

UNITED STATES OF AMERICA  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
TASK FORCE ON DRUG IMPORTATION  
STAKEHOLDER MEETING:  
INTERNATIONAL AND ACADEMIC PERSPECTIVES

TUESDAY,  
APRIL 27, 2004

The meeting was held at 1:00 p.m. in Conference Room 1066 of the Food and Drug Administration, 5630 Fishers Lane, Rockville, Maryland, Surgeon General Richard H. Carmona, Task Force Chairman, presiding.

PRESENT:

VADAM RICHARD H. CARMONA	
Chairman	
JAYSON P. AHERN	Member
LESTER M. CRAWFORD	Member
ELIZABETH M. DUKE	Member
TRACEY HARDIN	Member
MARK B. McCLELLAN	Member
MIKE OGRADY	Member
WILLIAM RAUB	Member
THOMAS REILLY	Member
AMIT K. SACHDEV	Member
ELIZABETH A. WILLIS	Member

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National Association of Pharmacy Regulatory  
Authorities

Ronald Guse  
The Manitoba Pharmaceutical Association

Jean-Yves Julien and Jocelyn Binet  
The Quebec Order of Pharmacists

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Patricia Danzon, Ph.D.  
University of Pennsylvania

Frank Lichtenberg, Ph.D.  
Columbia Business School

Iain Cockburn, Ph.D.  
Boston University

Jeff Lemieux  
Centrists.org

Jack Calfee, Ph.D.  
American Enterprise Institute

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Alastair J. J. Wood, M.D.  
Vanderbilt University

Marcus Reidenberg, M.D.  
Cornell University

Carl C. Peck, M.D.  
Georgetown University

Elena Rios, M.D.  
National Hispanic Medical Association

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

(1:42:54 p.m.)

1  
2  
3 CHAIRMAN CARMONA: Ladies and  
4 gentlemen, good afternoon. I'm Rich Carmona.  
5 I'm the Surgeon General. My apologies for  
6 keeping you waiting. There were several  
7 scheduling difficulties that challenged me today,  
8 and I just flew in from out of town, so my  
9 apologies. I know how important your time is to  
10 you, and I did the best I could to expedite, but  
11 I thank you for your patience, and I thank you  
12 for being willing to help my colleagues and I,  
13 and the President and the Secretary shed some  
14 light on this very complex situation.

15 Because of the lateness, I will waive  
16 the usual introductory remarks and just say that  
17 we are striving to keep this as transparent and  
18 open a process as possible. We desperately need  
19 all of the information that you can provide to us  
20 to help us to make the recommendations to the  
21 Secretary and the President and, ultimately, to  
22 our Congress as to how to deal with this very  
23 complex problem of importation that is before us.

24 And I think we all recognize that as we move  
25 further along in the process, we open the door  
26 for as many questions as we have answers. And it  
27 is quite more complex than any of us, maybe

1       except Dr. McClellan who had to deal with it  
2       before me, really understood. So, once again,  
3       thank you so much.

4               And why don't we just move onto our  
5       first panel member. We'll start off on the left.

6       Ms. Barbara Wells from NAPRA. Thank you, ma'am.

7               MS. WELLS: Chairman Carmona and  
8       members of the task force, I want to first of all  
9       thank you for this opportunity to appear before  
10      you today. And certainly I would echo the  
11      Chairman's remarks that this is a very complex  
12      issue, and certainly Canada has just as many  
13      issues I think as you do in grappling with this.

14              I represent the National Association  
15      of Pharmacy Regulatory Authorities in Canada, and  
16      that's the umbrella voluntary organization of the  
17      pharmacy licensing bodies in eight of our ten  
18      provinces, our two territories, as well as the  
19      Pharmacy Services Division of our Department of  
20      National Defense. And this issue has been on a  
21      front burner for us for a number of years now.

22              In February of 2003, we held a forum  
23      with stakeholders from both the U.S. and Canada  
24      to identify the issues with exportation of drugs  
25      to the U.S., and this prompted us to develop a  
26      communique jointly with the National Association  
27      of Boards of Pharmacy here in the U.S. to signal

1 publicly that we were concerned about the  
2 exportation and re-importation, and that we  
3 needed to work together to protect the citizens  
4 of both countries.

5 In October last year, you were aware  
6 that our Assistant Deputy Minister of Health,  
7 Diane Gorman, issued a letter to Canadian  
8 stakeholders alerting us to the potential for  
9 shortages of drugs in Canada due to the export of  
10 drugs here, and also alluded to the fact there  
11 could be human resource implications, health  
12 worker implications to this trade. And that  
13 prompted my association last fall, last November  
14 to call upon the Canadian government to ban the  
15 export of drugs to the U.S. until, first of all,  
16 there could be a study done on the long-term  
17 effects of this trade to the Canadian public.  
18 And pending that, that there was some regulatory  
19 structures put in place to help us regulate it  
20 better. And I want to very quickly just tell you  
21 some of the issues that prompted us to call for  
22 this ban.

23 First of all, there are legal issues.  
24 Our licensing bodies find that their  
25 investigations are somewhat hampered when you're  
26 investigating complaints and situations when  
27 customers reside, patients reside in the U.S.

1 There are issues in terms of issuing subpoenas  
2 from Canada to the U.S. if we need to ?? if our  
3 members need to call upon witnesses and so on.  
4 And there's even ?? with this trade we find that  
5 you may have physicians in one province co-  
6 signing prescriptions for patients of a pharmacy  
7 in another province. And we've heard that there  
8 are barriers to sharing information between the  
9 pharmacy licensing bodies and the medical  
10 licensing authorities from province to province  
11 in some cases.

12 We also have ?? we're troubled a  
13 little bit by some of the ethical issues. We are  
14 concerned about Canadian pharmacists aiding and  
15 abetting American citizens to, in effect, break  
16 the law by importing drugs. And we also ?? there  
17 are issues with -- a lot of our medical licensing  
18 bodies have concerns and consider it to be  
19 malpractice or mispractice to co-sign a  
20 prescription from a U.S. physician, unless that  
21 physician has a personal relationship with the  
22 patient, has a bona fide professional  
23 relationship with that patient. And some of our  
24 medical licensing bodies have come out against  
25 physicians who do co-sign prescriptions, so we're  
26 saying well, we have an issue with pharmacists  
27 honoring those prescriptions if they know that

1 the patient and the physician did not have a true  
2 patient/physician relationship.

3 Obviously, if Canada gets less than 5  
4 percent of the pharmaceuticals in the world, and  
5 you folks get around 50 percent, obviously, this  
6 is causing us some real supply issues, as well.  
7 We know that pharmacists are now having trouble  
8 getting supplies. The supply issue hasn't quite  
9 reached the public in Canada yet because  
10 pharmacists are scrambling to come up with  
11 supplies for them, so it hasn't quite hit the  
12 public yet, but it is taking time up for our  
13 pharmacists to secure these supplies.

14 I, myself, have had a call in the last  
15 week from a major drug company asking about the  
16 chances of a product being exported to the U.S.  
17 They are looking at releasing, launching a new  
18 drug in Canada that is available in the States,  
19 and they're looking at not launching it in Canada  
20 if there's a chance it could be re-imported into  
21 the U.S. So we're seeing those kind of issues  
22 now.

23 With the increase in pressure to the  
24 exporters to get supplies of drugs -- because you  
25 know some of the drug companies have cut-off the  
26 exporters -- we see now that they are purchasing  
27 medications from community pharmacies right

1 across Canada, and they offer them a 10 or 20  
2 percent premium to purchase their drug supplies.

3 And that is keeping these large amounts of drugs  
4 being ordered from being on the radar screen to  
5 the Canadian companies.

6 And we also are seeing things where  
7 some of the websites have direct links to  
8 pharmacies in other countries -- in England and  
9 other places -- to obtain drugs. And, of course,  
10 there's allegations that some are bringing drugs  
11 into the country illegally, unapproved drugs, to  
12 satisfy the orders.

13 There's also ?? we have a shortage of  
14 pharmacists in Canada and, of course, this is  
15 exacerbating that shortage, as well. So I think  
16 aside from these issues that we have pointed out  
17 to our government, I think, too, that my members  
18 could not condone this style of pharmacy service.

19 We feel that it's certainly not in your public's  
20 best interest to have fragmented pharmacy care in  
21 this way, that they're getting drugs from  
22 companies in Canada as well as their community  
23 pharmacies in the U.S. And certainly, searching  
24 the Internet for drugs does not bode well for  
25 optimal health. And I thank you again.

26 CHAIRMAN CARMONA: Thank you, ma'am.  
27 Let's move on to Mr. Ronald Guse from the

1 Manitoba Pharmaceutical Association. Thank you,  
2 sir.

3 MR. GUSE: Thank you. And thank you  
4 to Chairman Carmona and the committee for the  
5 opportunity to address this issue on drug  
6 importation to the United States. And I bring  
7 greetings from my president, Gary Cavanagh, and  
8 my past president, Lois Cantin.

9 The Manitoba Pharmaceutical  
10 Association has made a written submission, and I  
11 believe it's before the committee, and I strongly  
12 encourage you to refer to that submission. And  
13 just for clarification, the Manitoba  
14 Pharmaceutical Association, although the name may  
15 seem to indicate that we represent the drug  
16 industry, we do not. It also may indicate that  
17 we're a self-interest group, and we certainly are  
18 not that either. The association itself is the  
19 regulatory authority in the Province of Manitoba,  
20 and it would be analogous to your boards of  
21 pharmacy that exist in the United States.

22 The MPhA has been on the forefront, if  
23 not the chopping block, of this issue for the  
24 past couple of years, and we have gained some  
25 experiences, and I wish to share them with you  
26 today.

27 The two major concerns that we want to

1 highlight for the committee, and the report does  
2 that, is one issue that was stressed and re-  
3 stressed in a presentation we heard just a couple  
4 of days ago by the former Secretary, Donna  
5 Shalala. And the former Secretary strongly  
6 supports the idea of watching patient safety in  
7 the issue of drug re-importation. In our  
8 submission, that's one of the two principles  
9 we've identified to you; one is patient safety,  
10 and certainly the second one is product quality  
11 and safety.

12 From our experiences, and any health  
13 care professional or board protecting the  
14 public's safety, introducing more and cheaper  
15 drugs does not necessarily equate to better or  
16 enhanced care, and that's important for the  
17 community to remember.

18 I'd also like to take you back briefly  
19 to prior to the year 2000 when pharmacies in  
20 Canada in attempting to supply medications to  
21 Canadians temporarily residing in the United  
22 States (some of our winters being a little more  
23 aggressive than some of your winters), the  
24 pharmacies trying to ship the medications to the  
25 Canadians had to make sure that there is a  
26 certain amount of information in the package, as  
27 well as the medication. And that information had

1 to confirm that the patient was, in fact, a  
2 Canadian, the medications were prescribed. There  
3 was some information that was required from the  
4 medical practitioner, as well. And even with all  
5 that information in those packages, frankly,  
6 there was no guarantee that the product would  
7 move through U.S. customs.

8 Well, we've gone from that to a system  
9 now where, with few exceptions, the borders are  
10 pretty well wide open. And that's caused the  
11 Manitoba Pharmaceutical Association to address  
12 what our pharmacists are doing with regards to  
13 patient care.

14 Also as recent as yesterday, we had a  
15 presentation at the National Association of  
16 Boards of Pharmacy conference from former Mayor  
17 Giuliani, and he referred to information that he  
18 saw at Kennedy Airport where 40,000 packages of  
19 medications from all over the world come through  
20 that customs location. It's his description that  
21 the staff only have the resources to review 500  
22 of those packages. His concern was to identify  
23 the great potential for lack of safety, lack of  
24 security, and risk of dangerous products, and  
25 perhaps even terrorism through that port.

26 Now this might be an  
27 oversimplification, but to me, if 500 packages

1 are the ones that are inspected and cleared, then  
2 500 packages should go through.

3 Also, there might be some solution  
4 through pre-authorization. Part of our ten-point  
5 priorities that we have in the submission is the  
6 idea of pre-authorized suppliers that might ship  
7 products into the United States.

8 I have to admit that I'm here  
9 presenting a bit of a schizophrenic position to  
10 the task force. Increased importation or the  
11 current issue of importation of drugs into the  
12 United States from Canada will harm and has  
13 harmed the healthcare system in Canada. However,  
14 I have to recognize, as well, there are a certain  
15 amount of pressures within our country in certain  
16 areas for this commercial activity to continue.

17 As certain authorities within the  
18 United States and Canada appear to want the  
19 cross-border industry to continue, the task force  
20 needs to therefore consider the ten points  
21 identified in our written submission. And I can  
22 explain these points further if that's requested  
23 by the committee, but I'd just like to take a few  
24 moments just to highlight them for you, and it  
25 starts on page 3 of our submission.

26 It's important that there is a  
27 development of international standards and

1 agreements that conform and enforce patient care  
2 as a primary goal, placed over commercial  
3 interest; the development of mutual international  
4 recognition for licensing wholesalers,  
5 pharmacists, and pharmacies located in Canada and  
6 the United States that choose to serve other  
7 countries; and development of memoranda of  
8 understanding regarding which laws are  
9 enforceable for the safety and benefit of the  
10 patient, as many of the businesses require  
11 disclaimers, agreements, and powers of attorney  
12 that basically remove the patient autonomy.

13           Until such time as the provincial and state  
14 pharmacy regulators can openly forward and  
15 receive information and intelligence from the  
16 American Food and Drug Administration, Health  
17 Canada, and the provincial and state prescribing  
18 licensing authorities, cross-border pharmacy  
19 sales of drugs under the authority of a  
20 prescription should be limited or temporarily  
21 suspended.

22           A review is required to identify the  
23 legal impediments and barriers of investigation,  
24 complaint investigation, jurisdictional issues,  
25 powers of subpoena, and the collection of  
26 evidence. As the international movement of drugs  
27 is based heavily upon issues of access to cheaper

1 drugs and professional care, the flow of  
2 medication across the international border  
3 through wholesale purchases ought to be permitted  
4 rather than, or in addition to the pharmacy  
5 distribution pursuant to a prescription.

6 As confirmed by all parties  
7 knowledgeable in this industry, the Canadian drug  
8 supply system cannot provide for all Americans  
9 requiring catastrophic medications, nor the cost-  
10 saving needs of private and/or state-run drug  
11 benefit programs. A plan is needed, therefore,  
12 to carve out the cross-border movement of drugs  
13 that can initially benefit those who need it the  
14 most, and ultimately address the needs of others.

15 The drug source needs to be confirmed,  
16 and only purchases directly from licensed  
17 wholesalers to pharmacies would be permitted for  
18 international sales on prescription. Our  
19 referral prescription programs to pharmacies and  
20 businesses located outside the country of the  
21 pharmacy of first contact must be approved by  
22 provincial or state licensing authorities prior  
23 to implementing that program.

24 And, finally, all advertisements of  
25 pharmacies servicing other countries must clearly  
26 indicate the jurisdiction of license, meet the  
27 requirements of international license authorities

1 based upon a program such as the National  
2 Association of Boards of Pharmacy IPS program,  
3 and no other pharmacy business would be allowed  
4 to advertise for international shipment of  
5 medications or participate in that activity.

6 In closing, Chairman Carmona, I'd like  
7 to again express appreciation for the opportunity  
8 to address the task force. Your decisions will  
9 affect Canada in the back-and-forth movement of  
10 drugs between the two countries. The issue of  
11 cross-border movement of legal drugs is very  
12 complex, as you've already alluded to. It  
13 involves and entwines professional, legal, and  
14 political jurisdictions; however, the overall  
15 goal must remain clear: patient safety and  
16 product quality and safety.

17 We look forward to future  
18 opportunities for further discussions and thank  
19 you for this opportunity again.

20 CHAIRMAN CARMONA: Thank you, sir.  
21 Our next speaker, Mr. Jean-Yves Julien from the  
22 Quebec Order of Pharmacists. Sir, thank you for  
23 being here.

24 MR. JULIEN: I thank you for the  
25 invitation, and I am accompanied by Mr. Jocelyn  
26 Binet, who is responsible for investigations, so  
27 he could answer some of the questions later on.

1           In the short period of time, I'll  
2 focus on some of the activities that we have been  
3 running in order to prevent this situation from  
4 spreading in the Quebec province.

5           The first message that we always give  
6 to people is to make the distinction between the  
7 drugs and the prescription. And what has been  
8 said, I share most of the comments to enforce the  
9 professional legislation and control. That's the  
10 key message out of the paper that I'm presenting  
11 today.

12           So about the drug itself. You know  
13 it's like in the United States, the jurisdiction.  
14 We don't have, in a province in Canada, the  
15 jurisdiction over the drug itself, the moving of  
16 a drug. We have the jurisdiction over the  
17 professional activities.

18           The Quebec Order of Pharmacists is the  
19 licensing body for the Province of Quebec. The  
20 Quebec Pharmacy Law is unique in one sense in  
21 that it's only a pharmacist that can own a  
22 pharmacy in Quebec. And this is something that  
23 gives us a tool to act more easily than somewhere  
24 else in Canada. You have a few of the  
25 references. I won't go through that, but you can  
26 refer to it.

