drug Compliance and Surveillance, Center for

8 Drugs.

9 MS. O'ROURKE: Meg O'Rourke, Senior Regulatory

10 Expert, PDMA, Division of Compliance and Surveillance.

11 MS. STIFANO: Toni Stifano, Associate Director for

12 Labeling Policy and Medical Communication, Office of

13 Compliance and Biologics Quality in CBER.

14 MS. JACOBS: Mary Beth Jacobs, Associate Director

15 for Regulatory Affairs in the Office of Blood Research and

16 Review in CBER.

17 MS. AXELRAD: Before we actually start to hear

18 from presenters, I am going to describe very briefly what

19 led to FDA's decision to hold this Part 15 hearing. I also

20 want to explain the ground rules for our regulations for

21 this type of a meeting. Diane Maloney will address you and

22 talk to you about the blood issues after I do my opening

23 remarks.

24 The Prescription Drug Marketing Act, or the PDMA

25 as I will be referring to it -- it doesn't have a nice ring

1 to it like FDAMA; with PDMA you just sort of have to spell
2 it out I guess -- was enacted on April 22, 1988 to ensure
3 that drug products purchased by consumers would be safe and
4 effective, and to avoid an unacceptable risk that
5 counterfeit, adulterated, misbranded, sub-potent, or expired
6 drugs would be sold to the American public.
7 Congress decided that legislation was necessary
8 because there were insufficient safeguards in the drug
9 distribution system to prevent the introduction and retail
10 sale of substandard, ineffective or counterfeit drugs, and
11 that a wholesale drug diversion submarket had developed that
12 prevented effective control over or even routine knowledge
13 of the true sources of drugs. Among other things, the PDMA
14 requires state licensing of wholesale distributors of
15 prescription drugs. It requires wholesale distributors to
16 provide a statement identifying each prior sale of a drug
17 before sale to another wholesale distributor or retail
18 pharmacy and, with certain exceptions, it prohibits the sale
19 or offer to sell prescription drugs that have been purchased
20 by a hospital or another healthcare entity that have been
21 donated or supplied at a reduced price to a charitable
22 organization.
23 The PDMA was modified on August 26, 1992 by the
24 Prescription Drug Amendments of 1992. These amendments
25 recast parts of sections of the Federal Food, Drug and

1 Cosmetic Act. Among other changes, the amendments required
2 an unauthorized distributor to provide a statement of origin
3 identifying all prior sales, purchases and trades of
4 prescription drugs, and the names and addresses of the
5 parties to the transaction to all recipients of the drugs.
6 On March 14, 1994 the agency issued a proposed
7 rule implementing PDMA as it was amended. The proposed rule
8 called for the submission of comments by May 30th, 1994, and
9 the comment period was subsequently extended to August 15th.
10 We received very few comments. I believe that only one
11 comment objected to the requirement of a statement
12 identifying all previous sales, and two comments objected to
13 the definition of the term "ongoing relationship." So, we
14 were not really aware, as a result of the comments on the
15 rule, of what the implications of this might be for the
16 community.
17 On December 3rd of 1999, the agency published
18 final regulations in 21 CFR Part 203, implementing the
19 provisions of the Prescription Drug Marketing Act as it was
20 amended. The agency responded to the comments, explaining
21 that the PDMA requires the provision of a statement of all
22 sales going back to the manufacturer. The agency also said
23 that to facilitate compliance with the act, it is necessary
24 to have a formalized way of establishing ongoing
25 relationships between manufacturers and authorized

1 distributors. As a result, the PDMA final rule required,
2 among other things, the following:
3 Each manufacturer must maintain at its corporate
4 offices a current written list of all authorized
5 distributors of record. An authorized distributor of record
6 is defined as one that maintains an ongoing relationship
7 with the manufacturer to distribute the manufacturer's
8 products. An ongoing relationship, we have said in the
9 regs, is an association that exists when a manufacturer and
10 a distributor enter into a written agreement under which the
11 distributor is authorized to distribute the manufacturer's
12 products for a period of time or for a number of shipments.
13 An unauthorized wholesale distributor, one who
14 does not have a written authorization agreement with the
15 manufacturer, must provide a drug statement or pedigree when
16 selling to another wholesaler or a retail pharmacy, showing
17 the prior sales history of the drug back to the first sale
18 by the manufacturer. Under this requirement in the rules,
19 an unauthorized wholesale distributor who purchases a
20 product from a manufacturer or an authorized distributor of
21 record, without an identifying statement showing the prior
22 sales of the drug, could not provide an identifying
23 statement to its purchasers and, therefore, could not
24 conduct future or further wholesale transactions of the drug
25 in compliance with the regulation.

1 After we published the final rule we received a
2 lot of letters and petitions, and had discussions with
3 industry, industry trade associations and even members of
4 Congress objecting to certain provisions of the regulation.
5 As I said, we really didn't have any inkling from the
6 comments that we received on the proposed rule what the
7 implications of this were going to be so really we were not
8 quite prepared for the controversy that began almost as soon
9 as we published the regulations.
10 In addition to these and other informal
11 communications, we received a petition for stay of action
12 requesting that the relevant provisions of the rule be
13 stayed until October 1 of 2001. That petition was supported
14 by numerous letters submitted to the docket by entities that
15 would be considered unauthorized distributors under the
16 final regulation.
17 On March 29th we met with representatives from the
18 wholesale industry to discuss their concerns. We also had
19 meetings and discussions with the blood centers that
20 distribute blood derivative products and provide healthcare
21 as a service to the hospitals and patients they serve. The
22 blood issue arose as a sort of second issue in the
23 regulations that caused problems. Again, we had had one or
24 two comments on the proposed rule on this issue but we had
25 no idea, you know, of the broader implications of this.

1 Based on the concerns expressed by everybody, and
2 the concern about the effective date of the rule that was
3 supposed to take effect December 4th of 2000, we published a
4 notice in the May 3rd Federal Register delaying the
5 effective date for the sections of the rule 203.3(u) and
6 203.50 -- those are the ones involving authorized
7 distributors -- until October 1st, 2001. We also delayed
8 the applicability of section 203(q) to the wholesale
9 distribution of blood derivatives by healthcare entities
10 until the same day, October 1st, 2001.
11 The Federal Register notice also reopened the
12 administrative record and gave interested persons until July
13 3rd, 2000 to submit written comments. As stated in the
14 notice, the purpose of delaying the effective date for these
15 provisions was to give the agency time to obtain more
16 information about the possible consequences about
17 implementing the provisions and to further evaluate the
18 issues involved. It was at this point that we began to plan
19 for a public meeting because it became apparent through our
20 discussions with various parties that different people had
21 different views, and when we were hearing from them
22 privately people were saying conflicting things to us and we
23 really had no way of deciding what was the actual situation
24 here. So, we decided that it would be a good idea to have
25 an on the record, you know, transcribed hearing where people

1 could hear what each other was saying, and we could ask
2 questions and try and determine what the real situation is
3 here.
4 On May 16th, the House Committee on Appropriations
5 stated in its report, accompanying the FDA's appropriation
6 bill for 2001, that it supported FDA's action to delay the
7 effective date for implementing certain requirements of the
8 PDMA until October 1st, 2001, and reopened the
9 administrative record to receive additional comments. In
10 addition, the committee stated that the agency should
11 thoroughly review the potential impact of the proposed
12 provisions on the secondary wholesale pharmaceutical
13 industry. The committee directed the agency to provide a
14 report to the committee by January 15th, 2001 summarizing
15 the comments and issues raised, and agency plans to address
16 the concerns. So, as soon as this hearing is over and the
17 comment period closes on November 20th, we are going to have
18 to get together and do our best to get a report to Congress
19 in, you know, really a fairly short time, telling them what
20 we think in terms of our plans involving the regulations and
21 whether we are going to recommend any legislative changes.
22 In light of the complexity of the issues involved
23 and the potentially serious economic and public health
24 consequences that implementation of the relevant provisions
25 of the rule may have, we believe that it was appropriate to

1 hold this hearing to get information from those affected by
2 it. We believe that this will help develop an adequate
3 factual basis which the agency can use to determine whether
4 it is in the public interest to take steps to modify or
5 change the requirements of the rule or to recommend
6 legislative changes.
7 To promote a more useful discussion at this
8 meeting, we developed a list of questions which we
9 identified as being of specific interest to the agency. The
10 list which was not, of course, intended to be all inclusive,
11 was published in the notice announcing the meeting. We hope
12 that those making presentations today will try and address
13 those questions, as well as other issues to the extent that
14 they are pertinent to the provisions of the PDMA regulations
15 that we are discussing here today.
16 Now, I just want to go over briefly the rules of
17 the proceedings. Under 21 CFR Part 15, the Commissioner of
18 Food and Drugs is to designate a presiding officer for the
19 hearing. I am that person. The presiding officer is to be
20 accompanies by a panel of FDA employees with relevant
21 experience. Persons who wish to participate in the hearing
22 are required to file a notice of participation with the
23 Dockets Management Branch. The agency allocated the time
24 available for the hearing among the persons who filed
25 notices of participation, and I think we are pretty much

1 able to accommodate everybody's requests here. If time
2 permits, interested persons attending the hearing who did
3 not submit a written notice of participation in advance may
4 make an oral presentation at the conclusion of the hearing.
5 Under section 15.30(f), hearings are informal.
6 The rules of evidence do not apply. However, no participant
7 may interrupt the presentation of another participant. Only
8 the presiding officer and panel members may question any
9 person during or at the conclusion of each presentation.
10 Public hearings under Part 15 are subject to FDA's
11 policy and procedures for electronic media coverage of FDA's
12 public administrative proceedings. Representatives of the
13 media may be permitted, subject to certain limitations, to
14 videotape, film or otherwise record our administrative
15 proceedings, including presentations. The hearing will be
16 transcribed as stipulated in section 15.30(b), and a
17 transcript of the hearing will be available on the Internet.
18 I think it is in our Dockets Management site in the docket.
19 You can place orders today for copies of the transcript by
20 filling out a form, which you can obtain at the table in the
21 back of the room. I have been asked to tell you that it
22 takes 15-20 working days before the transcripts are ready
23 for distribution so please be patient.
24 The Dockets Management staff have also asked me to
25 let you know that we will be accepting comments to the

1 docket electronically over the Internet. They encourage you
2 to make use of this capability of you can as they have begun
3 to pilot a new system which also will allow agency staff to
4 access your comments almost immediately from their desktops.
5 You can pick up information on how to submit your comments
6 electronically at the desk in the back of the room.
7 Now I am going to turn to Diane Maloney and ask
8 her to talk a little bit to you about CBER's perspective on
9 this Part 15 hearing.
10 MS. MALONEY: Thank you, Jane, and good morning.
11 I would also like to extend my welcome to you.
12 The Prescription Drug Marketing Act and FDA's
13 rules apply to products regulated by both centers that are
14 represented here today, the Center for Biologics and the
15 Center for Drugs. As you have already heard, one part of
16 today's meeting will focus on the wholesale distribution of
17 drugs. We will also discuss one area of particular concern
18 to the Center for Biologics, and that relates to blood
19 derivatives.
20 Our challenge is to execute the spirit of the
21 Prescription Drug Marketing Act, while assuring that the
22 public health continues to be served. The current rule
23 applies to blood derivatives such as albumin,
24 immunoglobulins and Factor VIII. In many cases, derivatives
25 are distributed and used like other pharmaceuticals. We

1 have heard from industry that the rule may impede their
2 ability to provide care and may disrupt the distribution of
3 these important products. If the final rule were in effect,
4 blood derivatives could not be distributed by blood centers
5 that are also considered healthcare entities under PDMA.
6 At this time, when there are substantial shortages
7 of a variety of blood derivatives, we are very interested in
8 knowing whether this rule would add to the shortage
9 situation and have serious consequences to the health of the
10 public. We received a number of examples of suggestions
11 from industry to adjust these issues. They include
12 suggestions to exempt from the rule only a subset of
13 shortage of blood derivatives or to redefine the term
14 "healthcare entity" so as to permit limited patient
15 treatment by the blood centers.
16 CBER believes answers to the following questions
17 are needed to provide a thoughtful solution to the problem
18 raised by industry with regard to blood derivatives. One,
19 what distribution systems are available for blood
20 derivatives? Do these distribution systems differ from
21 those for other types of prescription drugs and, if so, how?
22 Two, what effect would the final rule, as
23 published, have on the distribution system for blood-derived
24 products? What, if any, adverse public health consequences
25 would result?