27           About the prescription dispensing:

1 our pharmacies are allowed to dispense or fill a  
2 prescription only if it's signed by a Canadian,  
3 or especially a Quebec physician. So for myself,  
4 I cannot - I don't feel I'm authorized to fill a  
5 prescription coming from an American physician.  
6 This is very important. That's what we are  
7 acting on to prevent.

8 About the Internet: we are not  
9 against the use of the Internet as a tool of  
10 communication. Everyone would be really  
11 surprised if we said that we don't like to use  
12 the Internet. It's a common tool. But I'd just  
13 like to underline that we never experienced fax  
14 pharmacy, we never experienced phone pharmacy, we  
15 never experienced delivery pharmacy, the  
16 widespread use of this designation. But now with  
17 the Internet, everything goes, and we feel  
18 because we use an Internet pharmacy, that it's  
19 full pharmacy. It's not. We should make people  
20 aware of that.

21 Internet and the challenge across  
22 borders. I guess the main thing is professional  
23 activities. Again, it's not because a  
24 prescription is transiting through the Internet  
25 that it becomes a legal prescription in Canada.  
26 We should stop that to move. That's what we do  
27 in our jurisdiction.

1           Three steps that we have been trying  
2           to work on in order to prevent that. First,  
3           disciplinary action against our member. Those  
4           who are involved, we bring them in front of the  
5           disciplinary committee and stop them from doing  
6           it. They are fined or other actions are taken  
7           against them. Penal lawsuits for people who are  
8           not pharmacists and are operating a website from  
9           the Quebec territory. We have been suing them.  
10          It's not easy, as has been mentioned. We need  
11          help because it's a very complicated situation.  
12          Mr. Binet can talk about it.

13                 And the third type of action is public  
14          awareness, public information. And when I say  
15          public information, I mean the public in general,  
16          but as well, the authorities, because it's not  
17          always easy. It seems easy to say that they're  
18          different, a prescription is not a drug, and the  
19          opposite. But it's not always easy when I  
20          mention that to some politician in Quebec or some  
21          civil servant. They say, oh, it's the same. No,  
22          it's not the same, because it's the key to  
23          preventing that situation from spreading more.

24                 So disciplinary action. We have been  
25          acting for pharmacists and non-pharmacists.  
26          Penal lawsuits. We simply do not have the  
27          important financial resources needed to conduct

1 all inquiries we would like to do. But more  
2 importantly, we do need the support, technical  
3 and financially, and collaboration of all  
4 jurisdictions that are implicated in that law  
5 enforcement. That's what has been mentioned.

6 And a great example of that is drug  
7 importation itself. The Quebec Order of  
8 Pharmacists cannot control what transits through  
9 the border. It's up to other legislation, but we  
10 can stop, from the pharmacy, the sending of  
11 messages or information to the Internet when it's  
12 not considered legal.

13 Public information. It is important  
14 to make the public informed about that. Public  
15 protection. It's an issue on both sides of the  
16 border to protect the people. When we stop  
17 pharmacists doing that, we know that they are  
18 losing money. It has been mentioned that it is  
19 an important issue. We know that they are losing  
20 money, but it's not the way to make money. We  
21 feel that. And I think it's a protection for the  
22 U.S. citizen, as well.

23 Canadian drugs. I don't think the  
24 quality of Canadian-made drugs are at stake here,  
25 are an issue, but the problem is that if we allow  
26 an illegal practice, why don't we allow, as well,  
27 counterfeit drugs. That's the risk of mixing two

1 types of illegal activities. That will increase.

2 That's what we find very threatening, so that's  
3 why counterfeit drug is a real threat, as well,  
4 because if we let things go, everything will  
5 come, like has been mentioned, from everywhere in  
6 the world.

7 The important distinction for the  
8 public in-between a service, that's something  
9 that we continuously repeat. The loophole that  
10 helps to facilitate that is the fact that if I  
11 cross the border with my personal medication for  
12 90 days, I will be allowed to do that. That's  
13 rational, but not more than that. So then, it is  
14 complicated to control, as has been mentioned.

15 Practice control. The important point  
16 is the fact that for a prescription to be valid,  
17 it has to be issued by a physician in Quebec or  
18 in Canada. And we should make the people aware  
19 of that. They are putting themselves in danger  
20 if they are calling and getting services from  
21 distance like that.

22 Negative impacts have been mentioned.

23 We share that. Societal challenge for the  
24 future. The key message there that we're trying  
25 to send is it's unfortunate when we see a public  
26 person, mayor, other, in Canada, politician in  
27 authority who says, Go and buy your cheapest

1 prescription through the Internet, for instance.

2 I mentioned, in Quebec and Montreal, that it's  
3 exactly like if the mayor in Montreal told the  
4 people, Go to the reserve, buy your cigarettes.  
5 It's going to be cheaper. I think it's a type of  
6 societal behavior that should be condemned  
7 publicly. This is very important, because it's  
8 part of this issue.

9 And, finally, I do think that I would  
10 not like to be in a world where we have pharmacy  
11 paradise like we have fiscal paradise. That's my  
12 comments.

13 CHAIRMAN CARMONA: Thank you, sir. I  
14 appreciate it. I understand Mr. Binet is just  
15 here for questions and will not make a statement.

16 Is that correct?

17 MR. JULIEN: Yes.

18 CHAIRMAN CARMONA: Okay. Then I would  
19 open the questions to my fellow task force  
20 members. Anybody have any questions of our  
21 panelists? Go ahead, please.

22 DR. O'GRADY: Yes, just a couple of  
23 questions. One, in terms of both what Monsieur  
24 Julien and Ms. Wells brought up, is the role of  
25 the physician as sort of a co-signer of a  
26 prescription. I just wonder what sort of  
27 liability is there under Canadian law for a

1 physician -- or if there is any liability -- a  
2 physician who sort of really doesn't ever examine  
3 this patient, sees that an American colleague has  
4 signed, and therefore, just goes ahead and signs  
5 a Canadian version of the same script?

6 MS. WELLS: Well, I can ?? as I  
7 mentioned in my presentation, there are a lot of  
8 the licensing bodies now for physicians who have  
9 come out against co-signing. And I know that the  
10 agency in Canada that covers liability for  
11 physicians has also publicly stated that there  
12 would probably be a problem if there was an error  
13 or a mishap with an American patient who had  
14 received a prescription that was just co-signed.  
15 There may not be coverage for that physician.

16 MR. JULIEN: We are working with the  
17 College of Physicians, and they have been acting  
18 on that. They have sanctioned their members who  
19 co-sign prescriptions. Their public message is  
20 not to do that, and they are acting against that.

21 DR. O'GRADY: Could I ask one more  
22 question?

23 CHAIRMAN CARMONA: Please. Go ahead,  
24 Dr. O'Grady.

25 DR. O'GRADY: Sure. Ms. Wells, you  
26 brought up a discussion that you had either over  
27 the phone or whatever with a drug manufacturer

1 who was thinking of introducing a new drug into  
2 Canada but was hesitating in some sense. Now can  
3 you just sort of expand for us a little bit,  
4 without any confidences here, if I'm a drug  
5 manufacturer and I've already introduced  
6 something in the States, and I'd like to think  
7 about introducing it in Canada, if there's not ??  
8 I mean, much of what is behind the whole  
9 importation thing has go to do with price  
10 differentials between the two countries. So if  
11 I'm a manufacturer, don't I just offer it in  
12 Canada at the same price as I'm asking for in the  
13 United States, and then sort of the incentive to  
14 import or re-import goes away? Or are there  
15 other limitations on that manufacturer's ability  
16 to simply charge the same amount as they do in  
17 the States?

18 MS. WELLS: Yes. We have the Patent  
19 Medicine Prices Review Board in Canada. There  
20 are price controls on pharmaceuticals in Canada,  
21 so I'm presuming that would stop them from  
22 charging the same prices in the U.S.

23 DR. O'GRADY: I see. So if the  
24 Canadian Board basically allowed them to charge  
25 the same prices, their incentive to not offer in  
26 Canada would go away?

27 MS. WELLS: Well, I mean the price

1 differential is probably the main driver.

2 DR. O'GRADY: Yes. I guess all I'm  
3 thinking about, in terms of the board and its  
4 responsibilities in terms of access to drugs for  
5 Canadian citizens, that at some point there is  
6 that notion of price versus gaining access to  
7 what you view are needed drugs. So that dynamic  
8 between the manufacturer and the board in Canada  
9 seems to be somewhat separate from either our  
10 world or your world, other than we're both  
11 affected by the price differential and its  
12 effects.

13 MR. GUSE: If I can add to that just  
14 briefly, what we're seeing in recent history is  
15 that the introductory prices set by the board  
16 that Ms. Wells described, the amount is pretty  
17 well on line with what the American introductory  
18 prices are. One of the requirements under the  
19 Patent Medicine Prices Review Board is that the  
20 price increases thereafter, and your price  
21 increases are at a greater rate than what our's  
22 is. So what the starting point might be, same or  
23 similar, the gap grows as the years pursue.

24 CHAIRMAN CARMONA: Thank you. Dr.  
25 McClellan.

26 DR. McCLELLAN: Yes, thank you. This  
27 is actually for any of you. You all expressed

1 some concerns about safety on both sides of the  
2 border, with a disconnected system, with us each  
3 going about our own ways of trying to meet our  
4 medical needs. You all talked about a fragmented  
5 system for filling prescriptions over here, with  
6 people going across the border and having  
7 prescriptions written by doctors that hadn't seen  
8 patients, and not being connected to our safety  
9 systems. And on the Canadian side about  
10 potential problems in access to medicines, as  
11 well. They just aren't marketed or there's not  
12 enough supply of them given the U.S. demands for  
13 those medicines.

14 I clearly understand all the problems.  
15 I just wonder if you all have any other  
16 suggestions on how we can work together to  
17 address them. In my former job at FDA, I spent a  
18 good deal of time with Deputy Assistant Minister  
19 Gorman on our new collaborations in some areas.  
20 We signed a joint memorandum of understanding to  
21 work together on, not just cross-border safety  
22 issues, but also drug manufacturing methods,  
23 harmonizing regulatory approaches, steps that  
24 collectively might bring down the costs of  
25 medicines in both countries. And I wonder if  
26 there are other ways to do that, as well.

27 For example, in the United States

1 there obviously are some real concerns about the  
2 differences in the prices of brand-name  
3 medicines, and we'd like to find ways to bear  
4 less of the share of those costs, and reduce our  
5 price burdens here. On the other hand, in  
6 Canada, as I understand it, most generic  
7 medicines are significantly more expensive than  
8 in the U.S., perhaps as a result of price  
9 regulation or other steps that maybe got in the  
10 way of what should be a very competitive market,  
11 and they're not used as widely as they are in the  
12 U.S., a significantly lower share of generic  
13 prescriptions.

14 Well, maybe there's something we could  
15 learn from each other that would reduce the price  
16 differences between the countries without having  
17 to spend more on prescription drugs in Canada.  
18 Any thoughts like those about how we could work  
19 together on this, because it seems like when  
20 we're working separately it reinforces both  
21 higher costs, access problems, and safety  
22 problems.

23 MR. GUSE: Yes, thank you. And I  
24 think it's a great issue, and there's some  
25 answers out there that we need to look at, for  
26 sure.

27 A couple of things on those points.

1 The overall perception is, on even a limited  
2 category of drugs, that Canadian prices are much  
3 better than the American price. In fact, that's  
4 what driving the industries in some regard. But  
5 there is differential pricing within your  
6 country, through organized - I don't know if I'm  
7 going to use the right term - but organized  
8 purchase groups that get phenomenal prices, I'm  
9 sure, probably better than what some of the  
10 Canadian prices are.

11 However, the profile appears to be  
12 with the individuals that can least afford to pay  
13 the higher prices. In fact, those are the ones.

14 And when you take that population, the prices  
15 they're paying, then the Canadian price seems to  
16 be a great advantage, and obviously that's why  
17 they're purchasing the product from Canada. So I  
18 think those issues are right on.

19 The issue about generics, the thing  
20 you described is also correct, in that our  
21 generic prices appear to be higher than they are  
22 in the United States. And again, as much as we  
23 can look at the issues of price and disparities,  
24 and why that's occurring, we can't lose sight of  
25 the patient care. And if you boil this issue  
26 down to price differences, how do we get the  
27 right price -- and I don't mean disrespect -- but

1 you also have to clearly roll into there is it  
2 the right drug, are they being taken, is it the  
3 compliance. Because I think there's a lot of  
4 cost savings when you look at patient compliance  
5 and the pharmacists doing the care that they  
6 ought to be providing.

7 MR. JULIEN: Yes, if I might comment.

8 For the generic, we know that what we see of the  
9 price, it's higher in Canada than in the United  
10 States. We have to learn from you. For the  
11 original drugs, as has been mentioned, it's not  
12 always ?? it's sometimes misleading for the  
13 public, because the price that is paid that we  
14 see in general -- we have a buying group or we  
15 have, for instance, in Quebec the insurance for  
16 all the population, so the price that we see is  
17 the price that the government pays or the  
18 pharmacist will pay. So sharing information  
19 about the real acquisition costs through  
20 different groups in the United States would be  
21 useful in order to understand what is the real  
22 differential at the end. It's certainly higher  
23 in the United States, but some action means that  
24 it's higher for part of the population, but not  
25 for all. So if we compare hospitals, for  
26 instance, they might be lower than in Canada, or  
27 a bit higher, but it has ?? we need more

1 information. And I think people dealing with  
2 that need to share information that would be  
3 helpful on that situation.

4 CHAIRMAN CARMONA: Dr. Crawford, and  
5 then Dr. Raub after.

6 DR. CRAWFORD: Monsieur Julien, you  
7 mentioned that it's not possible under Quebec law  
8 for a prescription to be filled that's written by  
9 an American physician unless the American  
10 physician is also licensed in Quebec. Is that  
11 correct?

12 MR. JULIEN: Yes, that's the situation  
13 that we are enforcing, the interpretation - that  
14 the prescription ?? the pharmacist is authorized  
15 to fill prescription by an authorized prescriber,  
16 meaning someone authorized in Quebec, or in some  
17 circumstances from other provinces, but it's  
18 mainly in Quebec. So a prescription I interpret  
19 -- and that's what we enforce, that a physician  
20 that signs a prescription from the States is not  
21 authorized in Canada. If I receive it, it's not  
22 a legal prescription, and it's illegal for me to  
23 fill it.

24 DR. CRAWFORD: Whether or not the  
25 physician is licensed in Quebec?

26 MR. JULIEN: If he is licensed in  
27 Quebec, then the other step that we will look --

1 it doesn't mean that we'll encourage that, to  
2 have a physician in Florida that is authorized in  
3 Quebec and signs prescriptions and that over the  
4 Internet, because we're going to look at  
5 comprehensive pharmacy services. So will the  
6 patient get in touch with his pharmacist and so  
7 on. So we're looking at another aspect. But at  
8 the very first, most of the prescriptions that  
9 transit through the border through the Internet  
10 are for us considered illegal prescriptions.  
11 That's where we stop pharmacists from using it.  
12 And if a Quebec physician countersigns, we even  
13 say that it's not allowed. It's not good  
14 practice, and we don't consider it the thing to  
15 do, and we stop that, as well.

16 DR. CRAWFORD: Okay. Thank you.

17 DR. RAUB: Thank you. This is a  
18 question for anyone or everyone on the panel, and  
19 it's about capacity. If we had a satisfactory  
20 system for importation of prescription drugs from  
21 Canada to the United States, and if the  
22 pharmaceutical manufacturers were willing to sell  
23 to Canadian pharmacies all the drugs that they  
24 wanted to buy, where does the strain begin with  
25 the Canadian system? Would twice the current  
26 volume of transactions break it? Three times?  
27 Five times? What is the capacity of the

1 infrastructure to go significantly beyond the  
2 volume of sales that you handle now, especially  
3 pharmacists, facilities, and the like? It's  
4 unfair to ask for any particular numbers. I  
5 don't mean that, but just some attempt at a  
6 quantification.

7 MR. JULIEN: If I may start and try, I  
8 don't think it will work like that. It won't  
9 break, because if we open the door, we have a lot  
10 in the United States that will come up to service  
11 our sales. So there's no ?? they will have a  
12 problem, a short-term problem, but the fact is  
13 that we're not going to authorize the moving of a  
14 drug. What we will do if we allow the system to  
15 continue, we will, in fact, allow the  
16 professional moving like free trade. Free trade  
17 does not include right now the professional free  
18 moving in one country to another. When a mayor  
19 from a city here said, Go buy your drug, I say he  
20 should say, Come, Mr. Julien, to work in my city,  
21 because that's what he's saying. He's saying to  
22 people the services offered up North are good.  
23 Why not bring the professional here. So why do  
24 we stay there? Because of the product. Then, I  
25 guess, what will happen is the price will go up  
26 and moving across the border, and certainly we'll  
27 find American pharmacies wise enough to try to

1 send cheaper drug, cheaper prescription up in  
2 Canada, even though there is a differential of  
3 price. We have seen a very big transaction so  
4 far with pharmacies and people on both side of  
5 the border, so I cannot say that it will break  
6 the system. It will reach a point where other  
7 measures work, and probably some pharmacists will  
8 work for Americans, and other will work for  
9 Canadians from the States, beside the fact that  
10 there is a problem, but the price will go up in  
11 Canada, certainly.