1 Three, if blood derivatives were excluded from the
2 sales restrictions, that is, if such products were permitted
3 to be sold by healthcare entities, would there be an
4 increased risk of distribution or counterfeit, expired,
5 adulterated, misbranded or otherwise unsuitable blood
6 derivatives to consumers and patients?
7 Four, do manufacturers of blood derivatives
8 provide these products to healthcare entities, particularly
9 those that are also charitable organizations, at a lower
10 price when compared to other customers? Do manufacturers
11 sell these products to charitable or for-profit healthcare
12 entities with the understanding that the products will be
13 used for patients of the purchasing healthcare entity and
14 will not be resold to other healthcare entities,
15 distributors or retail pharmacies.
16 I apologize that I will not be able to stay for
17 the meeting today. I have to be downtown at a meeting at
18 10:30. So, I will actually have to run right after these
19 remarks, but we have a number of people from the Center for
20 Biologics that are here and we really want to hear from you
21 so we are eagerly awaiting your input on these important
22 issues, and I want to thank you for coming today and
23 providing your valuable input. Thank you.
24 MS. AXELRAD: Thank you, Diane. I believe there
25 are agendas outside on the table. As the agenda indicates,

1 we are intending to have four speakers; then we will have a
2 break; then four more speakers; and then we will break for
3 lunch; and then the rest of the speakers in the afternoon.
4 So with that, I would like to call the first
5 speaker, who is Susan Winckler, Executive Vice President of
6 the American Pharmaceutical Association.
7 MS. WINCKLER: Good morning. Actually, let me
8 first clarify, I am not the executive vice president for
9 APHA but I am the group director of policy and advocacy, and
10 if we could all share that with John Gants, he will
11 appreciate that I have not removed him from his position.
12 We do appreciate the opportunity to be here this
13 morning and present the views of the nation's pharmacists on
14 the implementation of certain requirements in the
15 Prescription Drug Marketing Act relating to the wholesale
16 distribution of drugs. For your information, APHA is the
17 national professional society of pharmacists, representing
18 more than 50,000 pharmacists, pharmaceutical scientists,
19 pharmacy students and pharmacy technicians.
20 As the healthcare professionals responsible for
21 dispensing prescription medications and monitory medication
22 therapy use, the drug distribution system is, obviously,
23 vital to our members. My comments will focus on two of the
24 questions posed by the agency for today's discussion.
25 Specifically, I will discuss the final rule's impact on the

1 drug distribution system and pharmacists' ability to obtain
2 prescription drugs, and the benefits and risks of allowing
3 unauthorized distributors to distribute drugs without
4 providing a drug pedigree.
5 As we expect you will hear from the wholesale
6 distributors today, two specific aspects of the final rule
7 will limit the ability of some wholesalers to engage in
8 product distribution. This limitation affects pharmacists
9 and patients at the end of the distribution chain. The
10 revised definition of authorized distributor will move some
11 now authorized distributors into the unauthorized category,
12 and the drug pedigree requirements imposed on these now
13 unauthorized distributors will impose substantial
14 administrative burdens. Such administrative burdens can
15 yield inability to resell medications, leading to a
16 reasonable conclusion, now unauthorized distributors unable
17 to sell drug products will be forced out of business. The
18 closing of these now unauthorized distributors will,
19 undoubtedly, create a disruption in the drug distribution
20 system.
21 APHA members working in the nation's independent
22 and chain pharmacies, hospitals, long-term care facilities
23 and countless other institutions rely on a network of
24 wholesale distributors to deliver drug products necessary to
25 their businesses and patients. Pharmacies do not carry

1 inventories with one hundred percent available products but,
2 rather, focus their inventories on the products most
3 typically used in their practice. The complexity of the
4 drug distribution system, having a number of wholesale
5 distributors available, ensures the pharmacists and
6 pharmacies have more than one source of a drug product and
7 have access to products that aren't routinely stocked. Such
8 alternative sources are vital to both the pharmacist's and
9 the patient's ability to obtain a prescription drug.
10 The closing of unauthorized distributors will
11 significantly reduce the complexity of the drug distribution
12 system, and could even eliminate the primary or alternative
13 source of prescription drugs for many pharmacies. If the
14 now unauthorized wholesale distributor serving that pharmacy
15 goes out of business, prescription drug availability in that
16 community could be severely affected.
17 Now, it is true that larger authorized wholesale
18 distributors may enter the market vacated by the now
19 unauthorized distributors. However, these distributors may
20 decide it is more economical to schedule infrequent
21 deliveries or institute minimum order requirements. If
22 pharmacies cannot comply with such conditions they have a
23 smaller pool of wholesale distributors from which to choose
24 to work with and may have difficulty accessing products.
25 Beyond the access issues, the impact of now

1 unauthorized distributors has an economic side. As we have
2 heard from the Small Business Administration, the so-called
3 drug pedigree requirement could result in the closing of
4 numerous small businesses, a loss of jobs and a disruption
5 of the drug distribution system. Additionally, we are
6 concerned that it could lead to a decrease in competition
7 among distributors and an increase in prescription drug
8 prices to the pharmacy level. As now unauthorized
9 distributors close and the number of remaining distributors
10 decreases, distributors would have less impetus to compete
11 for a pharmacy's business. It is reasonable to conclude
12 that a decrease in the number of distributors serving a
13 given market will lead to a reduction in price competition
14 and an increase in costs to the pharmacy, which then must be
15 passed on to the patient.
16 Now, the risks and benefits associated with
17 allowing now unauthorized distributors to distribute drugs
18 without a drug pedigree should be evaluated against the
19 disruption to the drug distribution process that will occur
20 if the rule is implemented as it now stands. It is
21 predictable that the implementation of the drug pedigree
22 requirement would have a negative impact on the drug
23 distribution process, as I have just described.
24 The risks associated with allowing unauthorized
25 distributors to distribute drugs without a drug pedigree,

1 however, are less clear. If all accountability for
2 maintaining prescription drug records would be removed, the
3 risk that counterfeit, expired or otherwise adulterated or
4 misbranded drugs could enter the drug distribution could
5 increase. However, regulations regarding the minimum
6 requirements for the storing and handling of prescription
7 drug records have been in place since 1990, and those
8 regulations do set a floor for the information that is
9 required to be available. They require wholesalers to
10 maintain records of all transactions regarding the receipt
11 and distribution or other disposition of prescription drugs.
12 The transaction records required by the regulation contain
13 information on the source of the drug, identity and quantity
14 of the drug, date of the transaction and the purchaser.
15 Wholesalers maintain these records for a two-year period and
16 must make the records available for inspection by federal,
17 state or local law enforcement agency officials.
18 These current regulations fulfill the need for
19 wholesalers to maintain an accurate paper trail of drug
20 product transactions, without the unreasonable time,
21 manpower and cost involved in producing an excessive drug
22 pedigree that traces every drug transaction back to the
23 original purchase from the manufacturer.
24 Important to this balancing test, however, is the
25 reality that this problem need not be addressed by changing

1 the drug pedigree requirements for unauthorized
2 distributors, rather, the agency could address this problem
3 by revising the definition of authorized and unauthorized
4 distributors.
5 Returning to the agency's previous guidance
6 allowing a variety of evidence to demonstrate an ongoing
7 relationship between manufacturers and distributors and,
8 thus, determining an authorized distributor, would solve
9 many of the problems of those distributors summarily
10 deposited in the unauthorized category by the rigid
11 requirements in the new definition.
12 The distribution of quality, contaminant-free drug
13 products is vital to our members, their pharmacies and their
14 patients. APHA urges the FDA to return to the existing
15 standard where an ongoing relationship, consisting of two
16 transactions within a 24-month period, characterized an
17 unauthorized distribution. The final rule places an unfair
18 burden on now unauthorized distributors of prescription
19 drugs, a burden that could limit patient access to
20 medications.
21 APHA appreciates FDA's efforts to more carefully
22 study the potential effects of this rule on the drug
23 distribution system, and we appreciate your consideration of
24 the views of the nation's pharmacists.
25 MS. AXELRAD: Thank you. I think that the panel

1 wants to ask some questions here, and I thought I would
2 start.
3 To what extent are pharmacies and retail
4 pharmaceutical businesses supplied by the secondary
5 wholesale distribution industry? What percentage or what
6 approximate amount comes from secondary wholesalers as
7 opposed to authorized distributors?
8 MS. WINCKLER: As our members have told us --
9 well, I think it would depend on who ends up in that
10 authorized and unauthorized category, but as our members
11 tell us, many of them have a primary wholesaler from whom
12 they receive most of their products, but they will have at
13 least one, if not two backup wholesaler distributors to
14 ensure that they have access to a full range of products and
15 have immediate delivery of those. So, it is our
16 understanding from our members that they frequently deal
17 with more than one distributor and do use the secondary
18 market extensively.
19 MS. AXELRAD: Do they buy direct from the
20 manufacturers ever?
21 MS. WINCKLER: Some pharmacy do buy directly from
22 the manufacturers.
23 DR. TAYLOR: What percentage of unauthorized
24 distributors' business is done with small retail pharmacies
25 and/or small healthcare providers or other types of

1 entities?

2 MS. WINCKLER: I could not give you an exact

3 figure on that but we have heard from all of our members,

4 which are in all of those environments, that they use

5 distributors who would fall into, or they assume would fall

6 into this unauthorized category.

7 MR. TAYLOR: Okay.

8 MS. AXELRAD: What happens in the event of a

9 recall? One of the purposes of a pedigree, I think, is to

10 ensure that in the event of a recall we can trace the source

11 of a drug from a manufacturer all the way down to the retail

12 level. If you don't have a pedigree and all you have are

13 the records that you suggest could substitute for the

14 pedigree, how would a recall work, or how does a recall

15 work?

16 MS. WINCKLER: Well, the recall system today when

17 it gets down to the pharmacy level -- obviously, there is a

18 communication from the manufacturer communicating down to

19 the pharmacy level broadly the recall and the lot numbers

20 that are affected. So, that goes down to the pharmacy level

21 and then pharmacies assess their stock and what they have to

22 go through to assess if that recall affects the products

23 that they have used.

24 MS. AXELRAD: So a manufacturer notifies all

25 pharmacies, or does it notify its authorized distributor who

1 then notifies the people who purchase from it?

2 MS. WINCKLER: Many recalls go directly -- the

3 information goes to the distributors and to the pharmacies.

4 In fact, that is something we strongly support, that the

5 information goes directly to the healthcare professional who

6 is going to have to communicate that recall information to

7 the involved consumers.

8 MR. TAYLOR: In describing the minimum

9 requirements that are in place now, essentially, you know,

10 the documentation of the transactions, just to make it

11 absolutely clear, it is your feeling that having those

12 transaction records in place provides a kind of protection

13 that is needed to ensure the integrity and the origin of the

14 products. I mean, you have stated that the pedigree is

15 somewhat onerous but that you agree that the opposite, the

16 absence of records, would be potentially damaging. It seems

17 that you think that right now the transaction records that

18 are in place do afford the type of protection that we are

19 looking for?

20 MS. WINCKLER: Yes.

21 MR. TAYLOR: Okay.

22 MS. O'ROURKE: When you say the transaction

23 records, you seem to be relating back to the wholesaler

24 record-keeping requirements, and that would apply only to

25 the wholesale distributors. Correct? Not to the

1 pharmacies?

2 MS. WINCKLER: That is correct.

3 MS. O'ROURKE: So, if I understand what you were

4 saying, you don't feel that the pedigree is necessary with

5 the wholesaler record-keeping requirements in place?

6 MS. WINCKLER: Correct.

7 MS. O'ROURKE: And one other question, you said

8 most of the pharmacies have a primary source and they have

9 one or two backup sources. Is that primary source one of

10 the authorized distributors, one of the large five, or do

11 they tend to be a lower level wholesaler?

12 MS. WINCKLER: I would be generalizing but I

13 believe that it is usually a larger wholesaler, but they do

14 make extensive use of the backup distributors that may land

15 in this unauthorized class.

16 MS. O'ROURKE: And that is because of unusual

17 products?

18 MS. WINCKLER: Precisely.

19 MS. O'ROURKE: Because they are faster than the

20 smaller ones?

21 MS. WINCKLER: Can be. I mean, the pharmacist

22 really relies on having a web, for lack of a better word --

23 a web of drug distributions to which they can go, so they

24 can go to a number of different distributors. If something

25 were to happen to one they can go to another.

1 MS. O'ROURKE: Thank you.

2 MR. RAY: I just have two questions. If the
3 requirements, as they kind of currently stand were
4 implemented, do you have any sense from your members that
5 there would be pharmacies in certain more remote areas that
6 would have great difficulty in obtaining certain products?

7 MS. WINCKLER: That is what our members have told
8 us.

9 MR. RAY: And, am I clear in understanding that
10 your proposal is that the pedigree requirement is kind of
11 fine as it is but you are suggesting that we revise the
12 definition, that we distinguish between authorized
13 distributors and unauthorized distributors?

14 MS. WINCKLER: Our primary recommendation is
15 revising the unauthorized versus authorized distributors.

16 MS. MCCONAGHA: I would like to follow up on that,
17 if I may, because I am a little confused in that respect.
18 It seemed, on the one hand, you said at first that there may
19 not really be a need for pedigree at all for anybody, in
20 response to Mr. Taylor's question, and, at the same time,
21 you seem to be suggesting that maybe one way to address this
22 is to kind of go with the status quo in terms of the
23 definition of an authorized distributor which, in effect,
24 would just mean that there would be fewer people that were
25 required to give a pedigree. I mean, is it your sense that

1 the status quo works right now?

2 MS. WINCKLER: It is. Our members believe in the

3 integrity of the drug distribution process that is taking

4 the product from the manufacturer to their facilities. Now,

5 I think what we are proposing is two options to approach

6 that. It seems the easiest option and the one that would

7 most clearly fit with what has happened to date is to revise

8 the definition of unauthorized distributor, or revise the

9 definition of authorized distributor that is changing those

10 who are now put into the unauthorized category.

11 MR. MCCONAGHA: Well, let's say that we were to

12 revise the definition of authorized distributor in a way

13 that required everybody to have a pedigree, what would your

14 response be to that?

15 MS. WINCKLER: I think that you could have

16 substantial administrative difficulties in pursuing that and

17 trying to get that through the wholesale distribution

18 process, but I would leave that answer to the wholesale

19 distributors who can address that more directly.