12 MR. GUSE: Dr. Raub, if I can just add  
13 to that. Again, it comes down to the idea of  
14 distribution. If we're talking about  
15 distribution pure and simple, I think the likely  
16 alternative, rather than having the product  
17 packaged and prepared in Canada, with due  
18 respect, it might very well be to have the  
19 product shipped to the States through the  
20 wholesalers, for example. And you have ?? I  
21 mean, our pharmacists, we've done some studies on  
22 how the pharmacists in the United States compare  
23 to the pharmacists in Canada, and the  
24 competencies are right- on equivalent. And  
25 you've got some good practitioners there, I know,  
26 and they can deliver the care. And if it comes  
27 down to where the product comes, it might very

1 well be the concept to have the wholesale ship to  
2 the pharmacies in the United States and provide  
3 the care locally.

4 MR. SACHDEV: This is a question for  
5 Ms. Wells and Mr. Guse. In your testimony, each  
6 of you talked separately about, Ms. Wells, the  
7 need for some study of the impact of importation  
8 and noted that your organization had called for a  
9 ban on importation until such study could be  
10 done. And, Mr. Guse, you mentioned the need for  
11 sort of an assessment or an analysis of the legal  
12 impediments related to importation. Can you both  
13 update us on what the status is of that, of your  
14 call to the government, but also of the effort to  
15 do that type of analysis?

16 MS. WELLS: I know there are groups in  
17 Canada right now looking at collecting  
18 information on drug shortages, for instance. And  
19 we also know that Health Canada has started to do  
20 some inspections in pharmacies looking for  
21 breaches in, if they are purchasing drugs from  
22 other pharmacies, they're acting as wholesalers.  
23 And if they don't have an establishment license,  
24 that would be illegal, so they're looking for  
25 that.

26 Health Canada is also looking for  
27 unapproved drugs being dispensed, so that's going

1 on right now, as well as studies on shortages of  
2 drugs, and impact on pharmacist manpower, so it's  
3 going on right now.

4 MR. SACHDEV: And in terms of your  
5 call for a ban, how has that been received?

6 MS. WELLS: Health Canada has pointed  
7 out that in terms of the exportation of drugs to  
8 the U.S., there's nothing federally that prevents  
9 that, so they're still sort of being watched  
10 right now by the federal government. We actually  
11 have a meeting scheduled for next week. The  
12 federal government is meeting with the regulators  
13 of pharmacy and medicine just to discuss some of  
14 these issues, so it is certainly something that's  
15 under study right now by the federal government.

16 MR. GUSE: Thank you. And with  
17 regards to the legal issues -- and I'm not a  
18 lawyer, I'm a pharmacist. But the idea of our  
19 jurisdiction, our public, if you will, is  
20 patients that receive medications from pharmacies  
21 located in Manitoba, so we have an obligation,  
22 and in fact do complaint investigations. The  
23 challenge around that is collecting evidence when  
24 the evidence is not located in my province, or in  
25 my country. The ability to subpoena witnesses  
26 has been a challenge, so we're still exploring  
27 some of those challenges, and I don't have all

1 the answers for you, but I do have a lot of the  
2 questions, or the challenges that we see.

3 MR. SACHDEV: A follow-up question.  
4 Actually, in all of your statements you note that  
5 it's not possible for any particular province or  
6 state regulatory agency to possess the resources  
7 or expertise to go beyond its borders. I think  
8 that was from Ms. Wells' statement. From Mr.  
9 Guse's, it's something to the effect of the  
10 provincial regulatory systems do not ?? really  
11 are not designed to allow for the regulation of  
12 the exportation of prescription drugs. And from  
13 yours, Mr. Julien, I think you talked about the  
14 loosening of public protections as a result of  
15 importation or exportation of prescription drugs  
16 where you think about issues like liability  
17 concerns.

18 To the U.S. consumer who is purchasing  
19 drugs typically through an Internet portal, what  
20 are you saying in terms of what they should  
21 expect from the provincial pharmacy regulator in  
22 Canada in terms of their oversight of the price  
23 coming into this country?

24 MR. GUSE: Well, there are some  
25 challenges also in that regard because first off,  
26 there's different businesses out there, and  
27 businesses, pharmacies, in fact, that we do

1 license, and they're required to display that on  
2 their website if that's all they're advertising.

3 But there's also businesses out there that leave  
4 the consumer with the impression that they are  
5 licensed in Canada, or they are Canadian, or in  
6 fact, they're licensed by us. And we have some  
7 challenges around that, where we try to convince  
8 them that they ought to remove that impression  
9 from their website. And if they wish to  
10 participate in that, then we have cooperation.  
11 We have a success. If they wish not to, and  
12 they're not located in Manitoba, or they're not  
13 located in Canada, frankly, I don't know what we  
14 do.

15 MS. WELLS: We developed some model  
16 standards a couple of years ago, not designed to  
17 speak to American citizens looking to buy from  
18 Canada, but for folks across Canada looking to  
19 use websites to interact with their pharmacies.  
20 And one of the requirements is that there be  
21 posted on the opening page of the website sort of  
22 a warning that if there is a problem, the  
23 consumer may not be able to find redress in the  
24 jurisdiction of where the pharmacy is located.  
25 They might have to seek some assistance from the  
26 licensing body where they're located. So when  
27 you say what do you say to the American citizens,

1 it's not clear how much assistance a licensing  
2 body in Canada could give them if there was a  
3 problem. They may have to go to their state  
4 board.

5 MR. JULIEN: May I make a comment and  
6 then Mr. Binet. What I wrote in the paper is  
7 that the public is losing. That's my opinion,  
8 and that's what we promote. The public is losing  
9 its legal umbrella protection when it deals with  
10 a pharmacist across the border for prescription  
11 drugs. In most of the provinces and states, we  
12 have consumers law protection. It works within  
13 this jurisdiction. Professional activities, it's  
14 about the same, so if someone ?? I cannot  
15 guarantee to an American citizen, come and buy  
16 through a pharmacist, that I will be able to  
17 protect him in case of an error, for instance,  
18 because we are suing the pharmacist not to do  
19 that. Since it's illegal, the pharmacist won't  
20 be protected by his professional insurance. So  
21 then we are losing, and it will be the same  
22 problem for someone in Canada buying from a  
23 distance. So this is very important, and that's  
24 what we are explaining to people, that we are  
25 losing this type of protection.

26 It's like if I buy a used car here  
27 today and drive up to Canada, I won't have much

1 protection with that car. So this is very  
2 important, and that's what we say to people.

3 MR. BINET: If I might just add, I'm  
4 the investigator, the chief investigator and  
5 director of the Order of Pharmacists, and you've  
6 just asked what would you say to one of our  
7 citizens. I had those complaints before. Some  
8 people called from Illinois, Hawaii, wherever in  
9 the States, and the answer is I can't help you.  
10 That's the problem, and that's the reason why we  
11 are working hard in Quebec, as Mr. Julien told  
12 you. We have a law that prevents anybody else  
13 not being a pharmacist to own a pharmacy and sell  
14 drugs. And this is our main success because if  
15 you have a website or a cyber pharmacy, it cannot  
16 be owned by other than pharmacists in Quebec.  
17 And this is not a type of practice that we allow,  
18 so we prevent this type of practice.

19 And those people who are buying the  
20 medication from a website that's in Montreal, or  
21 in Quebec, anywhere in the Province of Quebec,  
22 because it's illegal to practice this way, we  
23 don't have directly a sense or a manner to work  
24 for their problem. The thing we have to work  
25 upon is to go into court and have a penal lawsuit  
26 against those people. But because they're  
27 practicing illegal pharmacy, not directly

1 assessing the problem of the patient who called  
2 us having a problem with the pharmacy or the  
3 cyber pharmacy, so we're doing it generally to  
4 prevent this type of practice in Quebec.

5 MR. JULIEN: A final point on what we  
6 say to pharmacists: if you get engaged in this  
7 type of what we call illegal activities, you may  
8 feel protected because you are behind the U.S.  
9 border. But if you cross with your car or if  
10 your plane stops in the United States and you get  
11 caught there, you will have to answer a question  
12 from the patient then, and a lawsuit is possible  
13 over there. So professional ?? we have to  
14 protect our professionals who sometimes are led  
15 to get involved in that.

16 MR. SACHDEV: One last question for  
17 any of you. We've also read recently of accounts  
18 of more limited supplies occurring in Canada  
19 because of the restrictions that are being placed  
20 by U.S. pharmaceutical companies on supplies to  
21 Canada. And we've also read accounts of some of  
22 the larger suppliers of the pharmaceuticals back  
23 in the United States looking to alternative  
24 sources, sources where they hadn't previously  
25 looked to identify supply, including over in  
26 Europe, the U.K., and the like.

27 If, in fact, those operations of

1 pharmacies in the various provinces do decide to  
2 change their supply and start supplying product  
3 to the United States from those European sources,  
4 or England, or Ireland, would that be considered,  
5 under the provincial laws an acceptable practice  
6 in Canada? Would it be a legal practice? Would  
7 it be a practice that you all believe is an  
8 appropriate practice?

9 MS. WELLS: Are you speaking about  
10 using unapproved drugs?

11 MR. SACHDEV: Well, it's unclear. I  
12 mean, these are drugs that they would be ?? what  
13 we've read about in the recent articles is that  
14 these pharmacies -- whether it's the Internet  
15 website that's got a pharmacy behind it or a  
16 pharmacy that's a cross-border pharmacy that's  
17 sending drugs to the United States -- as they run  
18 out of certain supplies, perhaps they are looking  
19 elsewhere, including in Europe and the U.K. to  
20 find additional supply. What that supply is an  
21 open question. The question I'm asking is what  
22 your view would be of the shipment of those  
23 products into the United States if, in fact, they  
24 go from a pharmacy that's located in one of the  
25 provinces?

26 MS. WELLS: We would not condone  
27 pharmacists dispensing unapproved drugs

1           regardless of where the patient lived.

2                   MR. SACHDEV:   And so your view is that  
3           the drug would be unapproved in Canada when it  
4           came into your country.

5                   MS. WELLS:   That's right.

6                   MR. SACHDEV:   So the exportation of  
7           that product would not be something that you  
8           would support.

9                   MS. WELLS:   That's right, because one  
10          of the things that -- there seems to be a sort of  
11          a misconception that trans-shipment is allowed in  
12          Canada.   And we've had it confirmed by Health  
13          Canada that that's not the case.   There is a  
14          section in the food and drug regulations that  
15          there are some sort of misinterpretations of, but  
16          if our pharmacies were dispensing unapproved  
17          drugs to anyone, regardless, that would not be  
18          condoned.

19                   MR. SACHDEV:   So any of the drugs  
20          coming from   Europe ??  the so-called trans-  
21          shipped drugs -- would be not consistent with  
22          your import-for-export provisions?

23                   MS. WELLS:   If they weren't approved  
24          for use in Canada, right.

25                   MR. SACHDEV:   Other folks want to  
26          comment on that?

27                   MR. JULIEN:   Very briefly.       For

1 pharmacists, they are allowed to buy drugs from  
2 authorized manufacturer or wholesalers. We  
3 recommend to do that, so we assume that the drugs  
4 that they are selling have been authorized by  
5 Health Canada. And what we say to Health Canada  
6 is we should improve the supply, the security of  
7 the supply chain, and have a better recognition  
8 and probably some type of standard and permit for  
9 the wholesalers, a better framework with them in  
10 order to secure that, and be sure that the drugs  
11 that are sold are authorized in Canada. That's  
12 the main point about the product.

13 MR. SACHDEV: And just a follow-up on  
14 that comment. I think each of you, particularly  
15 Mr. Guse, you've mentioned that you're seeing  
16 sort of prescription brokers, pharmacy  
17 affiliates, prescription co-signers, fulfillment  
18 centers, international prescription service  
19 pharmacies. I guess the question I have for each  
20 of you that's a follow-on to this is: In terms  
21 of the distribution chain that you're talking  
22 about, what pressure are you already seeing in  
23 Canada as a result of the increased importation  
24 into the United States of these drugs to the  
25 distribution system, and what would you expect if  
26 Congress does - the U.S. Congress decides to  
27 legalize importation?

1                   MR. GUSE: Thank you. The difficulty  
2                   is that because this business is again, a  
3                   frontierism, gold- rush type of entrepreneurship  
4                   -- let's get into it -- we are seeing  
5                   prescription brokers, we're seeing a lot of  
6                   intermediaries between the patient and the  
7                   pharmacist or the pharmacy. So the challenges  
8                   are, from an investigation perspective, to follow  
9                   the drug, to follow the information, to follow  
10                  the money - the challenges are getting greater  
11                  and greater, and frankly, beyond the expertise  
12                  and resources of any one provincial licensing  
13                  authority to work on their own. So the  
14                  challenges that those types of situations present  
15                  are very grave, to say the least, because we have  
16                  difficulties looking for the chain, the  
17                  connection between these businesses.

18                  And I just wanted to clarify one  
19                  point. In Canada, when people use the term  
20                  ?internet pharmacies?, I just want to be certain  
21                  that the task force is aware that we really don't  
22                  have virtual Internet pharmacies. They would  
23                  have to have a location. They would have to have  
24                  a traditional -- if I can use that term --  
25                  license, so there is a hard and fast location.  
26                  They just choose to service Americans or other  
27                  jurisdictions outside of that location.

1           MR. SACHDEV:   So would you expect, if  
2           the U.S. Congress were to provide a broad  
3           legalization of importation, would you expect  
4           additional changes in the way your distribution  
5           system in Canada operates?

6           MR. GUSE:       The distribution for  
7           Canadians?

8           MR. SACHDEV:   Yes.

9           MR. GUSE:   I'm not certain. I guess, I  
10          don't ?? the impact that I would see is if the  
11          Canadian government reflects what your decisions  
12          or the American government has here, that not  
13          only is there a north-to-south flow, but there's  
14          a south-to-north flow. And that, yes, absolutely  
15          would have impact.

16          MR. SACHDEV:   And so you would expect  
17          to see more of these prescription brokers and  
18          affiliates and fulfillment centers?

19          MR. GUSE:   Well, I think as we work  
20          together to set up a framework where this can be  
21          done, and it doesn't have to be done in  
22          contravention of some of your laws, and maybe  
23          some of our's, so the agreements are set up, the  
24          standards are in place, and if it's going to be  
25          done, this is how it's to be done. I think it  
26          would take those types of activities, they would  
27          be diminished. And if pharmacies were involved

1 in those types of activities that maybe exploit  
2 the patient or take away the patient autonomy,  
3 that those businesses would discontinue.

4 CHAIRMAN CARMONA: Yes, Ms. Hardin.

5 MS. HARDIN: I just want to clarify  
6 one point that just came up. Ms. Wells, you  
7 mentioned that you've confirmed with Health  
8 Canada that trans-shipment is illegal in Canada.  
9 Do you know what penalties someone would face if  
10 they did engage in trans-shipment?

11 MS. WELLS: That would be, I guess,  
12 akin to illegal importation, and we don't  
13 recognize trans-shipment at all. So once a  
14 shipment of pharmaceuticals hits our shores,  
15 regardless of -- like where it's ending up is  
16 irrelevant, so I'm not sure of the penalties, but  
17 it would be considered to be illegal importation  
18 of drugs. But I don't know the penalties.

19 MS. HARDIN: So you don't have a sense  
20 of what kind of action either a provincial  
21 government or your federal government could take  
22 against someone who was engaging in that kind of  
23 activity?

24 MR. GUSE: Well, the federal  
25 government would be responsible for the product  
26 coming in and what type of activities, or not  
27 activity, what laws that would contravene. If

1 the pharmacy, for example, was using those  
2 products, then it would be a provincial  
3 jurisdiction of the regulatory authorities, and  
4 they could potentially lose their license from a  
5 provincial activity. But in Canada, the product  
6 - as our Quebec colleagues have said - the  
7 product is more so -- the quality and safety of  
8 the product is a federal jurisdiction. And if  
9 the product is coming in illegally and being used  
10 illegally, then it would be federal monitoring  
11 activity, and any fines and stuff would be the  
12 federal government. We would then, if it  
13 involved a pharmacist or pharmacy, then it would  
14 be up to the provincial licensing authorities to  
15 address that issue.

16 MS. HARDIN: And is the provincial  
17 authority to take away someone's license, is that  
18 the same penalty someone would face for, for  
19 example, filling prescriptions that were signed  
20 by a United States doctor or someone who wasn't  
21 licensed in Canada? Is that the same penalty, or  
22 is that the only penalty?

23 MR. BINET: Well for us in Quebec, the  
24 penalty could be the same. It depends on the  
25 disciplinary committee, but as it's written in  
26 our comments, I think, there was one pharmacist  
27 who engaged in cyber pharmacies, and his right to

1 practice was suspended for 18 months. And as I  
2 said before, to own a pharmacy in Quebec you need  
3 to be a pharmacist, so when you are suspended as  
4 a pharmacist, you don't keep your title  
5 pharmacist. So you cannot own your pharmacy, so  
6 you have to sell it. So it's a big, big penalty  
7 for a pharmacist engaged in ?? that's probably  
8 why we don't have a broad problem with cyber  
9 pharmacies in Quebec regarding pharmacists,  
10 because we act quickly. The problem is that  
11 those aren't pharmacists who are opening their  
12 sites. So what the penalty would be for those  
13 people who are now in front of the Superior Court  
14 for penal lawsuit for three companies, three  
15 cyber pharmacies, the fine that we're seeking is  
16 more than \$150,000 for engaging in those  
17 activities right now. So we're in front of the  
18 Superior Court, so we don't know until maybe 2006  
19 what will happen, but this could be the penalty  
20 or the fine for this kind of practice.