20 MS. AXELRAD: Suppose we were to require that the

21 authorized distributor pass it on? I mean, it seems to me

22 that one of the issues or comments we have had is that the

23 secondary wholesalers can't get the pedigree from the

24 authorized distributor. So, if we did what Bill was

25 suggesting and we required that the authorized distributor

1 pass the pedigree on and everybody passes it on, what would
2 your reaction be? Wouldn't it give pharmacists a little
3 more assurance that the drugs that they were getting were
4 truly legitimate drugs from the manufacturer?
5 MS. WINCKLER: Well, they do now rely on the
6 strength of the regulatory process and know that they can
7 access that information at the wholesaler level. I would
8 leave it to the wholesalers, our colleagues in the wholesale
9 industry, to respond to the administrative burden that may
10 be produced by having the drug pedigree go through the
11 system. I could not speak to that issue.
12 MS. AXELRAD: How can they access it? Did you say
13 they can access the information?
14 MS. WINCKLER: I believe that if they requested it
15 from the wholesaler they could get access to that
16 information.
17 MS. AXELRAD: So, they would at least just know
18 where that wholesaler got the drugs from --
19 MS. WINCKLER: Right.
20 MS. AXELRAD: -- the next purchase before them.
21 MS. WINCKLER: And pharmacies do choose their
22 wholesalers carefully because they do want to make sure that
23 they don't have to question if they pull a bottle off the
24 shelf; they do not have to question the content.
25 MR. TAYLOR: So, that is something that is part of

1 the selection process.

2 MS. WINCKLER: In choosing the wholesaler --

3 MR. TAYLOR: Right.

4 MS. WINCKLER: -- obviously, the integrity of the

5 wholesaler and their processes plays a major role in

6 deciding which wholesaler to use.

7 MR. MCCONAGHA: So, to be explicit about that

8 then, is it fair to say or is it not fair to say that your

9 members, pharmacists, would be more inclined or have a

10 greater degree of assurance if they were dealing with a firm

11 that had a pedigree as opposed to one that did not in terms

12 of the products they were getting?

13 MS. WINCKLER: Our members today are comfortable

14 with the system as it exists today and the information that

15 the manufacturers and wholesalers have available.

16 MR. MCCONAGHA: But I am curious, and maybe it is

17 impossible to speculate but, given the choice between a

18 situation in which you were getting drugs from a wholesale

19 distributor, whether they be an authorized distribution or

20 not but just a wholesale distributor that could provide a

21 pedigree versus one that could not, is there a real measure

22 of importance there for your clients or is that just not a

23 big concern?

24 MS. WINCKLER: Again, they are looking to make

25 sure that the system of regulation has this safety net so

1 that we know we are dealing with safe products. And, I
2 think we would have to look to any benefit that is gained
3 from the pedigree requirement over the existing requirements
4 and I couldn't speculate to fully answer your question.
5 MS. O'ROURKE: I have a question about the
6 pedigree again. The existing requirements you are referring
7 to are basically that an authorized distributor is defined
8 by two shipments within twenty-four months, and that is the
9 only requirement you are referring to?
10 MS. WINCKLER: That is the primary requirement we
11 are referring to, yes.
12 MS. O'ROURKE: And, you feel that that is
13 sufficient with the wholesaler record-keeping requirements?
14 That written authorization or a list of authorized
15 manufacturers would not be necessary and would be
16 problematic for the industry?
17 MS. WINCKLER: Yes, we believe that there is
18 sufficient evidence in having conducted those transactions
19 and being able to track those transactions, two in a twenty-
20 four month period, to provide evidence that, indeed, that
21 distributor is doing business with the manufacturer.
22 MR. RAY: Does your organization have any way of
23 providing information to us on the frequency of obtaining
24 diverted drugs, or adulterated or misbranded drugs from
25 secondary wholesalers?

1 MS. WINCKLER: We could ask our pharmacists if
2 they are aware of those situations and provide that
3 information to the agency. I could not predict the response
4 that we would receive but we could certainly ask the
5 question.
6 MS. AXELRAD: Yes, we are very interested in
7 trying to find out. I mean, obviously when they passed the
8 statute in '88 and amended it in '92 there were specific
9 concerns that the statute was addressing --
10 MS. WINCKLER: Right.
11 MS. AXELRAD: -- and we are trying to get a feel
12 for whether those problems still exist today, and to what
13 extent they exist today so that you can decide what the fix
14 would be and how rigorous it needs to be in order to solve
15 those problems. We are trying to get a feel for that. We
16 will be asking everybody probably similar questions about
17 what people's experience is with counterfeit, poor quality
18 or diverted drugs.
19 MS. WINCKLER: Sure. Well, we would be happy to
20 work with the agency on the appropriate questions to ask our
21 members.
22 MR. MCCONAGHA: I don't mean to belabor this issue
23 but I am just trying to get a sense, and I don't mean to be
24 difficult; I really am just trying to get a sense here of
25 the importance of a pedigree to the pharmacists because the

1 pharmacists are obviously a key player here in terms of the
2 fact that they basically are the outlet to the public.
3 So, I am going to ask my question another way. Is
4 it your sense that the pharmacists feel that the regs you
5 cited that the wholesale distributors are required to
6 maintain now are themselves a sufficient protection, such
7 that a pedigree is really not necessary for some measure of
8 protecting in terms of the product they are getting?
9 MS. WINCKLER: Although we have not asked that
10 specific question, yes.
11 MR. MCCONAGHA: Thank you.
12 MR. TAYLOR: Can I just ask one last question?
13 During your talk you noted some of the potential
14 difficulties that can result in supply if the rule is not
15 modified. You might not be able to answer this, but is it
16 your experience that manufacturers and authorized
17 distributors are unwilling to sell products to small retail
18 pharmacists and other small volume accounts, or is it just
19 sort of a subject of economic forces that makes it difficult
20 at times?
21 MS. WINCKLER: It is primarily on the economic
22 forces and, again, it is really more this assurance -- this
23 came up primarily when we were dealing with the Y2K issue.
24 MR. TAYLOR: Okay.
25 MS. WINCKLER: Could drugs get to pharmacists in

1 every portion of the country? And, what reassured
2 pharmacists and their patients was this distribution system
3 where you had many outlets to many different distributors
4 and so you knew if your wholesaler distributor was shut down
5 from the Y2K crisis, which thankfully did not happen, you
6 had a number of other sources to secure that product. What
7 we are concerned about is -- we are past the Y2K crisis --
8 we don't want to be put in another position where there is a
9 natural disaster, taking out one authorized distributor, and
10 then our members are left with perhaps not a single
11 distributor along the chain but at least fewer people
12 involved in that distribution system that leads to the
13 pharmacy.
14 MR. TAYLOR: Thank you.
15 MS. AXELRAD: I would like to ask one more
16 question. We are going to hear later this afternoon from
17 the International Academy of Compounding Pharmacists. Does
18 APHA have a position on how our regulations for PDMA might
19 affect its members who do the pharmacy compounding?
20 MS. WINCKLER: We have focused primarily on the
21 problems with the authorized versus unauthorized
22 distributor. We have some questions about the applicability
23 of PDMA to prescription drug products versus bulk drug
24 substances but have not developed a formal position.
25 MS. AXELRAD: Thank you. I have not been to very

1 many Part 15 hearings, but I have sort of understood from my
2 colleagues that there is not usually not quite so much
3 questioning when people sort of get up there and they give
4 their talks. But, as you can see, we are trying to really
5 answer some questions that we, ourselves, have about how
6 things operate out there. So, we are going to be doing
7 fairly active questioning. So, everybody can be prepared
8 now that they have seen what happens --
9 [Laughter]
10 With that, I would like to call Anthony Young,
11 representing the Pharmaceutical Distributors Association.
12 MR. YOUNG: Thank you, Ms. Axelrad. I am Tony
13 Young. I am the general counsel of the Pharmaceutical
14 Distributors Association, an association of licensed
15 prescription drug wholesalers that are not authorized
16 distributors of record for all the pharmaceuticals that they
17 distribute. Nonetheless, association members have ongoing
18 purchase relationships with manufacturers. The association
19 was formed to assure that PDMA is interpreted fairly and
20 equitably, and in a fashion that will not, frankly, destroy
21 their businesses.
22 The wholesale drug distribution system encompasses
23 a variety of businesses. There are the five big full-line
24 wholesalers that carry most, if not all, of the drugs
25 distributed in this country, and we think they distribute a

1 lot of them, ninety percent and perhaps more. These full-
2 line distributors distribute to everyone -- hospitals,
3 grocery stores, the savings outlets that we have now, the
4 Costco's, all the way down to pharmacies and buying groups.
5 Most of the pharmaceuticals they distribute are purchased
6 directly from manufacturers but not all of them.
7 Second, there are many regional and specialty
8 wholesalers that carry a large line of pharmaceuticals but
9 don't buy most of their inventory directly from
10 manufacturers. In that group, there is a species of
11 wholesaler known as secondary wholesalers and that is who
12 our members are.
13 Finally, there are small wholesalers who service
14 small areas. These are the ones who take the drugs to
15 clinics, physician offices, workplace dispensaries, small
16 military installations, veterinary offices and the like.
17 All wholesalers are required under PDMA to be licensed under
18 state law and they must maintain full and complete records
19 of the purchases and sales they make. So, their records are
20 always there, at the licensed wholesaler level. That is
21 required by PDMA.
22 You have asked six questions and we are going to
23 try and address those. The first one has to do with the
24 ability of unauthorized distributors to engage in drug
25 distribution under the final rule. The final rule requires

1 the not authorized distributors to provide their customers
2 with a history of sales back to the manufacturer. At the
3 beginning I said most drugs go through the major
4 wholesalers, and they do not give pedigrees. They do not
5 tell you who they bought the drug from. They don't do so
6 because the law specifically says they are not required to;
7 the law only imposes that requirement on those who are not
8 authorized, and the cost would be substantial. Therefore, a
9 wholesaler who is not authorized, who buys from an
10 authorized distributor, will not be able lawfully to sell
11 that drug because it won't be able to create a pedigree that
12 goes further back, through and past the authorized
13 distributor, and I think you all have recognized that in
14 your stay notice and in the notice announcing this meeting.
15 There is not practical way for the not authorized
16 distributor to obtain that information from the wholesaler.
17 Sure, you can call and ask for it and they may well give it
18 to you and, of course, a wholesaler who is not authorized
19 could offer to pay a premium for it. And, I would assume
20 that if full-line wholesalers got a lot of phone calls and a
21 lot of interest in getting that information they would find
22 a way to charge for it, and that would not be inappropriate
23 in our economic system. But it was never contemplated by
24 Congress that PDMA would be a vehicle for doing that kind of
25 thing.

1 We think question number one should be turned
2 around. After twelve years of operating under an FDA
3 guidance that required the sales history only to go back to
4 the authorized distributor why do we now feel that it must
5 go back to the manufacturer? We have never seen a good and
6 sufficient reason for that, and we think it is not required
7 by the law, and we don't believe there is any demonstrable
8 health and safety reason that we have ever been made aware
9 of.
10 You asked whether the final rule diminishes the
11 ability of unauthorized distributors to engage in drug
12 distribution and what would the consequences be. We think,
13 yes, it does and we think, despite increasing concentration
14 in the wholesaler distribution business and the creeping
15 entry by pharmaceutical companies themselves in the
16 distributor, secondary wholesalers continue to play an
17 important role.
18 The more than four thousand secondary wholesalers
19 nationwide serve these end users, and they do it on a
20 service basis. They are small businesses. They are small
21 capitalized; there are a small number of employees. These
22 small distributors are severely threatened by the rule.
23 Indeed, as we have looked out and reached out and tried to
24 talk to these small distributors, what we have found is they
25 have never heard about PDMA. They have never heard about

1 pedigrees, and they have not been giving pedigrees. So,
2 don't be surprised that you don't see them here, at this
3 meeting, these small distributors. They are keeping their
4 heads down because they fear they will find themselves the
5 subject of an enforcement action if they choose simply to
6 stay in business despite this rule. I think we all
7 recognize this rule would make it very difficult for them to
8 stay in business.
9 They are also keeping their heads down because if
10 they are direct with some manufacturers, they fear that
11 raising their head against this final rule may well lead to
12 them being cut off from those manufacturers that they do
13 deal with directly. I know they believe that these small
14 wholesalers, if they go out of business, there will be a
15 serious disruption of drug distributor to those they now
16 serve.
17 The flu vaccine situation I think is an example of
18 when you have a shortage, trying to get materials down
19 through the distribution system to those who need it, and
20 that system, because of shortages right now, is disrupt ed
21 and you all are trying to deal with it. You should look at
22 the wholesaler aspect of it because there are some aspects
23 there of the availability to some small wholesale
24 distributors but not an availability to others, and those
25 small distributors who serve the doctors with the initials M

1 through Y may not be able to get drug readily and get those
2 materials to their clients. That is a system dealing with
3 shortages, but it is the kind of thing that happens when you
4 have a disruption in distribution.
5 We are surprised that the pharmaceutical
6 manufacturers aren't, in fact, supporting our effort to go
7 back to the status quo, and the reason is that the drugs the
8 small wholesalers distribute and the drugs that the
9 secondary wholesalers buy and sell in the marketplace are
10 their drugs. These are the drugs that they are distributing
11 and the disruption will be with respect to their products.
12 You have asked about economic cost. Appended to
13 my testimony are the reports of two economists that we
14 retained to provide opinions on the impact of the final
15 rule. One of them is Prof. Hamilton at Johns Hopkins, and
16 Prof. Mullens at the University of Maryland School of
17 Pharmacy. We will make those part of the record. I am not
18 going to try to detail their testimony. The end result, Dr.
19 Mullens concludes, will be higher drug prices; higher
20 insurance premiums; and enhanced ability to charge premium
21 prices if the final rule remains in effect with respect to
22 its drug distribution aspects. Dr. Hamilton applies
23 standard Department of Justice Federal Trade Commission
24 economic analysis to all of this, and states that there is
25 going to be a serious potential increase in concentration,

1 the kind that the government generally would look at in any
2 given markets.
3 Let me remind you, we understand we are dealing
4 with six percent maybe, maybe ten percent at the maximum of
5 the drug distribution system down to the lower levels, but
6 it is an important ten percent. If you live out somewhere
7 in North Dakota and you go and drive into a pharmacy and
8 they don't have that drug and you have to drive two hours
9 again the next day, this is a true inconvenience, and those
10 kinds of breakdowns, we believe, could occur if those
11 service-minded small distributors are driven out.
12 You ask if the requirement for the pedigree were
13 deleted by Congress would there be a risk of adulterated
14 drugs entering the market. Certainly, there might well be
15 some slight increase with less regulation but under the
16 current system counterfeit drugs are found because they
17 appear to be counterfeit to someone in the distributor
18 system, whether it is a physician, whether it is a
19 pharmacist, someone notices something and says there is a
20 problem and that is how they are found. They are not found
21 necessarily by looking at pedigrees.
22 And, the drug pedigree is not the principal source
23 for tracing the history of a drug's distribution. The
24 principal resources are the purchase and sale records of the
25 distributors in the chain. That is where you all go, I

1 believe, from an enforcement aspect when you are looking at
2 something squinty-eyed, and that is where our members go
3 when they need to get the answer from someone who has given
4 them a pedigree that says they are an authorized
5 distributor. If you say, well, you are the authorized
6 distributor and I need to know where you bought it because
7 my customer has reported there is some kind of problem with
8 it, you will usually tell me who you bought it from and, if
9 not, we can find someone at the FDA who would get you to
10 tell them.
11 The amendment co-sponsored by thirty members of
12 Congress, we would remind you, is sponsored by Congressman
13 Dingell, who was PDMA's author, and we think that piece of
14 legislation, HR-4301, would preserve the integrity of the
15 drug distribution system.
16 You ask about the amendment by Congress to require
17 authorized distributors to provide a pedigree, and we do not
18 speak here for the authorized distributors. The "big five"
19 aren't here; they are out in California at their annual
20 meeting and they will be submitting comments to the docket.
21 But the kinds of systems that would be required by the major
22 wholesalers to be put in place are substantial and
23 burdensome. They move a lot more drug than the smaller
24 distributors. So, when you are talking about McKessen or
25 Cardinal or Bergen putting in the kinds of systems that now

1 exist at these smaller wholesalers who have been doing this
2 for the last ten, twelve years, you are talking about a
3 substantial burden on them and we don't believe that there
4 has been a health and safety justification put forward for
5 putting that burden on them, and we think it would be truly
6 impolitic for the agency to propose that that burden be
7 placed on there in the absence of any kind of health and
8 safety justification.
9 It is pretty clear everyone in this country is
10 concerned about the high cost of pharmaceuticals. We pay
11 handsomely for the fact that we have an outstanding drug
12 regulatory system and a patent system that rewards
13 innovation and brings that innovation to us as consumers and
14 patients. We have high drug prices. We also have the best
15 drug pharmaceuticals in the world. Any proposal to add
16 additional costs to this already extraordinarily costly
17 system, without a demonstrable health and safety reason, we
18 think has no chance of serious consideration.
19 You ask about specific changes in the pedigree
20 that could be made to make it easier for wholesalers.
21 Again, with think that question is misguided. These would
22 be for authorized wholesalers; how could it be made easier
23 for them? We think that is misguided. We think there are
24 already substantial records maintained by them and
25 maintained by the system that allow the agency to get the

1 information it needs when it needs to get it.

2 You ask about actual sales by a manufacturer to a
3 distributor being used as the only criterion to determine
4 whether an ongoing relationship exists. That is the status
5 quo. If FDA were to return to the guidance of the past
6 twelve years, that two transactions in a two-year period
7 constitute an ongoing relationship, there would be no
8 increase. You have asked whether there would be an
9 increase. Would there be an increase in the number of
10 distributors who are authorized? No, because that is the
11 status quo, and that is a market that has been settled for
12 twelve years. So, there would not be an increase of those
13 who are authorized under the meaning of that regulation.

14 The final rule interprets ongoing relationship to
15 require a written contract. We seriously question that
16 because it gives manufacturers the absolute authority to
17 designate which companies, if any, are to be known as
18 authorized distributors under PDMA. It would apply even if
19 a distributor purchases drugs from a manufacturer on a
20 weekly basis. There would be two classes of people doing
21 business with that manufacturer.

22 There are some comments in the administrative
23 record that describe what happened after that concept was
24 first proposed. And, what happened was that some people who
25 had letters that they were authorized, those letters were

1 withdrawn. Those letters were withdrawn by the
2 manufacturers and the contractual relationships were not
3 renewed but the buy-sell relationship continued vigorously
4 and happily for the next six or seven years.
5 We have asked the manufacturers to provide us with
6 those lists of who the authorized distributors are. We did
7 receive one invitation to travel to New Jersey to see that.
8 We have received -- and this is in our comments -- I believe
9 we have received forty no responses at least, and I believe
10 we have received one response that said we really don't need
11 to make anything like that available to you until after the
12 rule goes into effect, and that is true.
13 Since manufacturers have been reducing the number
14 of distributors to whom they sell directly over the last
15 decade or more, it is really logical to expect manufacturers
16 would further reduce the number of authorized distributors
17 under the final rule.
18 The other obvious result of the final rule is to
19 give them further pricing power. There is a value in being
20 an authorized distributor. Some major wholesalers will not
21 buy from the secondary market. Because the major
22 wholesalers, the "big five", do buy drugs coming from the
23 bottom up, they won't buy unless you are an authorized
24 distributor. So, that market power we already see being
25 used out there. And, we think manufacturers would use the

1 unilateral, unreviewable ability arbitrarily to designate
2 which are authorized and which are not to exact higher
3 prices. It is a natural behavior pattern in a free economy
4 that allows the regulation for you to do these kinds of
5 things. Those higher prices would be passed on to
6 consumers.
7 We don't understand why FDA, in the final rule,
8 chose to upset the status quo and give more power to the
9 pharmaceutical companies here. This is an economic part of
10 the regulation. This is not, we believe, something hooked
11 into drug safety or quality. This part of the regulation is
12 truly something that is going to have a substantial impact
13 on competition.
14 Now, I have enclosed in these materials the
15 declaration of Steve Simms, our Association's lobbyist. He
16 is the staff person for Congressman Dingell in a past life,
17 the author of PDMA, and he was one of the ones involved in
18 its drafting and he states in his declaration that it wasn't
19 the intent of Congress in '92 and '88 to upset the system
20 this way.
21 I want to briefly discuss our Association's needs
22 with respect to timing. We would really like to know by
23 December 15th of 2001 how this is going to go, but we also
24 know that you all may not be able to make a decision that
25 quickly. If not, we would like to know that the final rule

1 only applies to drugs first distributed in commerce, and
2 this was in our stay petition after October 1st, so that we
3 don't need, beginning early in 2001, to run out inventories
4 to avoid disruption in the market as of October 1st. That
5 issue, we believe, could be resolved by correspondence
6 between the Association and the administration, and I will
7 initiate that by letter request next week because if the
8 rule only applies to drugs first distributed in commerce in
9 October of 2001, we have a lot more time to stay in
10 business. July 1st, 2001 we think is a reasonable date for
11 a final decision on all of this, and if we don't have a
12 final decision we will seek a judicial stay and review of
13 the final rule. The reason for doing so would be to give
14 the court a full opportunity to address the issues that we
15 will raise.
16 I want you to understand the reason is these are
17 our members' businesses and they intend to protect their
18 businesses. They will try to stay in business as long as
19 possible. We think that this regulation going back to the
20 status quo would level the playing field again and
21 everything would be okay, but until we see that happen we
22 will try to protect our businesses.
23 Thank you very much for the opportunity to have
24 all your questions.
25 MS. AXELRAD: Thank you. Why don't I turn to some

1 of my panel members. Who wants to start?

2 MS. OGRAM: Can you tell us if it is common

3 practice -- you said that years ago letters of authorized

4 distributors were actually withdrawn. Today, is it common

5 practice when a letter is requested for a manufacturer to

6 refuse it and, if so, do they give a basis and what would

7 that be?

8 MR. YOUNG: Mr. Ricciardi will testify in a moment

9 as to how many times he has been refused in the last six

10 months, and the answer is no response is common, and another

11 response is we have enough authorized distributors.

12 Remember, these are companies that you may be doing business

13 with on a weekly basis so that they see, at their level, a

14 distinction -- the companies, and they are not providing

15 those letters, although in some instances they are.

16 MS. O'ROURKE: What is the distinction? Do you

17 understand a distinction at that level about what makes an

18 authorized distributor to the manufacturer as opposed to

19 people they do business with every day?

20 MR. YOUNG: I don't know the distinction at their

21 level. I don't think we understand that. We do know that

22 you can do business direct -- okay? -- with a manufacturer,

23 and some manufacturers choose not to sell and they,

24 obviously, have a right to choose who they do business with.

25 But you can certainly do business with a manufacturer and,

1 at the same time, they will not give you a letter stating
2 you are an authorized distributor. Why they don't do so is
3 not often stated.
4 MS. O'ROURKE: Is it ever stated? Are there any
5 criteria?
6 MR. YOUNG: No, not that we are aware of.
7 Occasionally someone will say we have enough authorized
8 distributors in your area or region, or we are not adding
9 any more authorized distributors at this time.
10 MS. AXELRAD: But if you are a secondary
11 wholesaler and you are buying the drugs -- let's say one of
12 these people that are serving the citizens of South Dakota,
13 and you are buying the drugs direct from the manufacturer,
14 you have a pedigree. I mean, you have the record that shows
15 you bought it from the manufacturer and you turned around
16 and sold it to pharmacies in South Dakota. Why is it so
17 important for you to become an authorized distributor or to
18 get a letter indicating you are an authorized distributor?
19 MR. YOUNG: It is not. In that instance you would
20 have the information. Often, however, even if you are
21 buying direct from the manufacturer the drug will come to
22 you from McKessen or from Cardinal or from Bergen, and you
23 don't know where McKessen or Cardinal and Bergen got it
24 from. They may have gotten it from the manufacturer, and
25 certainly that would be the large percentage, but they also

1 may themselves have bought it in the secondary market and
2 because they are authorized they don't need to give you a
3 pedigree.
4 MS. AXELRAD: But how does that work? Okay, you
5 contact the manufacturer and you say I want to buy, you
6 know, twenty lots of whatever drug and they say okay, and
7 you pay them. How does it come to you from the distributor?
8 MR. YOUNG: You pay them and it comes from someone
9 who is distributing for them. That is often the case.
10 MS. O'ROURKE: I was wondering first about going
11 back to the pedigree. You are saying that you are in
12 support of House Bill 4301 which basically would state that
13 the drugs have at some point in time moved through an
14 authorized distributor. Now, that would essentially negate
15 the purposes of a pedigree because it would just be a boiler
16 plate type of document. So, I am questioning whether there
17 would be any purpose to it. Now, are you saying or do you
18 feel that a pedigree is not necessary because of the records
19 of the wholesale distributors are required to keep, similar
20 to what Ms. Winckler said?
21 MR. YOUNG: The answer to that I think is yes. I
22 think the wholesale records required to be kept under the
23 regulations now that are enforced by the states and by the
24 administration are adequate because they show plenty of
25 information there for the agency to get to and to work

1 through. With respect to the statement -- this drug was
2 first shipped through an authorized distributor, that is an
3 effort at compromise that allows the agency to have an
4 enforcement tool with respect to people who might
5 prevaricate on that kind of a statement because that would
6 be a criminal act, and it would provide the agency with an
7 enforcement tool that might not otherwise exist, if you are
8 simply going in and looking at records as to what has gone
9 forward or how that drug was shipped in the past.
10 MS. O'ROURKE: But in order for that enforcement
11 tool to be applied, we would have to go back through the
12 entire -- from wholesaler to wholesaler to wholesaler to
13 find the authorized distributor before we could prove
14 whether there actually was a fraudulent statement.
15 MR. YOUNG: That is correct.
16 MS. O'ROURKE: That is a bit burdensome.
17 MR. YOUNG: It is always hard to make one of these
18 cases in any event.
19 MR. TAYLOR: What percentage of secondary
20 wholesale distributors' inventories are composed of
21 prescription drug products? Do you know?
22 MR. YOUNG: Well, many of them are only
23 prescription drug products. I think when you get down to
24 the level of the four thousand, the smaller ones, you are
25 dealing with companies that are distributing prescription

1 drugs, the kinds that physicians and clinics want, medical
2 necessities and other durable goods, if you will, medical
3 durable goods. They really are trying to be the full
4 service to that office. So, it may not be more than fifty
5 percent or even twenty-five percent of their inventory; from
6 a value basis it may be an extraordinary part of their
7 inventory and what they move because of the cost of drugs.
8 MS. AXELRAD: How often do drugs flow the other
9 way, from secondary wholesalers to the authorized
10 distributors, and under what circumstances do they do that,
11 and why?
12 MR. YOUNG: They do it because of an arbitrage
13 system that exists with respect to pharmaceuticals. It is
14 hard to say how much. You would have to ask the "big five"
15 but all of them have trading departments where they buy
16 drugs from the secondary market.
17 Let me give you an example of a reason that might
18 occur. A pharmaceutical company at the end of a quarter
19 wants to make sales numbers on a particular drug, but they
20 may not be able to make that number on the routine purchase
21 by the "big five" and the routine sales. So, they will
22 offer that product at a discount below average wholesale
23 cost and perhaps a discount for cash, and secondary
24 wholesalers might have the capital to buy that drug and have
25 that drug at a lower cost than the full-line wholesalers are