21 CHAIRMAN CARMONA: Thank you all for  
22 taking the time. Thank you for your patience.  
23 We appreciate your input. I know some of you  
24 have to catch some flights, so thank you for  
25 staying a little longer with us to answer the  
26 panel's questions. We really do appreciate your  
27 input. We'll go ahead and switch over to the

1 next panel now. Thank you very much.

2 (Whereupon, the proceedings in the  
3 above-entitled matter went off the record at  
4 2:43:04 p.m. and went back on the record at  
5 2:45:06 p.m.)

6 CHAIRMAN CARMONA: All right. Ladies  
7 and gentlemen, we'll begin with Panel II. And  
8 let's start at the other end this time with Dr.  
9 Jack Calfee. Thank you, sir.

10 DR. CALFEE: Okay. Thank you. I'm  
11 honored to be here. I submitted some written  
12 comments, and I would just summarize those  
13 briefly. I assume at this point we should move  
14 along rapidly. I'll only look to two issues of  
15 the long list that were published in connection  
16 with these hearings, and that is Item 8 where the  
17 wording: "Assess the potential short- and long-  
18 run impacts on drug prices and prices for  
19 consumers associated with importing drugs from  
20 other countries." And Item 9: "Assess the  
21 impact on drug research and development and the  
22 associated impact on consumers and patients if  
23 importation were permitted."

24 On the first of those two items, which  
25 is the impact on drug prices, I think that the  
26 impact depends very much on what kind of  
27 importation law we have. If we have a simple law

1 that essentially permits free importation with  
2 some sort of reasonable safety standards to give  
3 people reasonable assurance that they're getting  
4 safe drugs, and nothing much more than that, then  
5 I think that the dynamics would be similar to  
6 some of those that the earlier panel was  
7 referring to briefly; and that is that the demand  
8 for drugs from Canada to be shipped to the U.S.  
9 would quickly exceed any volumes that are  
10 available in Canada. The manufacturers would  
11 restrict supplies to Canada. They would refuse  
12 to undercut their profits by shipping drugs to  
13 Canada, or by arranging for drugs to be shipped  
14 from Canada at Canadian prices.

15 The Canadian authorities would face  
16 some difficult problems. There would be movement  
17 towards trans-shipment from other nations, which  
18 I'll mention in a moment, but it's unlikely that  
19 the supplies that would arrive in the U.S. would  
20 be sufficient to lower prices very significantly.

21  
22 If Congress passes a different kind of  
23 law, the kind of laws that are now under active  
24 review, which more or less requires manufacturers  
25 to satisfy demand from wholesalers in Canada at  
26 Canadian prices, then it's possible that large  
27 supplies would arrive at the U.S. There is good

1 chance that there would be a mismatch between the  
2 kinds of drugs that have been approved in Canada,  
3 specifically the dosages, et cetera, which Dr.  
4 Danzon can tell you more about. But,  
5 nonetheless, at least for certain of the more  
6 heavily used drugs, we could expect supplies to  
7 arrive fairly rapidly. And the question then is  
8 what would happen to prices. And if the  
9 manufacturers are literally required to sell to  
10 wholesalers at Canadian prices, then we're going  
11 to get a supply of at least quite a few drugs at  
12 Canadian prices, and we would be in a very  
13 strange situation because there isn't just one  
14 price in Canada. The PMPRB regulates prices in a  
15 general fashion, but then the provinces have  
16 their own regulations, and those usually result  
17 in prices that are lower than the PMPRB limits,  
18 and different provinces are different. We would  
19 end up in a situation in which American prices  
20 are being linked to certain specific Canadian  
21 prices, which would be a very strange situation.

22  
23 If Canada were to permit mass trans-  
24 shipment, then at some point U.S. prices would be  
25 linked to prices in Greece or Portugal or Spain  
26 or some place like that, again a very, very  
27 strange situation which I don't think would be

1       tenable politically.

2                   On the question regarding research and  
3       development, I think the scenario that commands  
4       attention is the second one that I just  
5       mentioned, in which manufacturers are more or  
6       less forced to ship sufficient drugs so that the  
7       shipments have an impact on U.S. prices, and U.S.  
8       prices are pushed down towards Canadian prices.  
9       There, I think the analysis is pretty  
10      straightforward. Drug development is conducted  
11      in order to realize profits later on. If the  
12      expected profits are reduced, manufacturers will  
13      rationally reduce their R&D, and more  
14      specifically, they'll reorient their R&D, to the  
15      extent they pursue it, towards the kind of  
16      development that's less risky, that produces  
17      drugs that have less potential. And eventually,  
18      we would end up with some very serious adverse  
19      effects on R&D incentives. And that summarizes  
20      my remarks.

21                   CHAIRMAN CARMONA: Thank you, sir.  
22      Our next speaker is Mr. Jeff Lemieux.

23                   MR. LEMIEUX: Thank you, Dr. Carmona,  
24      for the opportunity to comment. My name is Jeff  
25      Lemieux. I'm with a small group called  
26      Centrists.org. Our mission is to help  
27      policymakers like you develop ideas that could

1 achieve lasting bipartisan support on some of the  
2 toughest national issues, like health care. And  
3 I know the panel has already heard from consumer  
4 advocates and elected officials talking about how  
5 important it is to reduce prices and improve drug  
6 coverage for the uninsured and people with low  
7 incomes, especially senior citizens, so I won't  
8 talk about that. And I know you've also heard  
9 from experts on security, and from people with  
10 serious illnesses who are very concerned about  
11 the safety of drugs imported, and so I won't talk  
12 about that either.

13           Instead, what I'd like to do is offer  
14 a very broad and admittedly simple economic  
15 analysis of globalization, and how medicines  
16 would be priced around the world if unrestricted  
17 trade and pharmaceutical prices became the norm.

18       And this follows on the comments from Jack.

19           First, there's three characteristics  
20 that differentiate medicines from trade and some  
21 other products, I think. The industry is  
22 extensively involved with government.  
23 Governments sponsor basic research, monitor  
24 safety, and act as the main purchasers and set  
25 prices in some countries.

26           Second, with medicines, there are  
27 strong moral issues and economic externalities;

1 that is, if some people don't take their medicine  
2 or get vaccinated, other people will get sick, so  
3 we have a public health issue.

4 And third, the main cost of medicines  
5 is in discovery and development. This is similar  
6 to the software industry and in some respects to  
7 the telecommunications industry. Usually, modern  
8 trade involves a search for the lowest production  
9 costs. If computer programmers in India can do  
10 the same job cheaper, companies all over the  
11 world will hire them. If toys can be made  
12 cheaper in China, we'll import Chinese toys, and  
13 this is a very good thing usually. Trade  
14 sometimes works in messy and disruptive ways, but  
15 usually countries that open themselves up to  
16 trade prosper, and countries that buy products at  
17 comparative advantage overseas prosper, as well.

18 However, my impression of the  
19 prescription drug industry is that the production  
20 costs are extremely low, and I believe they're  
21 fairly uniform across the world. So instead,  
22 international trade in medicines is essentially a  
23 search for the lowest pricing system.

24 I think, and I think this is  
25 consistent with what Jack said, that the long-run  
26 impact of unrestricted trade in pharmaceutical  
27 prices would be a new equilibrium with overall

1 global prices not too different from today's.  
2 However, the distribution of global prices would  
3 change, and the process of getting to this new  
4 equilibrium could be very messy.

5 U.S. retail prices for people without  
6 insurance or group discounts could fall, other  
7 developed countries with price controls could see  
8 some upward pressure on their prices. The  
9 problem in my mind is what could happen in the  
10 less-developed countries.

11 For most products, free trade leads to  
12 a long-run tendency toward one world price.  
13 Economists sometimes call this the tendency for  
14 exchange rates to change in a way that leads to  
15 purchasing power parity. Ten dollars buys ten  
16 dollars worth of a certain tradable good anywhere  
17 in the world if markets are relatively free. And  
18 the question is, do we want that for medicines?  
19 In a world with unrestricted trade and drug  
20 prices, companies will respond in their interest.

21 They'll try and estimate how much of their  
22 product is likely to be purchased for in-country  
23 use, and not allow more supply into that country  
24 than is needed. And those supply responses by  
25 producers in turn will lead importers to search  
26 for better deals in poorer and countries.  
27 Because prices for medicines currently vary

1 widely from rich to poor countries, this drug  
2 price arbitrage business will be so lucrative  
3 that they'll have a hard time resisting that  
4 temptation.

5           When Canadian trade tops out, for  
6 example, importers will turn to other rich  
7 countries with low government-set prices. When  
8 those sources run low, in turn they'll begin to  
9 import from lower-priced developed countries like  
10 Portugal or Greece or Taiwan. Ultimately, less  
11 developed countries will be targets, and their  
12 prices would be forced up toward world levels.  
13 And the question is do we really want Egypt or  
14 Thailand or Brazil or Turkey to pay the same  
15 price for medicine as the U.S. and Canada and  
16 Sweden. I mean, we may not be particularly  
17 concerned if Canadian or German prices have to go  
18 up a little bit, but with some of these other  
19 countries, there may be a compelling reason to be  
20 concerned.

21           Moreover, I certainly am not a safety  
22 expert, but imports from poorer countries would  
23 clearly pose a greater risk of adulterated,  
24 improperly handled, or counterfeit products.

25           Now the bills in Congress to make drug  
26 importation more widespread and legal say we're  
27 not going to import from these less developed

1 countries. But over time without a great deal of  
2 international cooperation, there would be  
3 tremendous pressure to do so, I think, and we  
4 could expect a lot of leakage. And let me wrap  
5 up with two quick recommendations.

6 First, it seems to me, I'm not a  
7 lawyer but I think the FDA should probably invest  
8 very heavily in tracking the production and  
9 transportation and storage of imported drugs,  
10 regardless of whether or not the legislation  
11 passes to make it legal. It's just too  
12 important. I think the FDA shouldn't get hung up  
13 on legalities. If people are importing drugs by  
14 various means regardless of the law, the FDA  
15 should still do everything in its power, and the  
16 budget should permit the FDA to do everything in  
17 its power, to make sure these things are as safe  
18 as possible.

19 And second, I think the best forum to  
20 discuss local drug pricing, and whether or not we  
21 really want to push toward one global price, or  
22 to manage it differently might be an organization  
23 like the World Trade Organization or other  
24 international forums. Perhaps less developed  
25 countries could be induced to help the developed  
26 world monitor and control counterfeiting in  
27 exchange for lower than equilibrium prices. To

1 some extent, markets are always going to tend  
2 toward one global price, and no trade regime is  
3 going to be air-tight in preventing that  
4 pressure. However, there may be some win-win  
5 outcomes where drug companies and distributors  
6 can be confident that they can essentially give  
7 away medicines in the poorest countries, and sell  
8 other medicines for prices that are reasonable in  
9 less developed countries that aren't so poor, but  
10 still not greatly undercut their prices in the  
11 richer developed countries. Thank you.

12 CHAIRMAN CARMONA: Thank you, sir.  
13 Our next speaker is Mr. Iain Cockburn.

14 DR. COCKBURN: Thank you. I'll  
15 briefly introduce myself. I'm a Professor of  
16 Finance and Economics at Boston University. I've  
17 devoted much of my professional career to  
18 researching competition pricing and innovation in  
19 the pharmaceutical business. Thank you, Mr.  
20 Chairman and task force members, for the  
21 opportunity to express my views on this  
22 controversial and difficult issue.

23 To that extent, my remarks in my  
24 written submission will echo those that have  
25 already been made. Let me highlight what I think  
26 are the most important aspects here.

27 At present, importation into the

1 United States is slightly larger than a trickle,  
2 but it's not quite a flood. Legislative change  
3 to promote or legitimize importation to the  
4 United States will surely have a dramatic impact  
5 on at least two fronts.

6 The impact is surely going to be, and  
7 I think is intended by the sponsors of this  
8 legislation, to lower U.S. prices, which will in  
9 turn result in lower global revenues for the  
10 pharmaceutical industry. Let me address how I  
11 believe this will affect incentives to do R&D.

12 I'm sure the panel doesn't need to be  
13 reminded that pharmaceutical R&D is notoriously  
14 costly, lengthy, and a risky process. Proponents  
15 of price regulation or importation I think are  
16 unrealistically sanguine about the impact of  
17 lower global revenues and profits.

18 We have little concrete evidence on  
19 this point, but in part that reflects the fact  
20 that the United States has played an  
21 extraordinarily important role in the global  
22 pharmaceutical market over the past 30 to 50  
23 years. People have attempted to draw lessons  
24 from the experience of Canada in the 60s and 70s  
25 and through into the 1980s with compulsory  
26 licensing, or experiments by Italy in abolishing  
27 pharmaceutical patents. The fact is that these

1 are irrelevant largely to decision-making for a  
2 business in which the United States constitutes  
3 50 percent of the market.

4 I think this is really a shot in the  
5 dark if the United States goes down the road of  
6 substantially lowering prices. I think it's very  
7 difficult to predict the outcome. My personal  
8 belief is that it will substantially reduce  
9 incentives for R&D. There's a lot of uncertainty  
10 on this point.

11 A more subtle issue than simply the  
12 effect on the total amount of R&D, I think, is  
13 the impact of trying to force U.S. prices into  
14 line with the prices charged or realized in  
15 countries with more aggressive price regulation  
16 scheme, as it will affect the composition, not  
17 just the level, of research spending.

18 Jack Calfee mentioned this question of  
19 business will respond by trying to please  
20 regulators rather than consumers, and we also  
21 need to recognize the very important role of the  
22 United States market in sending signals by  
23 market-determined prices to the industry about  
24 which projects to work on.

25 Re-importation or importation on a  
26 large scale surely will have the effect of  
27 substituting foreign price regulators' relative

1 valuation of different drug products for market  
2 signals in the United States. That will remove  
3 this important set of incentives and signals to  
4 the industry. I find this deeply concerning.

5 My second set of comments relate to  
6 the global impact of pressures to harmonize  
7 prices across countries. We should recognize, I  
8 think, the role of the international patent  
9 system in supporting the previous regime in which  
10 there have been significant price differences  
11 charged in different countries. If the United  
12 States legalizes imports, and these occur on a  
13 large scale, just imagine what will happen in  
14 Canada. I think we're deluding ourselves if we  
15 believe the Canadians will respond passively.

16 Canada has a number of options, one of  
17 which will be to, if they face serious domestic  
18 shortages and upward pressure on prices, they  
19 have a number of options. One is to ban export  
20 to the United States. Another, something like  
21 Canada has done in the past, will be to announce  
22 a national medical medicine supply emergency and  
23 take away patent rights in Canada. Now I think  
24 this is quite a real possibility. Or they can  
25 turn around and pass the buck on both of these  
26 fronts to some country which is further down the  
27 income chain.

1           I think there's a very real danger of  
2 this spreading as a contagion if the United  
3 States starts trying to absorb large amounts of  
4 production supply from other countries. And I  
5 think it's going to lead to a substantial  
6 weakening, if not a collapse of the international  
7 patent system, which I would note the United  
8 States has worked very hard for several decades  
9 to try to strengthen and harmonize.

10           The other issue where I think we're  
11 deluding ourselves is to suppose that we can ??  
12 the legislators can anticipate all of the actions  
13 that the industry can take to respond to attempts  
14 to put Canadian prices in place in the United  
15 States. As already mentioned, pharmaceutical  
16 companies have the option, a number of ways to  
17 resegment the market if patent rights and  
18 importation legislation are taken away. They can  
19 reformulate products, they could choose not to  
20 introduce them in different countries. Those are  
21 first guesses. I think we should be very careful  
22 not to underestimate the ability of the industry  
23 to come up with clever and effective ways to  
24 resegment the market, which will be socially  
25 costly.

26           These considerations lead me to urge  
27 the task force to very cautious about

1 recommending moves which would substantially  
2 increase the level of imports into the United  
3 States. Thank you.

4 CHAIRMAN CARMONA: Thank you, Dr.  
5 Cockburn. Our next speaker is Dr. Frank  
6 Lichtenberg from Columbia. Thank you, sir.

7 DR. LICHTENBERG: Thank you. I  
8 appreciate the opportunity to address the task  
9 force. I'm going to be less ambitious than Jack  
10 Calfee, who chose to address two of your issues.

11 I'm only going to address one, one of the same  
12 ones that Jack and Iain did - the impact on  
13 pharmaceutical R&D. I have prepared a set of  
14 slides labeled, "The effects of re-importation on  
15 new drug development." And if you could refer to  
16 those, that would be helpful.

17 I'd also like to say economists have a  
18 reputation for never being able to agree with one  
19 another, but my sense is actually there's a fair  
20 amount of agreement among the economists sitting  
21 here, at least.