1 buying it routinely, and the full-line wholesalers might
2 participate in these sales as well, and those drugs are now
3 in the market at a lower price, lower base price than
4 average wholesale cost, and those drugs are going to be
5 perhaps sold to other secondary wholesalers, sold to full-
6 line wholesalers who two weeks later may have a need to have
7 those drugs at a lower price than they can buy from the
8 manufacturer, and those drugs will kind of move back up
9 usually into the system of the full-line wholesaler. They
10 will move down as well to the smaller distributors who have
11 a need for those drugs.
12 No drug enters the market at a low price, except
13 by a decision of the manufacturer to sell it at a low price,
14 and they do so at the end of quarters, and there are
15 wholesalers who buy before price rises. It is predictable
16 that drug prices are going up, and one can buy inventories
17 of drugs and then sell them after a price rise at a lower
18 price than the new price. That is how drugs get into that
19 secondary market.
20 MS. AXELRAD: But what I can't understand is after
21 it has gone through five or six different transactions like
22 that, with everybody taking their cut off of it, how it ends
23 up at a lower price to the consumer.
24 MR. YOUNG: That is a fair question, and I think
25 what the economists have told us is that it has a dampening

1 effect on prices. It has a dampening effect on prices so
2 that when you have this outlet for manufacturers -- and,
3 remember, it all has to begin up there -- when you have this
4 outlet for them to sell drugs at lower prices it creates a
5 dampening effect on prices. So, does it mean that the
6 individual drug will get to a clinic in Bethesda at a lower
7 price? The answer is no, probably not but generally the
8 price will be maintained at a lower level because of a
9 system that allows the drug companies to peel off inventory
10 when they have a need, a commercial need to do so.
11 The major wholesalers are running at about a 0.64
12 net on sales. That is a very, very small margin. So, any
13 time they can buy in the secondary market at a price lower
14 than what they buy from the manufacturer, they will do so
15 because they can make another dollar to put to their bottom
16 line.
17 MS. STIFANO: I have a question. You used the
18 example of the flu vaccine where we have a documented
19 shortage of product. How would some of the suggestions
20 change the situation for distributors?
21 MR. YOUNG: I don't think it would. I just used
22 it as an example of what can happen when there is disruption
23 in wholesale distribution, and there is some disruption in
24 wholesale distribution right now in flu vaccine because it
25 is moving through certain channels that certain

1 manufacturers and distributors have established and the
2 general marketplace -- the hundred percent umbrella, a lot
3 of those people in that umbrella don't have access to those
4 distributors to get that drug. So, right now the flu
5 vaccine that is available in the secondary market or just
6 generally moving around is very, very high priced and that
7 is something that just happens when there is disruption of
8 either supply or distribution.
9 MR. TAYLOR: Earlier in your talk you were talking
10 about how, I believe, purchase and sale records is a useful
11 means of conveying information regarding tracing a product
12 and is essentially a useful tool, obviously, in determining
13 the original origin. This is sort of a general request, any
14 information that you can submit and provide to us to help us
15 better understand that process and the safeguards that you
16 feel are in place that would obviate the need for some of
17 the procedures that we are contemplating will be helpful in
18 this review. I know that both you and the previous speaker
19 certainly gave us some insight in that process, but anything
20 that you can submit for evaluation that goes, sort of
21 beyond, what you said today would be helpful to us.
22 MR. YOUNG: All right.
23 MS. AXELRAD: I would like to explore a little bit
24 about why the pedigree would be so burdensome to your
25 members. I mean, you just made the flat statement that it

1 would be burdensome but could you elaborate a little bit
2 about why it would be so expensive or so difficult for a
3 secondary wholesaler to keep a pedigree on the drugs,
4 assuming you could get it? Let's just say that, you know,
5 we could mandate that the manufacturers tell the authorized
6 distributors to pass it on, what would be the problems to
7 your members in terms of being required to obtain it, if you
8 could get it, and pass it on?
9 MR. YOUNG: Our members have no problem with
10 pedigrees. Our members do pedigrees now where they are not
11 the authorized distributor of record. We are that part of
12 the system that is not the "big five" and the wholesalers
13 who direct and who are not the small uneducated. So, our
14 members do give pedigrees now. What would be the burden
15 here is if you are buying a pharmaceutical -- if you are
16 buying from a major "big five" wholesaler who do also offer
17 deals to the secondary market often, again, at the request
18 of their friends in the manufacturing sector. You would
19 have to ask them for that information and they would have to
20 provide it, and I think, you know, what we see is that if
21 they have to provide that additional information they will
22 figure out a way to charge for it. But we do pedigrees now,
23 and doing a pedigree system for wholesalers who are doing a
24 billion and a half dollars a year and below is not a burden,
25 is not a burden. They do it when they need to do it.

1 MR. MCCONAGHA: I just want to follow up on that
2 thought because in some respects, it seems to me, you just
3 described the status quo --
4 MR. YOUNG: That is.
5 MR. MCCONAGHA: -- and so I guess what I am trying
6 to get at is a sense of how the rule as it is written now,
7 the tightening up of the definition of authorized
8 distributor, would necessarily affect the folks that you
9 represent. It sounds like in some respects it really
10 wouldn't, that they are not authorized distributors now;
11 they wouldn't be authorized distributors under this rule and
12 they would still face the same kind of pedigree challenges
13 that they always have.
14 MR. YOUNG: They are authorized distributors if
15 they have two transactions with a manufacturer in two years.
16 So, they are often authorized. Where they are not
17 authorized they are able to provide a pedigree back to the
18 last authorized distributor that they purchased from, and
19 that system works well. If they need to go beyond the
20 authorized distributor and get the information as to who the
21 authorized distributor bought it from, that will be
22 difficult.
23 MS. MCCONAGHA: I realize this is highly
24 speculative, but could you give me some sense of how many or
25 what percentage of the folks that you represent now that are

1 authorized distributors by virtue of two transactions with
2 the manufacturer might be cut out under the new definition?
3 I mean, is it really that high a group? Are there a lot of
4 people that do have these kind of two dealings with a
5 manufacturer?
6 MR. YOUNG: Yes.
7 MR. MCCONAGHA: Okay.
8 MR. YOUNG: Yes, and more than two dealings and,
9 as you will hear from the next speaker, requesting the
10 manufacturer to make them authorized is ignored. So, under
11 the new system we have predictive evidence that says it is
12 not going to happen.
13 MR. MCCONAGHA: Do you have a sense of the
14 percentage? Of the ten percent of these folks that you have
15 described who are providing these services nationwide, what
16 percentage of that group would you regard as authorized
17 distributors today who would not be under the new rule?
18 MR. YOUNG: It is really a guesstimate, but I
19 would say that maybe forty percent of the transactions are
20 not in products for which they are authorized and,
21 therefore, they provide pedigree.
22 MR. MCCONAGHA: Thank you.
23 MR. RAY: Tony, recognizing that you don't
24 represent the authorized distributors, you did say that you
25 didn't think that there was a public health and safety

1 benefit to requiring them to have to pass on the pedigree
2 and that there were some other financial concerns. Can you
3 explain the latter part of that a little more? Why would it
4 be so difficult for them to provide a pedigree or pass it
5 along?
6 MR. YOUNG: The reason is they handle so much more
7 product and they would have to now inventory that product
8 and keep a pedigree, and deliver a pedigree record for the
9 various dosages that they have, the various forms of a
10 product, and the various lot numbers that they receive for a
11 product. Unlike a secondary wholesaler who is doing maybe
12 five hundred million dollars total sales per year, these
13 multi-billion dollar companies are handling large amounts
14 and they don't have those record-keeping systems that allow
15 them to print out a pedigree, and that will be a substantial
16 burden in an industry that is only making 0.6 percent on net
17 sales. As you know, they were therefore exempted under the
18 law. This was not made a requirement for them under the
19 law.
20 So, our understanding is that this would be a real
21 burden on distributors who are already operating at the
22 margins, and at least one has gone out of business in the
23 last four years.
24 MR. TAYLOR: And I was going to ask that question,
25 Tony. It sounds like, based on your answer and your earlier

1 statements, you fear that that imposed burden will drive
2 some people completely out, or may drive some people out of
3 the business.
4 MR. YOUNG: No, they know how to pass the costs
5 on. They will do that before they go out of business.
6 MR. TAYLOR: Well, you said one was out --
7 MR. YOUNG: No, one did go out of business because
8 competition at that level is very stiff and so there have
9 been some failures. But, no, I am sure they would figure
10 out a way to put it in the invoice.
11 MS. AXELRAD: What is the role of your members in
12 a recall? What role to you all play if a manufacturer
13 announces a recall of certain lots of drugs? Does it come
14 direct to you? How does it come to you, if at all, and what
15 do you do?
16 MR. YOUNG: It comes direct. Recall information
17 does come directly from the manufacturers to whoever they
18 send it to. So, when we receive recall information we look
19 at our own stocks and then ascertain whether that
20 information has been passed on broadly by the manufacturer.
21 I think, as the pharmacy representatives have stated,
22 recalls generally are broadly broadcast by the drug
23 industry. These are not short communications with the two
24 distributors they use; they are broadly done. Our members
25 pass it on to their customers, but their customers often

1 know about it. Recalls work from the top down but the drug
2 industry spreads that information out promptly.
3 MS. AXELRAD: And, your records are kept for two
4 years?
5 MR. YOUNG: Two years, and I believe three years
6 under the final rule.
7 MS. AXELRAD: So, if you get a recall notice from
8 a manufacturer, you look at those records and see --
9 MR. YOUNG: And see if you handled the product,
10 and then you pass the information on if you did.
11 MS. AXELRAD: Okay.
12 MS. O'ROURKE: In other words, you are not tracing
13 by lot number; you are tracing by product.
14 MR. YOUNG: No, no, lot number. It depends on
15 what the recall says. If the recall has the lot number
16 information, then we trace by lot number. Our records are
17 kept by lot number expiration date.
18 MS. O'ROURKE: So, wholesalers do check by lot
19 number.
20 MR. YOUNG: The records of the wholesalers are
21 kept by lot number, yes.
22 MR. MCCONAGHA: You talked a little about the fact
23 that one of the concerns you had was that there would be
24 this enormous administrative cost, and there was a concern
25 that you had not yet heard articulated a kind of defensible

1 public health reason for this. I am just curious if you
2 have some sense in terms of the volume or percentages or
3 just raw numbers of how much of the drug supply in this
4 nation, you know, that kind of reaches the ultimate consumer
5 comes from what we commonly call the gray market, which is
6 to say drugs that are either stolen, illegally shipped to
7 the United States, adulterated, counterfeit. How much of
8 the drug supply currently is drawn from these sources? Do
9 you have any idea?
10 MR. YOUNG: No, I really don't. When our members
11 hear of information, either from their own examination or
12 from their customers' examination of records that it looks
13 like there may be something that is adulterated, misbranded,
14 counterfeit, they get on it and they notify the FDA and
15 involve the agency in the process. It doesn't happen that
16 often, but it happens.
17 MS. STIFANO: I have one last question, does this
18 include materials -- I know for biologic products storage,
19 shipping and handling and so on is a significant issue
20 because of the nature of the products. Does this include
21 product that you may get from a source that obviously has
22 not arrived cold, or whatever? You know, how do you ensure
23 that what you have gotten from this point back to your point
24 has arrived at a suitable temperature?
25 MR. YOUNG: The answer is the wholesaler

1 regulatory system of regulations for licensed wholesalers
2 requires that drugs, biologics -- drugs generally be kept as
3 required, refrigerated. Now, that system is in place to do
4 that. So, if you are dealing with a licensed wholesaler you
5 have to rely on the fact that you are licensed to do so and,
6 you know, if this is a big issue we probably ought to start
7 putting strips on products that would indicate if they have
8 ever gone out of their required storage conditions because
9 there is no ability to know how it was handled in the past.
10 We rely on guarantees from the people we buy from under the
11 Food and Drug Act, traditional guarantees that the product
12 is not adulterated or misbranded.
13 MS. AXELRAD: Thank you. Our next presenter is
14 Mr. Ricciardi, president and CEO of Purity Wholesaler.
15 MR. RICCIARDI: Good morning. Thank you for
16 having me today. I appreciate the forum.
17 You have asked a lot of questions of Tony Young.
18 If you want to keep them written down on your pad and
19 haven't checked them off yet, I would love to entertain the
20 opportunity to answer those questions as well.
21 My name is Sal Ricciardi. I am co-owner and CEO
22 of Purity Wholesaler Grocers. PWG is a privately held
23 company. Twenty years ago the company started in the
24 secondary wholesale business, with its first sale of Downy
25 liquid detergent. We actually started in the secondary

1 wholesale business in the grocery end of the business. This
2 year PWG will generate in excess of 1.5 billion dollars in
3 sales. With our founder and my co-owner, we have continued
4 to reinvest profits to grow our company. By building equity
5 in our company, our employees prosper now and in the future.
6 Our Supreme Distributor Division will have about 200 million
7 dollars in pharmaceutical sales this year. It is a growing
8 part of our business, and that is why I am here to talk to
9 you today, and not at the Wholesale Druggist Association's
10 annual meeting. That meeting is also important to our
11 business, but the PDMA final rule is more important and WDA
12 is not testifying because of that meeting.
13 For me, not being at the NWDA meeting and being
14 here was an easy choice because if the rule is not changed
15 there will be no Supreme Division left in my company. We
16 have approximately seventy employees that work in some way
17 in our pharmaceutical operations. Since the December 3rd,
18 1999 final PDMA regulation they have been looking at me,
19 their CEO, for answers about their future. Purchases such
20 as homes, cars, furniture are on hold for them. Are they
21 secure enough to start a family? The final rule has had
22 that impact on our employees.
23 And, from a business perspective, long-term
24 capital investments into this division have come to a halt.
25 Tony Young, counsel for the Pharmaceutical Distributors