22 So I begin with a hypothesis, and the  
23 hypothesis says that re-importation will reduce  
24 incentives to develop new drugs which will slow  
25 the rate of increase of longevity and quality of  
26 life. That's not to say that there may not be  
27 some short-run benefits of re-importation, so re-

1 importation, suppose, does reduce prices and  
2 increase access. And that would be of some  
3 benefit to consumers today. However, we have to  
4 also bear in mind the long-run consequences,  
5 which in my view, and I will try to provide some  
6 evidence of this, would be a reduction in future  
7 drug development, which would not be a good thing  
8 for future generations.

9 To sort of make this case, I have this  
10 very simple schematic representation of new drug  
11 development, which again puts at the center  
12 expected profits. Like or not, pharmaceutical  
13 innovation is a profit-seeking business, and  
14 expected profits of drug development depend  
15 primarily -- depend on several things, the  
16 expected drug price, the expected market size,  
17 and, of course, cost of drug development. And so  
18 changes in either expected drug prices, or  
19 expected market size, will affect expected  
20 profits and, therefore, affect the number of  
21 drugs developed, hence patient outcomes.

22 I've done a lot of research which  
23 tries to assess the effect of new drug  
24 development on longevity, quality of life, and so  
25 forth. This is sort of formalized a little bit  
26 in my fourth slide, which shows a very simple  
27 equation where profits from drug development

1 depend on the expected price, the expected  
2 quantity and cost, both variable and fixed costs  
3 of drug development.

4 Now basically, what this shows us is  
5 that given both variable and fixed costs, profits  
6 of drug development are reduced when either price  
7 or quantity is reduced. So if a drug company  
8 expects either a smaller price or a smaller  
9 quantity, then the expected profitability of drug  
10 development declines. Moreover, expected price  
11 and expected market size have similar effects on  
12 innovation incentives. That is, suppose I'm a  
13 drug manufacturer, and I suddenly found out that  
14 there are going to be half as many consumers of a  
15 product as I originally thought. Well, that  
16 means my revenue is going to be reduced by 50  
17 percent. That's going to make the market much  
18 less attractive.

19 However, if there are 50 percent fewer  
20 consumers, at least I only have to produce 50  
21 percent as many pills. Whereas, suppose instead  
22 that the price were reduced 50 percent, suppose  
23 that I thought the price was going to be \$20,  
24 instead it's going to be \$10. Again, my revenue  
25 is going to be reduced by 50 percent, but now I  
26 still have to produce the same number of pills  
27 approximately as I did before. So a reduction in

1 price has a more negative effect on profits than  
2 a similar percentage reduction in quantity. So,  
3 therefore, I think that evidence about the effect  
4 of market size on drug development can provide  
5 insight into the probable effect of re-  
6 importation or price controls on drug  
7 development, so I'm going to be a little less  
8 skeptical than Iain was. Iain said he  
9 thought that it was going to be very, very  
10 difficult to assess the impact of re-importation  
11 on pharmaceutical R&D. I'm going to take a stab  
12 at that. And here's how I'm going to ?? what I'm  
13 going to do is try to provide some evidence about  
14 the sensitivity of the number of drugs available  
15 to treat a disease to the prevalence of that  
16 disease, the size of the market. This pertains,  
17 by the way, to that poster over there on the wall  
18 that says "1983." That's the Orphan Drug Act.  
19 Congress passed the Orphan Drug Act because it  
20 recognized that there were weak incentives of  
21 companies to develop drugs for rare diseases.  
22 The market was too small, and the government  
23 explicitly created incentives to develop drugs  
24 for rare diseases. And, in fact, industry  
25 responded quite a lot to that.

26 So the illustration that I'm going to  
27 give you looks at 14 different kind of cancer.

1 So I have a table which shows basically two  
2 columns of numbers. It shows for different kinds  
3 of cancer, how many people have that kind of  
4 cancer. For example, in the United States, the  
5 most prevalent form of cancer is breast cancer,  
6 followed by prostate and lung cancer. Those are  
7 the most prevalent forms of cancer. And guess  
8 what, those are the forms of cancer that have a  
9 relatively large number of drugs.

10           Whereas, if we look at relatively rare  
11 forms of cancer, like eye, bone, and testicular  
12 cancer, there are very, very few drugs developed  
13 to treat those forms of cancer. That's because  
14 the incentives aren't there. And, in fact, when  
15 I do a very simple statistical analysis to try to  
16 assess the sensitivity of the number of drugs to  
17 the prevalence of cancer, I find that a ten  
18 percent increase in cancer incidence is  
19 associated with about a ten percent decrease in  
20 the number of drugs. And so what does that  
21 imply? That suggests that a ten percent decrease  
22 in drug price would result in at least a ten  
23 percent decrease in the number of drugs. If drug  
24 prices fall by ten percent in the United States,  
25 this would suggest that we might expect to see  
26 something like a ten percent reduction in the  
27 number of new drugs developed.

1           So if re-importation did, in fact,  
2 significantly reduce drug prices in the United  
3 States, then I would predict that in the long-run  
4 this will result in a significant reduction in  
5 number of new drugs developed, and that this  
6 would, in turn, have adverse effect on the rate  
7 of longevity increase, improvements in quality of  
8 life, and so forth.

9           This evidence is extremely  
10 preliminary, I would admit, and I think further  
11 study is needed. But I think other evidence  
12 suggests that, in fact, pharmaceutical R&D  
13 investment is very sensitive to incentives. I  
14 read an article on the airplane coming down today  
15 about Bioterrorism, and how, in fact, the  
16 response of the industry to developing  
17 bioterrorism medication seems to be very poor,  
18 perhaps due to weak incentives.

19           Also, there's a lot of evidence that  
20 the vaccine industry has diminished in response  
21 to very low prices. So in conclusion, I think  
22 the committee ought to keep in mind the distinct  
23 possibility that re-importation will reduce  
24 incentives to develop new drugs, which will slow  
25 the rate of increase of longevity and quality of  
26 life. Thank you.

27           CHAIRMAN CARMONA: Thank you, Dr.

1 Lichtenberg. Our next speaker is Dr. Patricia  
2 Danzon from Penn. Thank you, ma'am.

3 DR. DANZON: Good afternoon, Mr.  
4 Chairman, and thank you for the opportunity to  
5 address the task force. I'm going to sound a bit  
6 like a broken record, but I'm going to plow ahead  
7 anyway.

8 I'm going to try to reiterate certain  
9 points that my colleagues have made on the effect  
10 on prices, and particularly draw on some of the  
11 studies that I've done that may be relevant to  
12 the likely impact.

13 Let me start off by stating my  
14 conclusions, which are that the precise impact of  
15 an importation provision on drug prices in the  
16 U.S. are very hard to predict, but what is  
17 certain is that the savings to U.S. consumers  
18 would be less than appears simply by comparing  
19 say the prices available to consumers in Canada  
20 versus the U.S. for specific drugs now. And  
21 paradoxically, even though there would be little  
22 savings to U.S. consumers from lower prices, the  
23 impact on R&D could be significant, I think  
24 because of reduction in sales overseas. Let me  
25 give you the reasons why I come to those  
26 conclusions, and I list four in the written  
27 comments.

1                   First, there's a difference, a  
2 mismatch in formulations.           Second, the  
3 withholding of supply.   Third, the increase in  
4 prices abroad, and fourth, the question of  
5 whether any savings at the manufacturer price  
6 level would, in fact, be passed on to consumers.

7       So let me take each one of those in turn.

8                   First, the heterogeneity of products.

9       In a study that we recently completed, we looked  
10 at a sample of 249 compounds in the U.S. that  
11 accounted for about 60 percent of U.S. sales in  
12 1999.   These same compounds accounted for about  
13 the same percent, 60 percent of sales in Canada  
14 and the U.K.   So Canada and the U.K. have very  
15 similar pharmaceutical markets to the U.S.   But  
16 for the other countries in our study, the leading  
17 European countries, Japan, Mexico and Chile,  
18 these products accounted for only about 30 to 40  
19 percent.   And when we restrict the comparison to  
20 the matching formulation, or the same  
21 formulation, the same strength which would be  
22 necessary for importation, the matching share  
23 goes down by half, so we're really looking at a  
24 small fraction of both U.S. sales and an even  
25 smaller fraction of foreign market sales that are  
26 in the same formulations and the same compounds  
27 as the U.S.   That's even without controlling for

1 same manufacturer and whether it's on or off  
2 patent.

3 For those formulations that are the  
4 same, I would expect manufacturers to restrict  
5 supply to foreign countries. And so then the  
6 question would be, how willing are foreign  
7 wholesalers to divert some of the shipments that  
8 go to their countries to the U.S., rather than  
9 satisfying their own consumers. And again I  
10 think the conclusion has to be that because the  
11 U.S. market is so large in terms of volume,  
12 relative to most foreign markets, they would have  
13 to be willing to ship a very significant fraction  
14 of their volume to us in order to make a dent on  
15 prices in the U.S. So roughly, just as a back-  
16 of-the-envelope calculation, I'd say even if we  
17 had importation from Canada and all of Europe, so  
18 volumes would be comparable to the U.S., if they  
19 were willing to ship say 20 percent of their  
20 sales to us for the formulations that match, that  
21 would maybe make up 20 percent of our sales.  
22 Arguably, not enough to make a dent on prices in  
23 the U.S.

24 In the longer-run, I would expect  
25 manufacturers to respond by trying to move to a  
26 uniform pricing policy, and that would mean  
27 leveling up foreign prices rather than leveling

1 down U.S. prices. That comes out of straight  
2 economics.

3 Some foreign countries might be  
4 willing to pay those higher prices, and the drugs  
5 would be launched. There would probably be  
6 restricted utilization in order to stay within  
7 their health care budgets. But a significant  
8 number of foreign countries would probably not  
9 get those drugs, and the drugs would simply not  
10 be launched. And again, for some empirical  
11 evidence, I'd refer you to a study that's on my  
12 website done with Richard Wang and Liang Wang, in  
13 which we studied the launch of 80 NCEs in 25  
14 countries in the 1990s. And we found that in the  
15 countries with lower prices, and the countries  
16 that are significant parallel exporter countries  
17 in Europe, the launch of drugs in those countries  
18 was fewer, and they occurred with significant  
19 delay, so there's strong evidence of delayed  
20 launch and non-launch.

21 Finally, the question of: Even if  
22 there were availability of foreign product at  
23 lower prices, would those price differentials be  
24 passed on to consumer? That requires enough  
25 supply and competition at the wholesaler level  
26 for the lower prices to be passed on to  
27 pharmacies. And then an ability for third-party

1 payers and consumers to get those price savings.

2 I would submit that given the limited supply,  
3 the price, if there are price differences,  
4 they're unlikely to be passed on to retail  
5 pharmacy. And even if they were, it would take a  
6 sort of claw-back activity by third-party payers  
7 to reduce the reimbursement to pharmacies to  
8 capture the average savings. That sort of claw-  
9 back has occurred in the U.K. and the Netherlands  
10 in trying to get savings from parallel trade  
11 there, but if it were to occur in the U.S., I  
12 think it would really penalize those pharmacies  
13 who were trying to dispense U.S.-sourced drugs  
14 for reasons of safety, so there would be a lot of  
15 resistance to that.

16 For consumers who are paying out-of-  
17 pocket, there simply would not be enough  
18 competition for any lower prices to be passed on.

19 So the bottom line conclusion is, I think that a  
20 broad importation policy would likely harm  
21 foreign consumers significantly in terms of  
22 reduced access. It would not result in  
23 significant savings to U.S. consumers, but there  
24 would be reduction in R&D in the long-run simply  
25 because there would be lower global revenues, and  
26 hence, reduced incentives for R&D.

27 CHAIRMAN CARMONA: Thank you very much

1 for your comments. Panel members, questions for  
2 our guests? Dr. O'Grady.

3 DR. O'GRADY: Yes. I'd like to ask  
4 Dr. Calfee a question, please. I'm just trying  
5 to drill down a little bit in terms of the way  
6 you laid this out in some of your testimony, both  
7 written and verbal, in terms of thinking about  
8 how you get to an appropriate price in this area,  
9 and sort of your concerns about administered  
10 prices, or however you want to ?? formula-driven,  
11 or the way it's done in other countries. And I  
12 guess I wanted to ask you kind of how you think  
13 in terms of relative terms to the way that we set  
14 prices in this ?? clearly, we wouldn't be having  
15 this discussion if there was not much of a price  
16 differential between the United States and  
17 Canada, in particular. And I understand the  
18 concerns about having the government set the  
19 price. Can you talk a little bit about how you  
20 think that in terms of the market prices -- I  
21 mean are we at a point ?? I guess my concerns and  
22 my own thinking are, with third-party payment  
23 involved, it's very hard to have the kind of  
24 price sensitivity we would see in terms of this,  
25 as we do in other goods and services. Jeff's  
26 discussion of Toyotas and world prices.

27 In terms of an area where we have

1 third-party payers, an area where we have fairly  
2 strong patent protections, how do you view the  
3 kind of relative price settings between the two  
4 systems? And can you at least discuss that a  
5 little bit more?

6 DR. CALFEE: I'll take a shot at it.  
7 First of all, I would emphasize the difference  
8 between drugs being purchased by third-parties,  
9 and being purchased by consumers for themselves.

10 My overall take on the U.S. market is that most  
11 consumers are not very sensitive to drug prices  
12 because they don't pay very much for the drugs.  
13 Most third-party payers are quite sensitive to  
14 drug prices because they do have to pay for them,  
15 and they have to compete with other organizations  
16 so they have an incentive to minimize their  
17 costs, if they can.

18 There's a big difference between a  
19 therapeutic category, which is only one effective  
20 drug which we sometimes have for a while, and a  
21 therapeutic category in which we have two or  
22 three, or several effective drugs. As soon as  
23 that second drug enters the market, these large  
24 third-party payers get pretty aggressive in  
25 negotiating discounts. Some of those discounts  
26 can be pretty substantial. When you get three,  
27 four, or five different drugs like you do in the

1        statin cholesterol-reducing market, you get a lot  
2        of discounting. And in my own opinion, it works  
3        pretty well. And then you get the FDA moving  
4        along rapidly to get generics approved, and then  
5        you have a situation in which if you look back at  
6        the total spent in the year 2000, the drugs  
7        accounting for that spent are going generic at  
8        the rate of roughly ten percent of that market  
9        per year. By the end of this year, or by the end  
10       of next year, it's something like 50 percent of  
11       all the spending in the year 2000 will have been  
12       for drugs that have since gone generic. And so  
13       we're getting ?? the prices here are much more  
14       dynamic than we realize.

15                As far as prices overseas are  
16       concerned, what I would emphasize there is no one  
17       has a way to rationally regulate drug prices.  
18       There is no consistent way. That's why countries  
19       differ so radically. That's why it is that  
20       Canada relies mainly upon someone else's drug  
21       price controls rather than their own.

22                And I would just mention one real  
23       problem that's faced by all price controllers and  
24       where the foreign countries have completely  
25       failed, and that lies in the fact that a lot of  
26       new drugs when they're approved, you really don't  
27       know how valuable they're going to be. You often

1 learn much more about the value of a drug after  
2 it's approved than you do before, partly because  
3 of how usage works out, and partly because of how  
4 a drug does outside the controlled clinical  
5 environment in which it was tested. But also  
6 because in many cases, the research that's  
7 performed after approval can tell you more about  
8 the drug than the research that was done before.

9 The statin drugs are probably the leading  
10 example right now. We know a lot more about the  
11 value of statins now than we did five years ago,  
12 and that's all because of post-approval research.

13 As far as I can tell, there is no  
14 regulatory regime that attempts to take that into  
15 account. In a rational regime, if you do  
16 research that shows that your drug is more  
17 valuable, or if you demonstrate that a drug can  
18 be used effectively at one-half or one-tenth of  
19 the dosage, you'd want an adjustment in prices.  
20 That's the kind of thing that you would need in  
21 order to provide some kind of R&D incentives.  
22 You don't get that from price control regimes.  
23 They're very rigid on that kind of thing. Once  
24 they have a price, once the drug starts to flow,  
25 they have no reason to adjust those prices. So  
26 those are some of the reasons that, as you  
27 mentioned, I described in my written testimony

1 about how difficult things get as soon you start  
2 to get into the business of actually trying to  
3 control these prices.

4 DR. O'GRADY: As part of my job, I  
5 have to go out on the new Medicare drug bill and  
6 do town halls with seniors, and it gets down to  
7 fairly simplistic kind of simple statements that  
8 I have trouble answering. I have a cousin in  
9 Toronto. She pays less for her Lipitor than I  
10 do. Why?

11 I understand perfectly the answer you  
12 gave, but what do you think I should tell that  
13 little old lady in Buffalo next month when she  
14 asks about her cousin in Toronto? I mean, I  
15 still have ?? I mean, I understand perfectly the  
16 logic you've laid out. At the same time, she  
17 does know her cousin in Toronto is paying less  
18 than she is.

19 DR. CALFEE: Well, I mean my short  
20 answer is that the Canadians are indulging in a  
21 little bit of free riding on the rest of the  
22 world's research. The Canadians are relying upon  
23 the fact that Pfizer is going to continue to ship  
24 that drug.

25 But it's worth mentioning to some of  
26 these people that if you look back five or ten  
27 years and look at the drugs that were being

1       prescribed then, those drugs are a lot different.

2       A lot of the drugs that people are most worried  
3       about right now, that they're most upset about  
4       paying money for are drugs that didn't exist five  
5       or ten years ago.     And those drugs are very  
6       valuable.     They were all created, as these others  
7       have emphasized, they were all created with the  
8       expectation of making money out of those drugs.  
9       It's purely profit-driven.     But now they're all  
10      done, that's one thing.     But the truth is, if you  
11      look at these areas, heart attack rates are way  
12      down, but we still have a lot of heart attacks.  
13      Diabetes is still a big problem.     We're just  
14      starting to get some drugs that really work well  
15      for cancer.     The most important thing is to stay  
16      with the flow about the generics and certain  
17      prices going down.     Zocor will be generic within  
18      two years by the time the drug benefit gets  
19      going.     And then make sure that we maintain the  
20      R&D enterprise, so that we may have more drugs,  
21      so that people can complain about higher prices  
22      later on for miracle drugs we don't even have  
23      right now.     But don't ask me to go explain that  
24      to your town halls.     DR. LICHTENBERG:     Well,  
25      if I can just say, I mean I think part of the --  
26      we don't only want to listen to seniors about  
27      this, although I know that's politically -- we

1 want to think about people who are today middle-  
2 aged or even children, that we really want to  
3 think long term. Of course, once a patent  
4 exists, it's always in the short run consumers  
5 are going to benefit if you basically abrogate  
6 the patent, because access will improve. But the  
7 patent system is very important in the long run,  
8 so I think it's -- you don't just want to focus  
9 on today's consumers.

10 CHAIRMAN CARMONA: Dr. Cockburn.

11 DR. COCKBURN: Yes. I think it's a  
12 very simple response to these questions you  
13 received, which is a lot of things are a  
14 different price in Canada, including government-  
15 paid pensions, the salaries of elected officials,  
16 public servants and professors. I think there's  
17 a tendency in this debate for people to assume  
18 that lower prices in Canada reflect government  
19 price regulation. To some extent they do, but  
20 they also reflect -- and prices in other  
21 countries are the same -- they reflect the  
22 decisions of pharmaceutical companies to charge  
23 what the market will bear. People have less  
24 money to spend in Canada and sticking -- you  
25 know, if we do the experiment of sticking  
26 Canadians with American prices, you can expect  
27 consumption to go down a lot.

1 CHAIRMAN CARMONA: Dr. Danzon?

2 DR. DANZON: Yes. If I could follow  
3 up on that. In the study that we did of  
4 international price comparisons, when we compared  
5 the price of this market basket of product  
6 relative to income in different countries,  
7 including Canada, the European countries and  
8 Canada were roughly in line with income; in other  
9 words, the differential for drugs was similar to  
10 the differentials in income. The two exceptions  
11 were the low-income countries of Mexico and Chile  
12 where the prices are way too high for their per  
13 capita income. And I would submit it's partly  
14 because of the concern about importation and  
15 looking at prices in Canada that is leading  
16 manufacturers to charge such high prices in  
17 countries like Mexico, which are out of line  
18 relative to their per capita income, and that has  
19 significantly reduced their ability to use those  
20 drugs. So their volumes are very, very low. So  
21 that's one response -- incomes are different.

22 The second is in the case of Canada,  
23 the exchange rate has played a very significant  
24 role. So when we did the comparison but using  
25 the exchange rate at which the drugs were  
26 launched, which factored out the exchange rate  
27 changes, that wiped out 90 percent of the

1 differential -- 19 percent of the differential  
2 with Canada, so it was -- more than half of it  
3 was an exchange rate effect.

4 DR. O'GRADY: Can I ask one follow up  
5 on this, actually, Dr. Danzon? In terms of some  
6 of the other work you did, and Dr. Calfee brought  
7 up the idea of the free rider, but we also know  
8 that in the United States market we really see  
9 this fair amount of variation in terms of what  
10 different subpopulations pay.

11 And Dr. McClellan brought up a notion  
12 before about this sort of mix of generics versus  
13 brand name and how you're -- do you have a feel  
14 in terms of the research you've done of kind if  
15 you took that -- and let's stick with the  
16 Canadian-U.S. comparison for a sec -- if you took  
17 both what they took and how much they paid for it  
18 and the source of their group discount, do we  
19 have a feel for -- I mean they're sort of -- when  
20 you see sort of the USA Today comparison of  
21 Buffalo to Toronto or whatever, I'm assuming --  
22 and I don't want to speak poorly of USA Today but  
23 they're talking full retail prices in the United  
24 States -- do you have a feel for when we're  
25 talking about federal employees sitting at this  
26 table or whatever, how much of a real price  
27 differential there is between the two countries?

1       And then when you take in the greater use of  
2       generics among kind of American prescribing  
3       habits exactly -- kind of how those -- once we  
4       control for the appropriate things to control for  
5       kind of where we are on that comparison?

6                 DR. DANZON:   Yes.   Well, essentially,  
7       the numbers I quoted you control for that,  
8       because the comparison I gave you that said,  
9       "Relative to income Canada's about at the right  
10      level," that is looking at the overall market  
11      basket including generics and on-patent products.

12      And it's taking into account the average  
13      discounts on the branded products in the U.S. So  
14      it's not the retail comparison, which is the one  
15      that the seniors sees going to the pharmacy.  
16      There probably are differences. But it's looking  
17      at what something like a Federal Employee Health  
18      Plan would pay.

19                 DR. O'GRADY:   Or is the weighted  
20      average across all the different sort of sources?

21                 DR. DANZON:   It's the weighted average  
22      across all different sources. So, basically,  
23      when we applied the discounts, we made an  
24      assumption about Medicaid, about paying with  
25      discounts, without, cash paying, et cetera. So  
26      it's a weighted average of all those.

27                 DR. O'GRADY:   Thank you.

1                   CHAIRMAN    CARMONA:           I    certainly  
2    appreciate the discussion.  I want to have a few  
3    more questions, but I think that Dr. O'Grady hit  
4    the nail on the head in a very direct and simple  
5    fashion.  The practical aspects or the paradox  
6    that's been created here of the individual who  
7    just sees the need for medications today, an ill-  
8    informed or uninformed consumer who doesn't  
9    understand the complexities of what your lifelong  
10   pursuits who confronts us at meetings such as  
11   this to say, "But my aunt across the border buys  
12   it for X dollars less," versus the discussion of  
13   implications of short-term gains for importation  
14   policy and then of course the long-term  
15   implications of such policy which make it  
16   extraordinarily complex as opposed to the Band-  
17   Aid fix for the short haul that most people shrug  
18   their shoulders and say, "Well, maybe it won't be  
19   such a big deal."  But, obviously, we have to  
20   consider all of those.

21                   My question to all of you is, though,  
22    in doing this, this task force is here to serve  
23    the American public, to be able to give a  
24    recommendation to Secretary Thompson and on to  
25    the President and hopefully to Congress to decide  
26    on the implications for a policy for importation.

27                   How do we keep the American public involved in

1 this extraordinarily complex issue so that they  
2 understand that it's not simply that Auntie Besse  
3 across the border is getting this for a dollar  
4 less, that there are really huge implications for  
5 our industry, for research and development, for  
6 pricing, for global markets, for, again, all of  
7 the things that many of you have researched  
8 throughout your career? And, please, any of you  
9 please jump in.

10 DR. CALFEE: I was hoping the new head  
11 of CMS might make some wonderful speeches.

12 (Laughter.)

13 DR. McCLELLAN: We're asking the  
14 questions up here.

15 (Laughter.)

16 CHAIRMAN CARMONA: Please, sir.

17 MR. LEMIEUX: I think that this is an  
18 industry where there is a fair amount of price  
19 discrimination. As has been mentioned, full  
20 retail is a lot higher than if you have a  
21 purchaser working on your behalf to get discounts  
22 or a government working on behalf to get lower  
23 prices. And I wonder if the discount card that  
24 has been enacted as part of the Medicare bill  
25 will help take a little bit of the pressure off  
26 in terms of at least making sure that senior  
27 citizens in particular could get, if the discount

1 cards work and have good discounts attached to  
2 them, which I hope they will, a feeling that at  
3 least they're not being ripped off, that they  
4 have somebody working on their behalf to get the  
5 best price available or at least a better price  
6 than what they were able to get when they were  
7 going out on their own.

8 I mean I think that one of the reasons  
9 politically that we're having problems with drug  
10 prices in spite of passing a Medicare drug  
11 benefit is there's skepticism about whether or  
12 not that benefit will work. But the discount  
13 card that's supposed to come into effect this  
14 summer might help a little bit to explain to  
15 people that if they have someone working on their  
16 behalf, they won't have to pay the top dollar for  
17 drugs, and I think it will prove to be pretty  
18 popular if the discounts are substantial.

19 CHAIRMAN CARMONA: Thank you. Do we  
20 have other comments? Yes, Dr. Cockburn.

21 DR. COCKBURN: Not to sound like a  
22 broken record but I really think that this -- a  
23 lot of things are a different price in Canada.  
24 I'm a Canadian citizen, I lived and worked in  
25 Canada for ten years, and people should  
26 understand if they want access to Aunt Besse's  
27 price in Toronto, then they've got to imagine

1 living on Aunt Besse's income and paying Aunt  
2 Besse's rent, gasoline, heating taxes and so  
3 forth. It's a very complicated issue, which I  
4 think people -- I don't think this choice is ever  
5 put to people like this.

6           Indeed, if you called Aunt Besse and  
7 asked her how she felt her price of drugs was in  
8 Toronto, she would probably say, "Well, they're  
9 very expensive, and I can't afford them." It's  
10 not the Canadians are somehow getting their  
11 Lipitor at five cents a pill; they're not.  
12 Canadians feel like they're paying very high drug  
13 prices, and Canada went through an extensive  
14 public policy debate in the 1990s about  
15 reintroducing patent protection in exchange for  
16 increased R&D expenditure in Canada by  
17 pharmaceutical companies.

18           Our guests in the earlier panel, I  
19 think, spoke to this. The City of Springfield,  
20 Massachusetts can certainly save a lot of money  
21 of its drug bill if it was able to purchase drugs  
22 at some of these prices advertised by USA Today.

23           They could probably save even more money if they  
24 paid their employees Canadian salaries.

25           CHAIRMAN CARMONA: Yes, Dr. Danzon?

26           DR. DANZON: I think most people can  
27 understand that things would change radically if

1 importation became policy and we had Wal-Mart and  
2 Walgreen's and Eckard and McKessen and the like  
3 all going to try and buy all their drugs in  
4 Canada. Things would no longer be available at  
5 those cheap prices.

6 I mean the difference between an  
7 individual consumer going and buying some small  
8 fraction of the Canadian supply versus this  
9 becoming national policy and the U.S. trying to  
10 buy their entire drug supply abroad, people can  
11 understand, I think, that systems would adapt,  
12 and that as a consequence foreign prices would be  
13 higher, supply would dry up and all of the things  
14 that stop it making sense in the long run start  
15 to happen.

16 CHAIRMAN CARMONA: How do we explain  
17 that to the average citizen? I mean I think we  
18 all agree with you, but, again, these are  
19 extraordinarily complex issues that people are  
20 getting in sound bites in the media, and what I'm  
21 concerned with is is that the American public for  
22 decades has been insulated from the true cost of  
23 their health care or pharmaceuticals as part of  
24 that, and now all of a sudden as markets are  
25 changing, they have found a fixed market across  
26 the border that they can buy at a cheaper price,  
27 and really the consequences of all of these other

1 tangential issues that appear to be tangential  
2 issues that we bring up are really  
3 inconsequential to them. I just wanted for this  
4 amount because I can get it for that today or  
5 tomorrow and next week, not considering the  
6 longer-term consequences. Dr. Lichtenberg?

7 DR. LICHTENBERG: Well, I mean I think  
8 you show that, you try to develop compelling  
9 understandable evidence about the consequences  
10 of, you know, "I don't want to pay too much for  
11 this muffler," and you look at, for example, the  
12 vaccine industry and that there were 50 vaccine  
13 manufacturers in 1960 and now there are three or  
14 something like that, because the government has  
15 driven the price extremely low. So I think, in a  
16 sense, trying to document how responsive  
17 innovation and production and so forth is to  
18 incentives might be a good way. And, in a sense  
19 -- so when phrasing it to people at work, sort of  
20 letting them know, "Well, what if -- suppose that  
21 if the price did drop 50 percent, if U.S. drug  
22 prices did drop 50 percent, that this would lead  
23 to a significant reduction in future drugs, how  
24 do you feel about that?" So I think bringing  
25 that into the picture, but I agree it's subtle  
26 and it's difficult.

27 CHAIRMAN CARMONA: Thank you. Other

1 questions from the panel? Dr. Duke?

2 DR. DUKE: Just to follow up on that  
3 line of reasoning, you've given the reverse, that  
4 is how we would explain the negative impact when  
5 individual incentives clash with societal  
6 incentives. Could you give me an instance of a  
7 successful effort where the societal incentive  
8 had the effect of changing individual incentives  
9 into a positive line? You've given me the  
10 negative on vaccines, is there an analogy here  
11 that we could work from?

12 CHAIRMAN CARMONA: I think the orphan  
13 drug act is a very good example, because you can  
14 go to the FDA web site, and you'll see a very  
15 significant increase in the number of orphan  
16 drugs after 1983. There were some before then,  
17 but I think that that's one of the better  
18 examples around. And I mean the other evidence  
19 that I described showing how market size affects  
20 innovation incentives is sort I think not -- I  
21 think it is useful. It's not exactly the right  
22 thing, but I think it goes in that direction.

23 DR. CALFEE: If I could add just one  
24 thing. I've noticed that a lot of patient  
25 groups, leaving aside for the moment that they  
26 often get funding from the pharma industry, they  
27 seem to be quite sympathetic to the R&D arguments

1 and not at all sympathetic towards the notion of  
2 price controls, and I think that's because most  
3 patient groups consist of people who are waiting  
4 for cures. The people who are really cured  
5 they're no longer in patient groups.

6 They understand the argument, and  
7 maybe it's worth reminding everyone else, that  
8 we're all patients waiting for cures. The only  
9 difference is we don't know which particular  
10 cures we're waiting for. But the entire industry  
11 is looking forward, they're working on the things  
12 that we don't have right now. It's too easy, it  
13 seems to me, for the AARP members. It's too easy  
14 for them to think only in terms of how much they  
15 want their drugs that we have right now, while  
16 forgetting that the drugs they really, really  
17 want are the ones that we don't have yet.

18 CHAIRMAN CARMONA: Dr. Lichtenberg, I  
19 think that the vaccine example is a very good  
20 one, and certainly my colleagues and I from our  
21 various vantage points, from everything from  
22 prevention to preparedness, have dealt with that  
23 issue. But the orphan drug one is interesting on  
24 the positive side, but yet I think the public  
25 needs to remember that there's a great deal of  
26 federal subsidy in that equalization for that,  
27 providing the incentive, if you will, to move

1 forward. Otherwise there would be no market for  
2 that; it would have closed out long ago, most  
3 likely. Any comments on that?

4 DR. LICHTENBERG: Well, that's true.  
5 I mean there is sort of deep question about  
6 whether the Orphan Drug Act was really good  
7 policy. Do you really want to spend enormous  
8 amounts of resources on drugs that are not going  
9 to benefit very many people? I mean that's kind  
10 of a philosophical question. But, you're right,  
11 certainly federal subsidies or R&D tax credits  
12 played an important role in that.

13 CHAIRMAN CARMONA: Because I think  
14 with vaccines it's the same. If we don't create  
15 the appropriate incentives, people aren't going  
16 to come back into the vaccine market, and then  
17 we'll be talking about a government-owned vaccine  
18 market, which will be extraordinarily expensive  
19 and will just shift the payer to the taxpayer.  
20 So I mean, again, these become very complex  
21 discussions that we're trying to figure out a way  
22 to get in front of the American public so they  
23 can move along with this discussion and be truly  
24 informed when they speak to their elected  
25 leadership as to what they really want and they  
26 understand what they really want.

27 Other comments or questions? Dr.

1 Raub?

2 DR. RAUB: Is the status quo the best  
3 we can do? It seems that every potential change  
4 from where we are is bad. Is there anything that  
5 can be done that would in fact be better with  
6 respect to the problem of the costs of drugs but  
7 without threatening the R&D or dealing with the  
8 real or imagined free rider situations that the  
9 U.S. faces?

10 DR. DANZON: Well, one change that I  
11 think could be made to encourage competition and  
12 discounting within the U.S. would be to eliminate  
13 the best price provision in Medicaid. I think  
14 it's pretty well understood that the provision  
15 that requires that manufacturers give their best  
16 price to private buyers to Medicaid has put a  
17 floor underneath willingness to discount. Not  
18 for all drugs, there are certainly some discounts  
19 that go deeper than the 15.1 percent, but that it  
20 essentially implies a tax on discounting. And so  
21 many economists believe that one way of  
22 encouraging more vigorous competition within the  
23 U.S. would be to change that best price  
24 provision. And in a sense it's become irrelevant  
25 as more and more states have their own discount  
26 requirements.