1 Association, PDA, has provided specific answers to your six
2 questions, and you will find answers to those six questions
3 in the written presentation we will file in November.
4 I want to tell you about the wholesale drug
5 distribution business. PWG is relatively new to
6 pharmaceutical wholesaling. Four years ago we acquired
7 pharmaceutical wholesaler supreme distributors. We view the
8 secondary market in very simple terms: it is another prime
9 example of our nation's free market economy. A secondary
10 wholesaler business exists in grocery, health and beauty
11 aids and in pharmaceuticals because manufacturers create an
12 arbitrage opportunity for companies like ours to trade in
13 their products in the open market.
14 That opportunity will continue to exist because we
15 have learned from airline and surface transportation
16 regulation and deregulation that government-fixed prices
17 don't work to hold prices down and that a free market
18 economy does. Why don't the manufacturers just have one
19 price for prescription drugs? The reason is there are
20 similar drugs for similar purposes from different companies
21 and prices and market conditions fluctuate. FDA knows this
22 because FDA monitors and regulates what manufacturers say
23 about each other's products. For manufacturers the name of
24 the game is market share, and manufacturers offer deals to
25 achieve and maintain market share. They do not do that

1 where they dominate the market because they do not need to.
2 This pricing behavior applies to everything from
3 computers to blue jeans to food and, yes, to
4 pharmaceuticals. Supreme merely takes advantage of these
5 deals and the trade they generate. For example, in the top
6 twenty name prescription drugs sold worldwide, two are for
7 ulcers, four are for depression and psychosis, three are for
8 cholesterol reduction, two are for hypertension, and three
9 are antibiotics. The total annual sales for these fourteen
10 drugs exceed thirty-one billion dollars a year. In some
11 cases, these top selling drugs represent as much as twenty-
12 five percent of a particular manufacturer's total business.
13 While each is the sole supplier of its own brand, each
14 manufacturer must reach as many hospitals, doctors and
15 patients as possible to build brand loyalty. To do so, they
16 may lower prices in particular areas, and in this causes
17 regional price differences.
18 That is why a secondary wholesaler, such as
19 Supreme, can buy a drug from one region and resell it into
20 another region, generate a profit and help its customers in
21 that region remain competitive.
22 Another reason for branded item price fluctuations
23 is that after an item goes off patent and becomes generic
24 brand manufacturers must use pricing simply to maintain some
25 of the market share the item enjoyed while their drug was on

1 patent. This creates opportunities to buy and sell the
2 product in the secondary market.
3 Also, when brand and other manufacturers make
4 price increases, full-line as well as secondary wholesalers
5 will buy in heavily to take advantage of price increase
6 prices. This creates another opportunity for secondary
7 wholesalers to supply their customers with product post
8 price increase at pricing better than manufacturer's current
9 price, and some manufacturers traditionally change prices at
10 a certain time of the year. Some wholesalers buy on
11 speculation prior to such changes and they are rarely wrong
12 about prices going up.
13 Due to the various price differentials that
14 manufacturers create, secondary wholesalers are able to
15 bring products to market below everyday wholesaler
16 acquisition cost. This allows the retailer and wholesaler
17 to make a greater profit and to remain competitive. Even if
18 the exact savings are not passed on to the consumer on a
19 specific item, that profit is passed along to the consumer
20 indirectly. If retailers and wholesalers lost the extra
21 revenue derived from acquisitions by secondary wholesalers,
22 most would have to raise prices just to survive.
23 Prescription drug pricing is high on the public's
24 radar screen. I believe FDA's final rule will cause higher
25 prices. We believe ninety percent of all pharmaceuticals

1 are distributed by five major full-line wholesalers. The
2 secondary wholesaler market for Supreme and distributors
3 like Supreme provide important competition in a shrinking
4 drug distribution and retail segment.
5 Please understand profit percentages for the
6 wholesalers average approximately 0.62 points of 1.0
7 percent. At these levels, the wholesaler and retail drug
8 trade must take advantage of any savings or profits that are
9 available. The secondary market fuels the survival of its
10 customers by increasing otherwise marginal profits, allowing
11 these companies to remain competitive, and to offer lower
12 pricing and/or additional services to their customers.
13 Let me turn to small wholesalers. The top five
14 drug wholesalers distribute to large retail outlets like
15 chains. A small amount of market share is then divided
16 among small regional and local wholesalers. These small
17 regional and local wholesalers and niche distributors
18 deliver drugs to doctors' offices and to clinics. In its
19 present form, the final PDMA rule will make these businesses
20 illegal. Who is going to replace these distributors? There
21 is a reason that the "big five" don't distribute to this
22 level. They cannot do it in a cost effective way and if
23 they do need to go into this business, you can be sure they
24 will charge more for doing so than is charged presently.
25 The secondary market is vital to both the

1 wholesaler and retailer. It provides an alternate source of
2 supply to buy product at savings not otherwise available to
3 that wholesaler or retailer. It also provides a vehicle for
4 wholesale distributors to sell overstocks.
5 After our acquisition of Supreme Distributors, we
6 entered a wholesaler business that was regulated. We
7 understand and respect this because of the nature of
8 pharmaceutical versus grocery products. We immediately
9 assured our operation was in compliance with PDMA, and under
10 PDMA, as it was interpreted prior to December of last year,
11 our business has prospered. We have always wanted to do the
12 right thing in our business. Government regulation is
13 serious and we take it very seriously.
14 However, in its present form the final PDMA rule
15 has stacked the deck against our company. If this rule is
16 allowed to become final in its present form, our Supreme
17 Division will be gone forever. I also believe there are
18 hundreds of secondary wholesalers like Supreme and several
19 thousand small distributors further down in the
20 pharmaceutical distribution chain who cannot continue
21 lawfully in their business under the final PDMA rule.
22 There are over thirty thousand state
23 pharmaceutical licenses. While some companies have multiple
24 licenses, this is a lot of wholesalers. I ask FDA to look
25 at the state of pharmaceutical distribution in the United

1 States today. Over the last ten years we have witnessed a
2 reduction of pharmaceutical wholesalers in this country, and
3 I am sorry to say that most of the concentration has
4 occurred due to wholesalers going out of business and not
5 due to merger activity. And, this has occurred in an
6 environment where the FTC has blocked two mergers to
7 preserve competition.
8 The final rule is plainly anti-competitive because
9 it will put hundreds of distributors out of business and
10 make them lawbreakers. I am sure the FTC will interested in
11 this effect, and since pharmaceutical distribution is in
12 FTC's bailiwick, it would be inappropriate and capricious
13 for FDA not to seek out FTC's view of the impact of the
14 final rule on this industry.
15 I am sure you understand that I will fight as hard
16 as I can for the survival of our pharmaceutical business at
17 Supreme. My company and our trade association, PDA, will
18 continue aggressively to defend our business. In this
19 regard, we have, number one, support ed HR-4301 which we
20 believe addresses the FDA's final PDMA rule fairly and
21 allows secondary wholesalers to be in business.
22 Number two, we are prepared to take this matter to
23 court if necessary. However, number three, we feel our
24 efforts to make our case understood by FDA will bear fruit
25 and that we will convince FDA to change its course.

1 There are a few key dates that we are concerned
2 about. The stay date of October 2001 -- I understand this
3 date to mean that any inventory on that date that does not
4 meet the final rule will be rendered illegal and valueless.
5 As of today, ninety-three percent of our multi-million
6 dollar inventory would be rendered valueless because we have
7 not received the necessary letters from manufacturers
8 stating we are authorized distributors.
9 Let me read a few of those letters to you. I
10 won't name the manufacturer. "Dear Ms. Misurek" -- our head
11 buyer at Supreme -- "we are in receipt of your request for
12 consideration for Supreme Distributors Company to become a
13 distributor of this manufacturer. Unfortunately, this
14 manufacturer is not accepting new accounts at this time. We
15 appreciate your interest."
16 Another manufacturer: "This letter is to notify
17 you that this manufacturer will no longer sell its products
18 direct to Supreme Distribution as of January 1st, 2001.
19 This manufacturer thanks you for your past patronage."
20 "Our records indicate that you have purchased one
21 or more of the above-mentioned products directly from this
22 manufacturer. In order to improve our efficiency and cost
23 effective in the distribution of our products, this
24 manufacturer has decided to sell its products through the
25 wholesaler distribution network, not yours."

1 If a decision on this final rule is not made by
2 January 15th, 2001 -- I believe Tony Young said December
3 15th, 2001 and I think he meant to say January 15 -- Supreme
4 Distribution and many secondary wholesalers will have to
5 begin to reduce inventory levels to avoid total losses in
6 October. Therefore, if there is no decision by January, my
7 company and the PDA will have to consider legal action at
8 that time so that we may remain in business and protect our
9 second most vital asset next to our people, our inventory.
10 A compromise that would relieve this pressure
11 would be for FDA to rule that only drugs first entering
12 commerce after the October 1st, 2001 date are required to be
13 in compliance. If that compromise were effectuated, our
14 next key date would be July 1st, 2001. If there is no
15 decision by this date, we believe we need to ask counsel to
16 file lawsuits, seek judiciary stay and review. Please
17 understand this is our business and we intend to protect it.
18 Four years ago, when I purchased our Supreme
19 Division, I made it a priority to understand PDMA. I found
20 that PDMA was enhanced to protect the health and safety of
21 every U.S. citizen. It was not intended to put companies
22 like mine out of business. It also was not intended to give
23 manufacturers the power FDA would now give them.
24 It should not surprise FDA that this public forum
25 is actually keeping people away. There would be

1 substantially more witnesses here today if there were no
2 fear of retaliation from manufacturers. These manufacturers
3 already have market power and leverage over distributors
4 like Supreme and they can't wait to have the increased power
5 that the final rule will give them.
6 Recently we, at Supreme Distributors, have been
7 reaching out to manufacturers and asking for authorized
8 distributor status so we could adhere to the PDMA final
9 rule. This has been a futile efforts, as witnessed in some
10 of the letters that I have just read to you. The
11 manufacturers are not giving us anything. We contacted
12 fifty-nine manufacturers from whom we are currently buying
13 direct. They take our money and ship us drugs. Fifty-one
14 did not respond at all. One denied our request, and seven
15 gave us the required letter.
16 In addition, we contacted twenty-nine other
17 manufacturers from whom we are not currently buying directly
18 and we received seven denials, twenty-two non-responses and
19 no required letters as asked by the PDMA's final rule.
20 In addition, many large wholesalers have
21 requirements whereby they will only purchase from an
22 authorized distributor. Should the final rule be
23 implemented as is, our ability to sell to these entities
24 will be all but eliminated because we now rely on the fact
25 that we buy directly from manufacturers for our authorized

1 distributor status.

2 Allow me to ask this rhetorical question, what
3 purpose does the final regulation serve? Is it health and
4 safety? If so, I will tell you that PDMA. as it is
5 presently implemented, promotes health and safety. I can
6 speak from specific occurrences in my organization. Let me
7 give you a couple of those occurrences:

8 This year, a customer notified us that the FDA had
9 contacted them concerning possible problems with an item we
10 had sold them. We immediately contacted the FDA to discuss
11 this and were able to provide all sales and all purchase
12 history of this item. Our FDA contact was very appreciative
13 of our quick response. We have sophisticated systems to
14 track lot numbers and paper trails back to the authorized
15 distributor for every single item we carry.

16 Another occurrence, we received a call from a
17 customer indicating a concern with an item we sold them. We
18 immediately contacted the FDA and told them of our plans to
19 conduct a recall from our customers. Additionally, we were
20 immediately able to respond to the FDA's request for sales
21 and purchase history on this item.

22 Please note, in each of these cases the product
23 problem had to do with misprinted labeling and not validity
24 of the product, and in each instance the FDA did not advise
25 us or the manufacturer, to our knowledge, to recall product

1 on the basis of being adulterated or misbranded. There was
2 never a safety hazard to the public so far as we are aware.
3 The common denominator here is that the current
4 PDMA system in place gives the FDA the ability to obtain
5 drug pedigree information on very short notice. It is our
6 opinion that the proposed changes in the final rule,
7 specifically authorized distributor status being given by
8 manufacturer and paper trail back to manufacturer if you are
9 not an authorized distributor will do little to enhance this
10 capability.
11 We, at Supreme, also have been working closely
12 with FDA's contractor, Eastern Research Group, ERG, to
13 explain our role in the marketplace. As you know, ERG is
14 conducting a study of the impact of the final rule. Through
15 our conversations with them, it is clear that there is a
16 lack of understanding among those outside of our industry as
17 to how our industry operates and the role we play in it.
18 Hopefully, my testimony today will help shed further light
19 on what we do.
20 In conclusion, I would ask you to consider the
21 following: Please consider my business, my employees'
22 livelihoods, and the livelihoods of thousands of other
23 Americans that will be put out of their businesses or jobs
24 by this final rule.
25 Please look at the existing system and PDMA

1 guidelines. They work. Please do not give the keys of the
2 drug distribution system to the manufacturers and further
3 enlarge their market power.
4 Please consider the critical dates I have noted in
5 my testimony. Please understand that this is a survival
6 issue to mine and many other businesses across the united
7 States.
8 I thank you for your attention. I would be happy
9 to answer any questions you might have.
10 MS. AXELRAD: Thank you very much.
11 MR. MCCONAGHA: I have just one question just to
12 kind of clarify this for the record. You said a number of
13 times in your testimony that the rule, as proposed, would
14 put you out of business and I just want to make sure I
15 understand exactly what I think was implicit in there, which
16 is are you saying, in effect, that you would lose your
17 status as an authorized distributor and you wouldn't be able
18 to get pedigrees and that is essentially what would drive
19 you out of business?
20 MR. RICCIARDI: That is correct.
21 MR. MCCONAGHA: What if we were to do away,
22 hypothetically, with the authorized distributor definition
23 and just required pedigrees of everybody?
24 MR. RICCIARDI: It still would be a problem for
25 the primary wholesalers who we buy from, that they would be

1 able to supply that information to us.

2 MR. MCCONAGHA: I understand their concern and the

3 administrative cost, etc., but from your perspective that

4 would go some distance toward solving the problem. It would

5 keep you in business, would it not?