27 CHAIRMAN CARMONA: Dr. Calfee or Mr.

1 Lemieux, did you have a comment? Please.

2 MR. LEMIEUX: I was going to say the  
3 idea that we would begin to address international  
4 drug pricing in trade discussions would send a  
5 signal that the government understands this  
6 important public health and public policy issue  
7 here and that we are going to be using this in  
8 our negotiations with the rest of the developed  
9 world and to some extent with the developing  
10 countries, that that would be a signal that we  
11 understand this issue and that we're working it  
12 out internationally.

13 DR. RAUB: Could you play a scenario  
14 through -- I mean suppose this got brought up  
15 with our G-7 partners?

16 MR. LEMIEUX: Well, with other rich  
17 countries, the dispute would be how much of the  
18 global research and development budget should be  
19 shared and how -- between the rich countries and  
20 the poor countries, the issue is can we find ways  
21 to drive down prices in poorer countries in  
22 exchange for preventing counterfeiting,  
23 adulterated drugs and so on and so forth? I mean  
24 those are discussions that are not easy, they're  
25 going to be very messy and very difficult, but if  
26 it were part of the mix, and it may be becoming  
27 part of the mix, I think, even regardless, that

1 would be helpful.

2 CHAIRMAN CARMONA: Dr. Calfee?

3 DR. CALFEE: Well, speaking of  
4 negotiating with our partners, the Senate had  
5 hearings this morning on exactly that topic in  
6 which I was invited to speak, although I didn't  
7 have a whole lot to add, but most of the  
8 interesting comments actually came from either  
9 the Department of Commerce people or from the  
10 senators on the Finance Committee, many of whom  
11 have been talking to the Australians and others  
12 about this. And the consensus seemed to be that  
13 it's not going to be easy to persuade any of  
14 these countries to reassess any of their basic --  
15 anything that impacts strongly on their overall  
16 health care costs. But there are some areas in  
17 which some progress could probably be made, and  
18 one of them is on generic drugs, because a lot of  
19 these countries are very backwards in the use of  
20 generic drugs. They don't have the equivalent of  
21 a Hatch-Waxman Act, and so they're paying a lot  
22 more for generics than they ought to be, and in  
23 some cases their generics are not significantly  
24 cheaper than the branded drugs with which they  
25 compete.

26 Some of these countries also have very  
27 inefficient pharmacy retailing sectors, heavily

1 protected pharmacies, et cetera, and so they no  
2 incentive to compete, they have no incentive to  
3 minimize costs. So in some cases if you look at  
4 the retail price in some of these countries, a  
5 surprising large proportion of those prices go to  
6 either generic drugs or go unnecessarily to the  
7 retailer margins that are preserved by  
8 competition.

9 On the other question about what can  
10 be done about overall drug prices, et cetera,  
11 there's no easy way to get around the fact that  
12 R&D is really expensive and that it takes a lot  
13 of experimentation to figure out what new  
14 technologies work in research and development.  
15 But like a lot of economists, I do think that one  
16 thing that would help is if we reform health care  
17 generally so that consumers were in the position  
18 of making a lot more decisions about their own  
19 money or more price sensitive. And as long as  
20 all health care premiums are excluded from being  
21 taxed, the premiums that are paid by the  
22 employers, that means that almost all health care  
23 is going to run through insurance programs and  
24 then the patient will pay premiums but they won't  
25 pay much directly, which means when they buy  
26 their Celebrex they're not paying very much for  
27 Celebrex or Viagra or something else.

1           If we moved at least just a little  
2 ways towards limiting the tax exclusion for  
3 health insurance premiums, a lot more people  
4 would be getting higher deductible insurance,  
5 they'd be paying cash for more of their drugs,  
6 like almost all of us used to do, they'd be more  
7 sensitive, and I think the pharmaceutical  
8 manufacturers would find that they had to meet a  
9 tougher market test, at least for some of their  
10 drugs, and in some cases that might make a  
11 significance difference.

12           CHAIRMAN CARMONA: Thank you. I want  
13 to thank -- this is a very, very important  
14 discussion, and I appreciate your patience in  
15 staying with us. I know we've gone over a little  
16 longer than what we expected, but I mean this  
17 really gets to the crux of a lot of the matters  
18 that we're dealing with.

19           As the question was brought up  
20 regarding trade and using the tool of our trade  
21 negotiations, G-7 and otherwise large countries  
22 of wealth and those that are poor, I'd like to  
23 maybe get Dr. Danzon, Lichtenberg and Cockburn  
24 also to comment. Utilizing trade as a tool to  
25 further equate some global equity, maybe  
26 eliminate some of the free riderism, if you will,  
27 and other benefits of using that leverage, if you

1 will, that tool to try to equilibrate a global  
2 market, if there ever is going to be one. Would  
3 you, any of you or all of you comment on what  
4 your thoughts are?

5 DR. LICHTENBERG: I can just -- my  
6 understanding that in Canada there's a question  
7 if prices are very low in Canada and companies  
8 are worried about essentially that undercutting  
9 the U.S. price, why do they bother selling in  
10 Canada at all? It's such a small market, why not  
11 just write it off? Well, I've been told that,  
12 essentially, the reason why you would not just  
13 decline to sell in Canada is because if you  
14 refuse to sell your drug in Canada, they can  
15 essentially compulsorily license your patent.  
16 And so that means that there's really no  
17 intellectual property protection. It's not only  
18 that we dictate the price to you, but if you  
19 won't sell it to us, we'll find somebody who will  
20 sell it to us at that price even though you have  
21 a patent. That's a very serious issue of  
22 intellectual property protection. So it's not  
23 just price regulation but how that's connected to  
24 IP protection. I think that has been the subject  
25 of trade negotiations and no doubt will continue  
26 to be in the future, but I think that that's very  
27 important.

1                   CHAIRMAN CARMONA:     Thank you.     Dr.  
2     Danzon?

3                   DR. DANZON:    I think it's very tricky  
4     to make drug prices an item of trade negotiations  
5     just because there is so much variation across  
6     products in the price differentials.    So for some  
7     of the products, say France is comparable to the  
8     U.S. for other products, it's much lower for  
9     others, it's higher, and if one's talking about  
10    how much is each country contributing to the cost  
11    of R&D, number one, you've got to look at over  
12    the whole life cycle of the product and take into  
13    account price and volume, so that's much more  
14    difficult than anything anybody's measured yet.

15                  And, second, you've then got to  
16    decide, well, what are fair contributions?  
17    Should it be proportional to income?    I mean  
18    that's what people generally accept but there's  
19    nothing really firm that says it should be that.

20                  So aside from the practical difficulties, I  
21    think, of getting countries to change their  
22    health policies, I think that the underlying sort  
23    of deciding what the appropriate contributions  
24    would be and whether they are currently  
25    appropriate would be very hard to do.    So I think  
26    it's a very tricky are to go down.

27                  CHAIRMAN CARMONA:     Okay.     Dr.

1 Cockburn, any final comments on that?

2 DR. COCKBURN: Yes. If I may offer  
3 some remarks as a guest in this great country. I  
4 think there's a very great danger here that  
5 whether it be through trade policy or through  
6 passing importations legislation, you have to, I  
7 think -- people should understand how this is  
8 going to be perceived abroad. Canada I think is  
9 beginning to see drug shortages coming in. I  
10 think it's just the tip of an iceberg. I think  
11 how this is going to be perceived abroad is a  
12 question of can pay, won't pay. The United  
13 States is a massively wealth and successful  
14 economy. Voters and governments in other  
15 countries are going to view efforts to bully  
16 their prices into line with the United States  
17 prices with very little enthusiasm.

18 They have plenty of ways to respond.  
19 Again, it's getting a little repetitious, but the  
20 immediate tool at hand is to abrogate patent  
21 rights. If there's a contagion or a collapse of  
22 patent rights around the world because countries  
23 declare health emergencies and -- I mean we saw  
24 this with scares of bioterrorism not very long  
25 ago -- I think this is one area where we can be  
26 very confident that there will be an immediate  
27 and disastrous impact on R&D incentives.

1           You know, all the evidence I've ever  
2 seen suggests that the pharmaceutical industry is  
3 one where patent rights are absolutely essential  
4 to supporting R&D and development of new  
5 products. If that starts to collapse around the  
6 world, I think this is a very serious outcome.

7           CHAIRMAN CARMONA: Thank you, sir.  
8 Other comments, questions? Dr. Crawford?

9           DR. CRAWFORD: I'm just thinking, as  
10 we progress through dismissing the World Trade  
11 Organization and trade negotiations is a real  
12 possibility, it sounds more and more like an OECD  
13 kind of thing to me where perhaps -- would any of  
14 you care to comment on whether the rich nations  
15 of the world, through the Organization of  
16 Economic Cooperation and Development, might  
17 undertaken an initiative like this that wouldn't  
18 be quite as threatening as a WTO initiative, for  
19 example?

20           DR. CALFEE: There is at least a  
21 modest movement, not so much in OECD but within  
22 the European Commission itself, amongst some  
23 other staffers, especially the more economically  
24 oriented ones. Some of them are reassessing  
25 pharmaceutical controls, price controls in  
26 Europe, because they've been discouraged about  
27 the decline of the pharma industry there, and

1 they're wondering whether the short-run gains  
2 they're getting from the price controls may not  
3 be as great as the long-run losses they're  
4 getting from losing such an important industry  
5 and whether this is just another sector of the  
6 European economy in which they haven't done very  
7 well for the last ten years. I mean the European  
8 Union hasn't been growing very rapidly for  
9 several years now.

10 So I know at least there is some talk  
11 among some people that the member countries, the  
12 wealthier ones, ought to be thinking about the  
13 impact of their price controls on the pharma  
14 industry and pharmaceutical R&D, and maybe  
15 they'll come around. It's not easy. They still  
16 have -- each nation has their own self-interest  
17 in doing what they do, and right now each nation  
18 is pretty independent of the European Union as a  
19 whole in setting their prices.

20 CHAIRMAN CARMONA: Thank you, sir.  
21 Other questions or comments from Task Force  
22 members? Dr. McClellan?

23 DR. McCLELLAN: This probably is going  
24 to be more of a comment but maybe there's a  
25 question here at the end. You all talked about  
26 some of the intuition behind, at least the  
27 economic intuition behind any kind large-scale

1 importation not leading to the kinds of impacts  
2 on prices that many of its supporters have  
3 promised. I'm not sure that's quite so intuitive  
4 to the public. I mean what they see today is  
5 they walk into a drug store here, many people,  
6 especially seniors without coverage, and pay the  
7 highest prices in the world, and they see people  
8 and they talk to people who order drugs over the  
9 Internet or friends they know in Canada who are  
10 getting much lower prices, and it isn't intuitive  
11 to them why the price differences should be so  
12 great or why it's not possible to set up the same  
13 kind of safety system across our borders that we  
14 have within each country to assure safety. And  
15 if that's not the way they should be thinking  
16 about it, I'm not sure that that's come across to  
17 the general public. And I can tell you it's  
18 definitely not intuitive to the public that that  
19 is a fair situation, that Americans should be  
20 paying 50, 60 percent of the net revenues for  
21 pharmaceuticals around the world.

22           You all talked about the difficulties  
23 in addressing this problem, but I've heard some  
24 potentially useful steps in addressing this  
25 beyond importation out there, steps like trying  
26 to encourage the dollars that we do spend,  
27 whether -- or the money that we do spend around

1 the world, whether it's proportional to national  
2 income or not, but spending that money more  
3 wisely to encourage the development of new  
4 medicines and not pay any more for medicines that  
5 have been around and whose patents have expired  
6 than is necessary or taking steps in the United  
7 States, help people band together more to get  
8 lower prices, which many seniors can't do today,  
9 but that is about to change, or taking steps to  
10 reduce the cost of developing new medicines. All  
11 these things can potentially help.

12 I just encourage all of you here who  
13 have thought very hard and very deep about this  
14 issue to not give up. I don't think this is  
15 going away. I think it is perceived by many  
16 Americans as an unfair situation. I think that's  
17 extremely understandable given what look like  
18 very big differences in prices that don't seem to  
19 be justified on the basis of fairness. And I  
20 would like us to keep working hard to try to find  
21 ways to address this, maybe building on some of  
22 the ideas here as well as continuing to look at  
23 the importation issue itself.

24 CHAIRMAN CARMONA: Yes, please, Mr.  
25 Lemieux.

26 MR. LEMIEUX: Just very quickly, I  
27 mean this is the inevitable pressure of

1 globalization and information, and this is part  
2 of -- in every other product, the products where  
3 we don't have significant safety concerns and  
4 where there's not a lot of government involvement  
5 in the marketplace, you simply buy where you can  
6 buy things the cheapest. And people don't  
7 understand why it's not fair to do that in health  
8 care or it might not be fair to do that in  
9 pharmaceuticals, and I think it's just a question  
10 of having a very candid discussion about how this  
11 is a case where globalization could lead to an  
12 impact on prices in poor countries that we might  
13 not want, but it would take a lot of leadership.

14 CHAIRMAN CARMONA: Thanks very much.  
15 Panel, thank you so much for spending the time  
16 with us. This has been a very, very illuminating  
17 discussion for us. I would encourage you that if  
18 you have any afterthoughts based on our comments,  
19 please submit them to the docket. I assure you  
20 we will scrutinize them very closely. Thank you,  
21 once again, for all your help.

22 We're going to take a very short  
23 break. We'll be in session in ten minutes as we  
24 turn over for our last panel. So if anybody  
25 needs a break, please step out now, and we'll  
26 start again in ten minutes.

27 (Whereupon, the foregoing matter went

1 off

2 the record at 3:56 p.m. and went back  
3 on

4 the record at 4:05: p.m.)

5 CHAIRMAN CARMONA: Ladies and  
6 gentlemen, we'll reconvene. Again, thank you for  
7 your patience. I know we've run a little long,  
8 but we're getting a lot of good information among  
9 the deliberations that we've been having. Many  
10 of the issues that have come up are the economic  
11 ones and some of the very complex issues that you  
12 heard discussed. So thank you for your patience.

13 We'll begin this afternoon's third  
14 panel, and that will be with Dr. Eric Sheinin,  
15 from the U.S. Pharmacopeia, I believe.

16 DR. SHEININ: Yes. Thank you. Good  
17 afternoon. My name is Eric Sheinin, and I'm the  
18 Vice President for Information and Standards  
19 Development at the United States Pharmacopeia.  
20 The USP welcomes the opportunity to present our  
21 views on the important issue of drug importation.

22 I apologize for not being able to provide my  
23 comments in advance of today's meeting due to the  
24 short notice regarding our participation today.  
25 USP will provide a more detailed statement to the  
26 docket in the near future.

27 The United States Pharmacopeia

1 Convention, Incorporated is a not-for-profit  
2 company that was created in 1820 by a group of 11  
3 physicians interested in providing public  
4 standards for pharmaceutical products being used  
5 in the U.S. at that point in time. The First  
6 Pharmacopeia of the United States was published  
7 in 1820 and was essentially a book of recipes for  
8 botanical products. Over the years, USP has  
9 evolved so that today our standards mainly are  
10 applicable to the pharmaceutical industry and the  
11 Food and Drug Administration.

12 In 1975, USP acquired the national  
13 formulary from the American Pharmaceutical  
14 Association, and the two pharmacopeias, the USP  
15 and the NF, are now published in a single volume  
16 on an annual basis. These compendia contain  
17 approximately 4,000 monographs for drug  
18 substances, drug products, excipients, dietary  
19 supplements and other articles, as well as  
20 approximately 220 general chapters that provide  
21 information for the performance of many of the  
22 analytical procedures that are contained in the  
23 monographs.

24 Both the USP and the NF are recognized  
25 as official in the Federal Food, Drug and  
26 Cosmetic Act. So pharmaceuticals that are  
27 marketed in the U.S. must comply with the

1 standards established in the compendial  
2 monographs where a monograph exists. And this  
3 can be important in terms of drug importation  
4 then.

5 The development of monographs in  
6 general chapters is accomplished by approximately  
7 300 to 350 volunteers from the pharmaceutical  
8 community, both industry, academia and the  
9 government. The compendial standards that are  
10 developed are public standards whereas the  
11 standards approved by FDA during the review  
12 process are private standards between the company  
13 and the agency. It is USP's intent to have the  
14 public standard be in agreement with the private  
15 standard to the extent possible.

16 USP has some concerns with drug  
17 importation for the following reasons that are  
18 related to uncertainty regarding safety and  
19 efficacy of the products that might be imported  
20 into the United States. One, the reference  
21 listed drug is not the same in every country. In  
22 the U.S., generic drugs must be shown to be  
23 bioequivalent to the reference listed drug. This  
24 generally refers to the innovator product that  
25 was approved under the provisions of Section  
26 505(b)(1) or (b)(2) of the Federal Food, Drug and  
27 Cosmetic Act. Generic drugs are approved under

1 the provisions of Section 505(j) of the Act.  
2 Drugs being shipped to other countries and then  
3 imported into the U.S. may or may not be  
4 bioequivalent to the U.S. reference listed drug.

5 Second, presumably, generic drug  
6 products from other countries would be among  
7 those being imported. Unless data were available  
8 in the source country for imported generic drug,  
9 one would not know if it was bioequivalent to the  
10 U.S. reference listed drug.