6 MR. RICCIARDI: I want to make sure I understand

7 your question. I am not sure I do. As I understand today

8 PDMA, the paper trail that we provide on every single sale

9 transaction that we have, is that we provide a paper trail

10 back to the authorized distributor. If we are an authorized

11 distributor the paper trail reflects my company as an

12 authorized distributor. If we are not an authorized

13 distributor the paper trail reflects back one, two or three

14 times wherever that product is because that is required of

15 the companies we purchase that from as well.

16 From my position, I believe that that works today

17 whether it is a recall, or whether it is to ensure to the

18 pharmacist that the product that they receiving is

19 substantiated and there is a track record for them to go

20 back to in the unlikely case they would have to do that.

21 So, your question is --

22 MR. MCCONAGHA: Well, let me put it this way, the

23 first question, the question I was asking is I take if

24 everybody were required to keep a pedigree, I am trying to

25 get a sense of how that would affect your business. That is

1 what I am really after, and I welcome your thoughts on that.

2 MR. RICCIARDI: It can't be answered, I don't

3 believe, directly without understanding as well what other

4 requirements would be and if there still would need to be a

5 requirement that we, as a company, would need to be

6 authorized from the manufacturers. We have seen that we

7 have not, as a company, been able to accomplish that. So,

8 if you are going to do that without that other requirement,

9 I would have to look at it in the whole context, the rule

10 and the whole context. I don't know that I can focus on one

11 specific issue without understanding the whole rule.

12 MR. MCCONAGHA: Let me ask a separate question

13 then. You obviously regard yourselves as an authorized

14 distributor today with respect to many companies. I take it

15 in some cases you do provide pedigrees now.

16 MR. RICCIARDI: That is correct.

17 MR. MCCONAGHA: For what percentage of your

18 business roughly are you dealing with the pedigrees versus

19 being an authorized distributor?

20 MR. RICCIARDI: It depends throughout the year,

21 but give or take maybe 60-40, 60 percent authorized, 40

22 percent not authorized, but that is a moving target and it

23 can change. Please understand that as a secondary

24 wholesaler we do not have an item in stock for the purpose

25 of having it in stock when our customer needs it. We have

1 it in stock because an arbitrage situation has presented
2 itself and it makes sense for us to have it stock for
3 profits.
4 MR. MCCONAGHA: I guess what I am getting at is
5 just kind of the administrative cost to you as a business
6 owner of complying with a pedigree. I am just curious.
7 Obviously, you have some system in place now to deal with
8 pedigrees.
9 MR. RICCIARDI: Correct.
10 MR. MCCONAGHA: How onerous is that for you?
11 MR. RICCIARDI: It involves a good part of our
12 administrative staff. Of the seventy people that I had
13 mentioned to you, probably about ten people in the
14 accounting area, in the warehousing area to perform that
15 function. Now, if you want to take a multiple of that and
16 try and multiply that out for the primary wholesalers, I
17 think it could be quite costly, in the tens if not hundreds
18 of millions of dollars.
19 MS. O'ROURKE: I want to ask a question about when
20 the sales transaction occurs, following on Bill's question,
21 without doing away hypothetically with the authorized
22 distributor category but just requiring a pedigree, doesn't
23 the invoice normally contain the name of the product, the
24 strength and the lot number?
25 MR. RICCIARDI: Yes, it does.

1 MS. O'ROURKE: So, if that is automatically
2 received with every sales transaction, what would be the
3 difficulty of passing that along?
4 MR. RICCIARDI: We wouldn't get it. Some of the
5 customers we buy from, like the primary wholesalers or
6 chains, would not be able to provide that to us.
7 MS. O'ROURKE: The invoice that you receive from
8 them, that you pay them, doesn't that indicate the product
9 you bought from them by lot number --
10 MR. RICCIARDI: They are not required to do it
11 today as an authorized distributor.
12 MS. O'ROURKE: But they give you an invoice.
13 MR. RICCIARDI: Correct.
14 MS. O'ROURKE: And the invoice has the information
15 that we are talking about would be on a pedigree.
16 MR. RICCIARDI: Regardless of it being on an
17 invoice or not, Miss O'Rourke, we then, in our receiving
18 process, separate those items by lot number as they enter in
19 our distribution, which we do today.
20 MS. O'ROURKE: Right, but then with your
21 subsequent sales you provide an invoice to your customer and
22 couldn't you attach the invoice with the product that you
23 are shipping later?
24 MR. RICCIARDI: At this point we could, but that
25 would become additionally burdensome for us. Today what we

1 do is if we are not authorized distributor, we provide that
2 already -- not the invoice itself but we provide a paper
3 trail, if you will, to our customers that we are selling to.
4 MS. O'ROURKE: So, using the invoice to get a
5 separate document would not be any less burdensome?
6 MR. RICCIARDI: No, I believe using the invoice
7 would be more burdensome for us today.
8 MS. AXELRAD: Can I ask you to elaborate a little
9 bit on your comments about -- I wasn't clear about whether
10 you all buy from big chains or sell to big chains --
11 MR. RICCIARDI: We do both.
12 MS. AXELRAD: -- and dealing with the niche
13 distributors, can you sort of discuss a little bit about
14 that part of your business?
15 MR. RICCIARDI: Sure, I would love to. First of
16 all, we do both. It isn't a perfect science in our world.
17 Our world is predicated, again, on arbitrage. Tony Young
18 alluded earlier to manufacturers generating volumes in
19 certain regions of the country; I did as well in my
20 testimony. Frankly, opportunities for us to buy product in
21 the open market, to stop and think why that would occur,
22 would not make sense just looking at it from a real logical
23 way of thinking. A logical way of thinking would be
24 manufacturers sell products to distributors. It works that
25 way. They think this is what they are going to need for

1 their distribution and everybody is happy.

2 Well, that isn't the way it works. The way it

3 really works, whether it be pharmaceuticals or groceries or

4 blue jeans, is that the world isn't perfect and when the

5 manufacturer creates volumes and has manufactured product

6 that they think they are going to move in at very specific

7 point of time, at a specific price, and for some reason

8 another manufacturer for the same treatment is moving

9 product at less of a price, that manufacturer needs to

10 react. So, all of a sudden, now the open market system

11 begins to work. And, we may get a call today to buy 50,000

12 vials of an item from a wholesaler that has been presented

13 an attractive price, below average cost, for them to buy.

14 The reality is that that wholesaler can't use it,

15 but they are not going to pass on the opportunity to

16 generate additional profits for their company. I will give

17 you an example, Humulin. There are only so many diabetics

18 in the world, and movement on Humulin is very, very

19 disciplined. So, when a manufacturer that sells that item

20 goes into a particular area of the country and knows that

21 the movement on Humulin for this particular vendor that they

22 sell to has been 1,000 units a week for the last 52 weeks of

23 the year, and walks into their office one day and presents

24 an item to them that will expire in about the next four

25 months, and asks them to buy 50,000 units, I think they know

1 exactly what is happening with that item. They need to make
2 numbers.
3 We provide that opportunity to the companies that
4 we buy from and sell to. We buy often from the primary
5 wholesalers; we sell often to the primary wholesalers. We
6 buy often from local distributors and we sell often to local
7 distributors. That is how it really works in the system.
8 MS. AXELRAD: I was trying to get at the concerns
9 that have been expressed that if the rule goes into effect
10 and if we disrupt the secondary wholesaler distribution
11 system, consumers aren't going to get their drugs.
12 MR. RICCIARDI: That is a real issue and I think
13 it was explained earlier from the representative for the
14 pharmacists. I believe that that is true because in a lot
15 of situations when we are selling product to one of our
16 customers, they call us and say, "I'm out of stock on this
17 item; the manufacturer can't distribute it to me. Can you
18 overnight it to me? I need it tomorrow." That really
19 happens.
20 MS. OGRAM: Can I ask you to speculate on the
21 reason that a number of the requests that you have put out
22 to the manufacturers have been rejected? Do you know of any
23 liability that attaches to the manufacturer by providing to
24 you a contract or a letter of authorized for those that you
25 buy directly from?

1 MR. RICCIARDI: I don't know legally what the
2 answer would be. I believe that from the manufacturers'
3 perspective it is economics. I think for them to distribute
4 to one specific location or to five locations versus 500 is
5 probably, from a business perspective, a lot more economical
6 for them to do.
7 MS. OGRAM: But in those instances in which they
8 are already selling to you -- I believe you said you were
9 buying directly from 59 manufacturers --
10 MR. RICCIARDI: Correct.
11 MS. OGRAM: Do you have any idea why that piece of
12 paper would not be forthcoming?
13 MR. RICCIARDI: It would only be speculation on my
14 part. It might be an opportunity for them to become a
15 little bit more economic in their ways. I don't know. I
16 mean, that is pure speculation on my part. Frankly, the
17 courteousness that has been utilized by most manufacturers
18 to give us a specific answer that I could give you, to your
19 question, has not happened.
20 MR. MCCONAGHA: In most of those business
21 relationships that you have with a manufacturer, do you deal
22 with the manufacturer frequently just so that you can
23 maintain the status as an authorized distributor, or are you
24 actually regularly getting your drugs --
25 MR. RICCIARDI: It is a combination of both. At

1 times it is frequently. At times it is infrequently, and at
2 times it is very consistently. But in all cases we want to
3 make sure that we have the opportunity to maintain our
4 authorized distributor status.
5 MR. RAY: Is there any information that you can
6 provide on the incidence of diverted or inappropriate
7 products in the market?
8 MR. RICCIARDI: Oh, absolutely, and we provide
9 them on a basis where they occur. We are proud to say we
10 have a very, very good relationship with the field
11 representatives of your agency. As a matter of fact, I
12 would welcome the opportunity, and I have on many occasions,
13 to come and put your office in our warehouse. We believe
14 that there still needs to be a better understanding of our
15 business. If you can appreciate, from my perspective, I
16 tend to hear subliminal messages regarding the grey market,
17 and in some way, shape or form my business is put into that
18 arena. We, just as you, don't want to have bad product in
19 the system. We do not want to have bad people in the
20 system. And, I can present to you, and I will, I will be
21 more than happy to because they are already well documented,
22 that we have been a catalyst in getting those people out of
23 the system, and the field representation of the FDA is very
24 aware of our role in that.
25 MR. RAY: Are there any other kinds of things that

1 you can do, assurances that you can make if we were to
2 revise the requirements of the final rule to prevent those
3 kinds of problems from occurring?
4 MR. RICCIARDI: Yes, I think so, and I think that
5 we are a proactive company. Let me just explain to you what
6 we do as a company to ensure the validity and quality
7 control of items that we purchase. What we first do is we
8 classify within our vendor master file a manufacturer and a
9 primary wholesaler, such as Cardinal. Within our inventory
10 system, up until recently, what we did was we made sure that
11 we purchased that product from those manufacturers of those
12 primary wholesalers. I only allowed our inventory level to
13 go down -- we never completely eliminated our inventory
14 level to zero; we only allowed it to go down to one, always
15 understanding that that one unit that we had in stock was a
16 product that we purchased either from the manufacturer or
17 primary wholesaler. So, in the case where we would buy from
18 an unauthorized distributor, when we received that product
19 we would have an item that we knew was purchased directly
20 from a primary wholesaler or a manufacturer, and we compare
21 the two.
22 What we do today, because of the technology that
23 is out there so we can reduce the investment in that one
24 vial four thousand times, is we digitally take a picture of
25 the front, the back, the left side, the right side, the top

1 and the bottom of those vials. When they come in, we always
2 know that we have a very valid, quality controlled item that
3 we can compare receivings to that we would receive from
4 someone.
5 MR. MCCONAGHA: Isn't the pedigree a part of that
6 quality control process? In other words, you just described
7 a situation where you may identify something that you have
8 gotten from an unauthorized distributor, that you determine
9 to be violated for some reason, and you contact the proper
10 authorities. Is it not your sense that the pedigree is a
11 useful tool at that point in terms of giving us some
12 indication of where the drug has come from and who has
13 handled it?
14 MR. RICCIARDI: My sense would be that it is,
15 however, my sense also would be that I wouldn't be in
16 business to tell you if it would or it wouldn't. Based upon
17 the way the rule is written today, I would not be able to be
18 in the business because I would not be an authorized
19 distributor and the wholesaler would not be able to provide
20 that pedigree to us, and they have already said to us that
21 they would not be ale to provide it. In addition to talking
22 to manufacturers, we have talked to our customers who are
23 the wholesalers and retail chains, and they don't have the
24 systems in place to provide that information to us.
25 MS. AXELRAD: Let me try to get at this another

1 way. Let's just say that, you know, Congress repealed the
2 PDMA. Do you find the pedigree useful in any way? I mean,
3 do you use it in the course of your business at all?
4 MR. RICCIARDI: It is useful in the very minimal
5 circumstances where we have situations to go back to it if
6 there is a question either by our customers, ourselves, the
7 FDA or all the above. Please understand that that is a
8 very, very, very minuscule part of what we do, but when it
9 does occur we have proven to ourselves, to our customers and
10 to the FDA, as PDMA is written today, that the system works.
11 MS. AXELRAD: And if the pedigree didn't exist and
12 you had to rely on whatever the existing sales records are,
13 which is what other people have suggested be used, would you
14 find that acceptable?
15 MR. RICCIARDI: I still believe it would work. I
16 still believe that if you go down the line or up the line
17 the people that are distributing the product would be able
18 to provide that information to you in the case of a recall
19 or safety issue.
20 MS. O'ROURKE: Is there a way to make the pedigree
21 either, say, a standardized format or less or more
22 information, or different kinds of information to make it
23 more easily -- I guess a less onerous document?
24 MR. RICCIARDI: I haven't given that much thought.
25 The focus that I have had up until this point is to attempt

1 to suggest that the system today works, and it works well.
2 I can't address that at this point.
3 MR. MCCONAGHA: You did say at the opening of your
4 remarks that there were a couple of questions that were
5 addressed to Mr. Young and that you wanted to take a crack
6 at. I hope we haven't failed to ask you --
7 MR. RICCIARDI: No, I don't think you have failed!
8 [Laughter]
9 MS. AXELRAD: Thank you. Our next speaker is
10 Patrick O'Connor, representing the International Warehouse
11 Logistics Associations.
12 MR. O'CONNOR: Good morning, everybody. I am Pat
13 O'Connor. I am here in Washington, D.C. I am representing
14 International Warehouse Logistics Association, or IWLA as
15 the acronym is known.
16 Members of the Association are those companies
17 that are engaged in public warehousing and related logistic
18 services. The members of the Association operate facilities
19 in more than 2,000 locations and operate 325 million square
20 feet of warehouse space. The Prescription Drug Marketing
21 Act does impact those warehouses that store and handle
22 prescription drugs for manufacturers and wholesalers.
23 Ever since the PDMA was passed by Congress there
24 has been confusion about whether a public warehouse that
25 stores and handles prescription drugs is to be considered a

1 wholesaler or prescription drugs for the purposes of the
2 act.
3 There is a clearly defined difference between a
4 public warehouse and a wholesaler distributor. Each
5 provides starkly different functions. The public warehouse
6 provides space and labor for the movement and storage of
7 goods. It is a logistics intermediary, quite similar to the
8 common carrier. The customers of the public warehouse are
9 the manufacturers and wholesalers of products.
10 The wholesaler, on the other hand, is the owner of
11 the product, the owner of the prescription drugs. By
12 contrast, the public warehouse never, ever, takes title to
13 the product, nor does a public warehouse exercise
14 independent judgment or exercise independent control over
15 the product.
16 Legally, the public warehouse has a bailment
17 responsibility, a relationship with the owner of the
18 pharmaceutical products, again, the manufacturer or the
19 wholesaler. The public warehouse is never involved in the
20 sale or prescription of drugs. Listening to the earlier
21 speakers, you talked about invoicing and the buy-sell
22 relationships. There is not that kind of relationship
23 between the warehouse and the pharmacy or the ultimate
24 recipient of the product.
25 The PDMA has created a mistaken perception that a

1 warehouse is, in fact, a wholesaler. This came about
2 because of the wording of the legislative history that was
3 associated with the original act. In that legislative
4 history there was a reference to warehouses. Unfortunately,
5 that reference was supposed to be in the context of a
6 private warehouse, owned and operated by a wholesaler or a
7 drug chain, not a public warehouse.
8 Let me explain. The product in a private
9 warehouse is owned by the owner of the warehouse. That
10 individual has complete control and authority over his or
11 her product in his warehouse. Private warehouse owner owns
12 the product; is responsible for that product. The public
13 warehouse is storing someone else's product. Some states,
14 unfortunately, have mistakenly blurred this important
15 distinction between a private warehouse and a public
16 warehouse, construing the PDMA as requiring a public
17 warehouse to be licensed as a wholesaler, again, under the
18 assumption that all warehouses are the same -- that a
19 warehouse is a warehouse is a warehouse, and that is clearly
20 wrong.
21 The role and function of a public warehouse in our
22 economy is well defined. There is a bright line in law that
23 distinguishes a public warehouse from a private warehouse in
24 other sectors of the economy, including wholesalers. Public
25 warehousing is covered by Article 7 of the Uniform

1 Commercial Code. This section contains a law governing
2 transactions between a public warehouse and its customer.
3 The Uniform Commercial Code is the law in 49 of the 50
4 states, Louisiana having adopted a variation of the Uniform
5 Commercial Code.
6 Article 7 of the code defines warehouseman as a
7 person engaged in the business of storing goods for hire.
8 There are other distinctions readily available. The U.S.
9 Census Bureau does an annual survey of public warehousing
10 and transportation companies. That survey does not include
11 private warehousing. And, there are other examples that I
12 would be glad to share with you.
13 In response to a request that we made in 1993, FDA
14 confirmed that public warehouses are not to be considered
15 wholesaler distributors under the PDMA. In an April 27th,
16 1993 letter to our predecessor organization, the American
17 Warehouse Association, now renames IWLA, the FDA said, in
18 part, "accordingly, public warehouses, i.e., a warehouse
19 that only provides space and/or labor for the storage of
20 goods for hire, are not considered by the agency to be
21 wholesaler distributors when they are not involved in the
22 sale, trade, donation or the offer to sell, trade or donate
23 prescription drugs."
24 That letter was very helpful in 1993 and
25 succeeding years. But since receipt of that 1993 letter and

1 as time has gone by, there have been continuing situations
2 where the public warehouse has been wrongly identified as a
3 wholesaler by state agencies, by manufacturers and by other
4 wholesalers. Several states have taken the position that a
5 public warehouse must be licensed because the PDMA allows
6 states the discretion to require each facility operated by
7 the wholesaler to be licensed.
8 The fallacy in this reasoning is that the public
9 warehouse is not the wholesaler's place of business. The
10 wholesaler is not engaged in operating the public warehouse
11 facility. This confusion seems to exist because there is no
12 bright line either in the PDMA regulations or the related
13 guidance documents, no bright line explaining what a public
14 warehouse is. The 1993 letter that we received from FDA is
15 dog-eared and tattered as we try to get that out to
16 interested parties.
17 As a result, many warehouses find themselves
18 having to comply with rules in which they were not involved,
19 or being subject of possible compliance actions for not
20 being licensed when they had no reason to think they had to
21 be licensed. The implications of this mistake are
22 significant. A wholesaler, whether it is a wholesaler of
23 prescription drugs or a wholesaler of grocery products, is
24 considered to be a product seller under liability law and,
25 as such, can be liable for the performance of the products

1 sold or other responsibilities. If a public warehouse is
2 mistakenly required to be licensed as a wholesaler, the
3 warehouse may become subject to a range of legal obligations
4 and requirements intended for wholesalers and other product
5 sellers. The public warehouse is put in the untenable
6 position of being responsible for functions which are beyond
7 his authority to control and which may, in fact, violate his
8 contractual obligations to his customer if he were to try to
9 perform those functions.
10 The mistake also makes the public warehouse
11 subject to the recently passed legislation dealing with re-
12 importation of pharmaceutical products. The new law
13 includes reporting and record-keeping requirements for
14 persons licensed as a wholesaler under the PDMA. Therefore,
15 it appears that if a public warehouse has been licensed by a
16 state as a wholesaler the warehouse then will, in fact,
17 become subject to the re-importation provisions of that new
18 law although the public warehouse, again, is not engaged in
19 the importing of that product.
20 The final PDMA regulations that are the topic of
21 this hearing are further cause of concern for our members.
22 These regulations will compound our current frustrations.
23 There is a need for modification to the regulatory text of
24 section 203.50 to clearly state that the provisions of this
25 section are not applicable to a public warehouse because the

1 warehouse, again, is not the wholesaler distributor for
2 purposes of the PDMA.
3 We feel this modification in the regulatory
4 language would be consistent with your April 19, 1993
5 letter. We feel that without this modification the current
6 confusion and problems we face will be magnified. Let me
7 explain how.
8 Under the December, '99 regulations there is a
9 potential for a public warehouse to be wrongfully referred
10 to as either an authorized distributor or an unauthorized
11 distributor and, of course, neither term is correct because
12 a public warehouse is not a wholesaler in any sense of the
13 word. The need for a modification is underscored by section
14 203.50(d) which requires a manufacturer to maintain a
15 current list of all authorized distributors of record, and
16 to make this list of authorized distributors of record
17 available on request to the public for inspection or
18 copying.
19 To us, these requirements seem to confer on the
20 manufacturer the ability to unilaterally determine that a
21 public warehouse is a wholesaler distributor and subject to
22 the requirements for an authorized distributor or subject to
23 the requirements of the unauthorized distributor. Let me
24 give you a possible scenario.
25 If manufacturer A, for whatever reason, were to

1 list a warehouse as an authorized distributor but
2 manufacturer B does not, it then may be wrongfully
3 interpreted that the public warehouse is an unauthorized
4 distributor of manufacturer B's products and, thus, subject
5 to the requirements of an unauthorized distributor. Again,
6 that is simply because manufacturer A will have included the
7 warehouse on the list of authorized distributors and
8 manufacturer B has not. Yet, in reality the public
9 warehouse should be neither. The public warehouse should
10 not be considered an authorized distributor and it should
11 not be considered an unauthorized distributor. It is not a
12 wholesaler distributor.
13 We feel stating this clearly in the rule will
14 eliminate a problem we have had since 1992 and a problem
15 that seems to be getting worse with the re-importation
16 provisions and now these regulations. Thank you very much.
17 MS. AXELRAD: Thank you. Anybody have any
18 questions?
19 I think in our 1993 letter we have clarified that
20 we don't believe that public warehouses are wholesaler
21 distributors. If we do decide to make changes in the
22 regulations, we will certainly consider whether to make a
23 clarification in that. So, you got off easy because we
24 won't be questioning you like we had to question the others!
25 MR. O'CONNOR: Thank you very much.

1 MS. AXELRAD: Thank you. At this point, we are
2 going to take a break until eleven o'clock. We are running
3 just a little behind schedule but we will take a little over
4 a ten-minute break and be back here at 11:00. Thank you.
5 [Brief recess]
6 MS. AXELRAD: Our next presenter will be Ty
7 Kelley, the Director of Government Relations for the Food
8 Marketing Institute.
9 MR. KELLEY: Good morning. My name is Ty Kelley,
10 and I am Director of Government Relations for the Food
11 Marketing Institute. I appreciate the opportunity to
12 testify at this public hearing this morning, and I would
13 also like to commend FDA for delaying the effective date of
14 its final PDMA regs, and this allows the agency to receive
15 some further information with respect to the implications of
16 the rule-making on the distribution of prescription drug
17 products in the United States.
18 What I plan to do this morning is to summarize
19 from our full statement that we will be submitting for the
20 record to the Docket Management Branch. By way of
21 background, let me explain who FMI is. The name really
22 doesn't tell you much, other than that we are in the food
23 business, but we represent food retailers and wholesalers.
24 Our domestic member companies are responsible for about
25 three hundred billion dollars in annual sales every year.

1 That is more than half of all sales in the United States in
2 the grocery business. Hopefully, you will recognize some of
3 the names of our member companies. Hopefully, they are
4 familiar names -- Safeway, Giant, Kroger, Albertson's,
5 Publics. We represent large chains, medium size regional
6 chains and single store owner operators.
7 Within the past ten years, I think it is fair to
8 say that supermarket within store pharmacy departments have
9 become a very prominent player for outpatient prescription
10 drug purchases. We currently estimate that we have 123
11 member companies in the pharmacist business, operating close
12 to 8,000 pharmacy departments throughout the country.
13 Our interest in this proceeding is based on the
14 fact that supermarket pharmacies do, in fact, routinely
15 purchase prescription drugs from secondary wholesalers, and
16 we do so for two key reasons: One, available of product
17 when we need it; when we can't get it from a full-line
18 authorized distributor. Two, lower prices.
19 With respect to the final regs, we would urge FDA
20 to do the following, we would like to see section 203.3(u),
21 relating to the definition of ongoing relationship,
22 rescinded. Secondly, we would like to see rescinded section
23 203.50 which establishes requirements for wholesaler
24 distribution. While FDA may have issued these provisions in
25 an effort to enhance patient safety, we don't see any

1 evidence whatsoever that there is enhanced health and safety
2 to consumers. In fact, we view these provisions as being
3 very disruptive to the efficient distribution of
4 prescription drugs that will likely result in higher prices
5 to consumers. Moreover, since the Prescription Drug
6 Marketing Act of 1987 established significant safeguards to
7 protect consumers from counterfeit, adulterated, misbranded,
8 subpotent and expired products, FMI believes that these
9 provisions simply aren't necessary.
10 Let me go over some of the questions that were
11 contained in the Federal Register notice so that we can give
12 you a sense as to how we see this situation. FDA's final
13 rule requires an unauthorized distributor to obtain a
14 pedigree in order to legally sell a product. The Catch-22
15 here is that the regulations don't require either the
16 manufacturer or an authorized distributor to provide them.
17 Additionally, we don't believe that pharmaceutical companies
18 and full-line wholesalers would be inclined to provide them
19 on a voluntary basis simply because the pedigree, in our
20 opinion, doesn't provide any useful purpose and we also be
21 very burdensome and costly to provide.
22 In terms of question number two, it is our
23 industry's concern that the two sections of the regulations
24 that I have just referenced will have a significant adverse
25 impact on drug distribution. Secondly, patients' access to

1 life-saving medications will be significantly reduced, and
2 consumers can expect to pay more for their prescriptions if
3 these provisions are implemented.
4 Moreover, I don't believe that we can overlook the
5 fact that the regulations would close down a large number of
6 wholesalers that are out there right now, or force them to
7 drop pharmaceuticals as a product line.
8 On question number three, FMI does not believe
9 that deleting the pedigree requirement would place consumers
10 at risk. Instead, I think the issue here is how extensive
11 does the record-keeping have to be to protect consumers, and
12 what Congress intended when Congress passed PDMA into law.
13 It is our position that Congress never intended to
14 place a so-called unauthorized distributor basically at
15 competitive disadvantage by imposing the pedigree
16 requirement on this segment of the industry. It should be
17 noted that the drug distribution system as a whole, in our
18 opinion, has performed extraordinarily well since the
19 passage of PDMA in delivering medications safely and
20 efficiently without the pedigree requirement. This has been
21 accomplished by following FDA guidance, issued back in
22 August of 1988. Therefore, in our view, pedigrees just
23 aren't needed.
24 In place of pedigrees, FMI would advocate that we
25 can achieve accountability and appropriate safeguards