11 Third, as I indicated earlier, the  
12 compendial standard is a public standard, while  
13 the FDA-approved standard is a private standard.

14 These are not always in agreement. The same  
15 situation presumably holds in other countries  
16 with a competent regulatory authority and a  
17 pharmacopeia. The United States patients and  
18 practitioners would have to depend on the public  
19 standard in the pharmacopeia in the other country  
20 since access to the private standard might not be  
21 readily available. Without scientific scrutiny,  
22 it would be difficult to determine if the public  
23 standard in the exporting country was equivalent  
24 to the USP standard.

25 Fourth, drugs do not always have the  
26 same name in every country. For example, in the  
27 U.S., the active ingredient in Tylenol is

1 acetaminophen, while in Europe it is parasetimol.

2 I realize this is an over-the-counter drug, but  
3 it carries over to prescription drugs as well.  
4 U.S. pharmaceutical users and health care  
5 providers are familiar with the USP-NF names and  
6 labeling. Therefore, the use of products labeled  
7 per other pharmacopeias may be confusing. In  
8 many instances, the dosage strengths are  
9 different as well, which may lead to additional  
10 confusion on the part of the practitioner and the  
11 patient.

12 Fifth, the same dosage forms are not  
13 always available in all countries. For example,  
14 in the U.S., a distinction is made between  
15 tablets and capsules. This is not true in all  
16 other countries. A patient who has been taking  
17 tablets might receive their drug in a capsule and  
18 be concerned about taking the wrong medication.  
19 Similarly, the dyes used to color solid oral  
20 dosage forms are not the same in all countries.  
21 Again, this could lead to confusion on the part  
22 of the patient.

23 Sixth, and last, the situation becomes  
24 more complex for modified or delayed release  
25 products. Depending on the exact formulation of  
26 the product, the release characteristics may be  
27 different. This can lead to the patient

1 receiving the active ingredient at a different  
2 rate, which may well affect the safety and the  
3 efficacy of that product.

4 In conclusion, UPS feels that it will  
5 be difficult to guarantee the safety and efficacy  
6 of drugs imported from other countries,  
7 regardless of the adequacy of the regulatory  
8 process in those countries. There are many  
9 unknown variables and questions involved, and we  
10 do not have the answers to all of these  
11 questions.

12 USP would be pleased to work with the  
13 Task Force and with the FDA on the issue of  
14 importation of pharmaceuticals from other  
15 countries, and I again thank you for your  
16 attention and for this opportunity.

17 CHAIRMAN CARMONA: Thank you, Dr.  
18 Sheinin. Our next speaker, Dr. Alastair Wood  
19 from Vanderbilt. Thank you, sir.

20 DR. WOOD: Thank you. Dr. Carmona,  
21 ladies and gentlemen, I'm Alastair Wood from  
22 Vanderbilt School of Medicine. I'm also the Drug  
23 Therapy Editor of the New England Journal.

24 Let me begin by saying I certainly  
25 don't envy you your task. As we've heard this  
26 afternoon, importation is simultaneously -- every  
27 position on drug importation is simultaneously

1 wrong and right. And that makes this an  
2 extraordinarily difficult circle to square. And  
3 given the hour, I will try to summarize just my  
4 written comments.

5 But as you heard from the last group  
6 of speakers, consumers will search for the lowest  
7 price, and that search has been helped by better  
8 pricing information on the Internet. Once such  
9 price transparency exists, consumers will not  
10 tolerate major pricing differentials. On the  
11 other hand, pharmaceutical companies are entitled  
12 to a financial return that adequately reflects  
13 the costs and risks of drug development. But  
14 they will have to ensure that these costs of drug  
15 development are borne equally and equitably by  
16 all consumers, whatever their nationality. Both  
17 sides are right.

18 Safety is another example where both  
19 sides are right. Clearly, drugs sold in Canada  
20 to Canadians, by Canadian pharmacies are of high  
21 quality and are as safe and effective as those  
22 sold in the United States. To suggest that such  
23 drugs are unsafe is simply foolish. However,  
24 when a U.S. consumer orders drugs over the  
25 Internet purporting to be from Canada, that  
26 consumer does not know from whence these drugs  
27 come. In fact, these drugs may be from anywhere

1 in the world, and they may be mislabeled,  
2 adulterated or counterfeit and are clearly  
3 unsafe.

4 I could go through each of the  
5 arguments you will and have heard and make the  
6 same point, that both sides are right, but  
7 frankly that would not contribute much to your  
8 deliberations. Therefore, I want to try and  
9 focus on solutions to the current problem.

10 In my view, the reimportation issue is  
11 really a symptom of a deeper problem, and it is  
12 critical not to allow society to become  
13 distracted by the illusionary quick fix of  
14 reimportation. Much of this controversy has  
15 arisen because medical treatment has recently  
16 changed dramatically in ways that will forever  
17 change the economics of prescription drugs.

18 Until very recently, patients were  
19 treated for discrete episodes of disease usually  
20 for a limited period of time. Because of that,  
21 they became accustomed to buying drugs for  
22 relatively short courses. Think of the usual  
23 ten-day course of an antibiotic. But we're now  
24 in an age of livable chronic disease, and we can  
25 now even prevent future disease by treating  
26 patients with drugs, so-called primary and  
27 secondary prevention.

1           Examples include lowering cholesterol  
2           or blood pressure. In these cases, patients will  
3           take medications every day, month in and month  
4           out for the rest of their lives. Although the  
5           financial implications may appear negative, the  
6           long-term health implications are hugely  
7           positive.

8           The proportion of our health care  
9           dollars spent on drugs will increase in the  
10          future. It should increase in the future. And  
11          that is good news because much of that  
12          expenditure is going into prolonging our disease-  
13          free lives.

14          Let me also address some of the other  
15          issues. It's estimated to cost upwards of \$800  
16          million to develop a new drug today. That cost  
17          is too high. It's unsustainable and must be  
18          reduced. In spite of all the scientific advances  
19          that we have made recently, the clinical drug  
20          development process has changed little, except  
21          trials have become ever larger and ever more  
22          expensive. Drugs to prevent or cure many common  
23          diseases, such as Alzheimer's or osteoarthritis,  
24          are still tantalizingly out of sight. It is  
25          therefore essential that we think creatively to  
26          develop new and potentially radical drug  
27          development paradigms.

1           We have learned that the patent  
2 extension offered by the Pediatric Rule has  
3 encouraged drug studies in children. Perhaps,  
4 therefore, we need to have drug approvals that  
5 can be staged. First, rapid approval for  
6 surrogate endpoints, and hence smaller, cheaper  
7 trials with patent extension offered for later  
8 studies that demonstrate efficacy and clinical  
9 relevant meaningful endpoints.

10           Perhaps we need to offer longer patent  
11 life for truly novel therapies, such as the first  
12 drug to prevent Alzheimer's disease. The  
13 introduction of market-based financial incentives  
14 that reward the most risky and innovative  
15 research is most likely to be successful.

16           Therefore, in conclusion, our future  
17 health, your and my future health, is utterly  
18 dependent on the development and marketing of new  
19 drugs to treat the many common diseases for which  
20 we currently have no effective therapy. We need  
21 to make sure that we do not allow ourselves to  
22 become distracted by reimportation as a solution  
23 rather than recognizing the true issue, which is  
24 reducing the cost of drug development and  
25 spreading that cost evenly across all consumers.

26           Thanks for the opportunity to present  
27 my views.

1                   CHAIRMAN CARMONA:       Thank you, Dr.  
2 Wood. Our next speaker, Dr. Reidenberg.

3                   DR. REIDENBERG:       Thank you, Mr.  
4 Chairman. I'm Marcus Reidenberg. I'm an  
5 internist and a pharmacologist at Cornell, and  
6 I'm going to address the medical concerns about  
7 drug importation, focusing on the risk to  
8 patients importing substandard products.

9                   A substandard drug product can be  
10 unintentional or intentional. Unintentionally,  
11 it's due to either incompetence or human error,  
12 whereas an intentional one, a counterfeit  
13 product, is due to criminal activity.

14                  Counterfeiting is an activity  
15 involving production and distribution by people  
16 who know what they are doing. While this is part  
17 of the illegal drug trade, the lesser intensity  
18 of enforcement and the smaller degree of  
19 punishment for being caught makes this a less  
20 dangerous part of the illegal drug trade for the  
21 criminal than selling opiates or other hard  
22 drugs.

23                  The medical consequences of  
24 counterfeit drugs can be illustrated by published  
25 examples of counterfeit antibiotics being  
26 marketed with no antibiotic content in the  
27 tablet. These are described in my paper

1 submitted for your briefing material. Given the  
2 potentially fatal consequences for sick people  
3 who take these, the criminals who make and  
4 distribute counterfeit drugs without life-saving  
5 medicine in them should be considered as if they  
6 have attempted murder or even committed murder,  
7 and enforcement and punishment should be  
8 appropriate for the enormity of the crime.

9 In considering counterfeit drugs, we  
10 usually ignore the second victim of these crimes,  
11 the legitimate manufacturers whose products are  
12 counterfeited. Manufacturers usually keep secret  
13 the information they have about counterfeiting  
14 because they fear correctly that public  
15 information that a particular product is  
16 counterfeited will lead to a loss of sales of  
17 their product. Hence, public ignorance about a  
18 counterfeit product is beneficial to the  
19 legitimate manufacturer. Informing the public  
20 about a counterfeit to protect patients hurts the  
21 manufacturer that fulfills this civic duty. This  
22 problem of the other victim, the manufacturer,  
23 must be addressed because secrecy protects the  
24 criminals and should not continue.

25 The more general problem of  
26 substandard drug products is a worldwide problems  
27 that's been considered at length by the World

1 Health Organization. My experience with the WHO  
2 has been as a member of the WHO Expert Panel on  
3 Drug Evaluation since 1989. I've served on six  
4 expert committees and as a temporary advisors to  
5 several WHO programs concerned with medications.

6 The WHO has various activities designed to  
7 inform the purchaser of the sources in regulatory  
8 procedures of specific drugs products to help the  
9 purchaser assess the quality of the products, and  
10 this is all on a WHO web site in my written  
11 material.

12 The procedure described leads to a  
13 certificate of pharmaceutical product. These  
14 certificates are only as good as the national  
15 authority under which they're issued, and the  
16 quality of the product must be evaluated from  
17 this point of view. The medical issues around  
18 reimportation relate to the quality of the  
19 products. Products made by companies for the  
20 U.S. market and shipped also to countries with  
21 legal and regulatory environments equivalent to  
22 ours and then reimported into the United States  
23 meet the U.S. standards of satisfactory quality.

24 Finally, the problems that concern  
25 doctors the most are that the product does not  
26 contain the labeled amount of the drug or the  
27 product is not bioequivalent or the product

1 differs in some other way from the FDA-approved  
2 product, such as with different excipients or  
3 contaminants so that unexpected bad effects  
4 occur.

5           One can generalize that drug product  
6 testing laboratories can be established to test  
7 samples from batch product to batch to see that  
8 it meets all the USP or European pharmacopeia  
9 specifications for the product. Organizations  
10 like state Medicaid or employee programs,  
11 purchasing cooperatives and so on wanting to  
12 purchase medication from sources not under FDA  
13 regulation have the responsibility to determine  
14 that the product is so labeled. They also have  
15 the resources to arrange for laboratory testing  
16 of the products.

17           The potential problems of bio-  
18 availability and of different excipients or  
19 contaminants can only be addressed by being sure  
20 that the products were made by manufacturers in  
21 countries with strong regulatory authorities that  
22 are part of honest governments that do not  
23 tolerate corrupt officials. Drug products must  
24 be made by manufacturers in countries with laws,  
25 policies and implementation equivalent to those  
26 of the United States for one to be sure the  
27 products will be equivalent to those in the

1 United States. And I'd be happy to expand on any  
2 of these points in the discussion.

3 CHAIRMAN CARMONA: Thank you, Doctor.  
4 Our next speaker, Dr. Peck.

5 DR. PECK: Thank you, Admiral Carmona  
6 and members of the panel. Thank you for the  
7 opportunity to present my views on safety and  
8 effectiveness of imported drugs.

9 I'm Professor of Pharmacology and  
10 Director of the Center for Drug Development  
11 Science at Georgetown University. I trained in  
12 medicine and clinical pharmacology and have had  
13 more than 30 years experience in testing drugs,  
14 research and regulation, including six years at  
15 Food and Drug Administration as head of the  
16 Center for Drugs.

17 I think I can best contribute to your  
18 task by explaining, or reminding, as the case may  
19 be, of the high standards that FDA applies to  
20 drugs manufactured and distributed in our  
21 country, and I'll follow that with three points  
22 to consider with respect to safety, quality and  
23 effectiveness of drugs that would be imported.

24 We have confidence in FDA-approved  
25 drugs that are manufactured here because of these  
26 high standards and extensive testing, even if  
27 they're manufactured in a foreign country that we

1 have approved the manufacture of. As explained  
2 in more detail in my written statement, these  
3 standards and procedures apply to both active and  
4 inactive ingredients in the product as well as to  
5 the particular form of the product, the  
6 formulation, whether it be a tablet, a capsule or  
7 a solution.

8 Very often the formulation itself, the  
9 capsule or the tablet, and the storage conditions  
10 of the product influence the safety and  
11 effectiveness of the drug product. The key  
12 safeguard that FDA affords is the conduct of  
13 field inspections and audits for manufacturing  
14 facilities and periodic reinspections and  
15 analyses of the sampled products in the supply  
16 chain.

17 The test procedures employed include  
18 chemical analyses, evaluations of the performance  
19 of the drug formulations themselves and human  
20 bioequivalence tests. The chemical quality  
21 standards, as you would imagine, related to  
22 identifying the active ingredients in the product  
23 and affirming that the dose labeled is exactly or  
24 in the neighborhood of what is purported, as well  
25 as an evaluation of the impurity profile. These  
26 tests require advanced monitoring and analytical  
27 technologies and are applied routinely during

1 manufacturing, distribution and storage.

2 The formulation, the capsule or the  
3 tablet, is tested for size, hardness, dissolution  
4 profiles in simulated gastric juice and so forth.

5 These storage tests sometimes involve many  
6 months of storage under extreme conditions to  
7 confirm that the product would withstand those  
8 kinds of variations in temperature and humidity.

9 The human bioequivalence testing is an  
10 approach to confirming the near identical profile  
11 of the blood concentrations of the drug once it's  
12 ingested by a human. The bioequivalence test, as  
13 you may know, is the basis for confirming the  
14 expected safety and effectiveness of generic  
15 drugs and is often applied also to new drugs  
16 under development.

17 Safety and effectiveness is affirmed  
18 in a particular disease by extensive human  
19 clinical trials. But a key element in all of the  
20 trials that are done is a knowledge of the  
21 manufacturer and the product qualities of these  
22 test acceptances. And once that's settled, it  
23 implies then that -- once the safety and  
24 effectiveness of a new drug has been adequately  
25 proven, the continued safety and effectiveness is  
26 assured by closely adhering to the just described  
27 strict chemical manufacturing formulation and

1 manufacturing and bioequivalence quality  
2 standards.

3 Thus, as a result of the compliance  
4 with these requirements, Americans have long  
5 enjoyed reliable safety and effectiveness in the  
6 approved drugs that they obtain in their  
7 hospitals and pharmacies.

8 Now, a few points about imported  
9 drugs, their safety and effectiveness. With  
10 respect to the current dialogue, I proposed in my  
11 written testimony two categories. Category one I  
12 will call FDA-approved products. They're  
13 manufactured in the United States or in an  
14 approved facility for which there is full  
15 compliance, that approved could be in another  
16 country. But that has been inspected and fully  
17 compliance records are available. These may  
18 reenter the United States as an import.

19 The second category would be drug  
20 products, possibly with the same active  
21 ingredient of an already approved drug in the  
22 United States but the product itself would not be  
23 approved by the FDA. It could enter the United  
24 States if permitted from foreign manufacturing  
25 sites, but it would not have records of quality  
26 and performance testing or of regulation by  
27 competent regulatory authorities or one might not

1 even know the transportation and storage  
2 conditions.

3 My points: The category one and two  
4 drugs differ significantly on the potentially  
5 available information about their quality and  
6 performance and therefore vary in the burden and  
7 cost of assuring safety and effectiveness.  
8 Assuming that the full pedigree and history could  
9 be confirmed for the category one drugs, the  
10 questions raised mainly would be due to any  
11 deviations in the specifications for storage and  
12 transportation. So if Lipitor, for example, were  
13 transported to Canada and it sat in a warehouse  
14 in New Jersey in August without air conditioning  
15 for two weeks, one could wonder whether the  
16 hardness of that tablet had firmed up and that  
17 would not dissolve properly and would not enter  
18 the body at the same rate or extent, thereby  
19 depriving the patient of a sufficient amount of  
20 lipid-lowering action to be effective. Perhaps  
21 the physician might increase the dose on another  
22 batch coming through that had not had those  
23 storage conditions, might be getting a higher  
24 dose, and then the patient would be at risk to  
25 the toxicity of Lipitor, which could involve  
26 muscle breakdown and kidney damage or hepatic  
27 damage. So there well may be some strategies for

1 dealing with these category one drugs that we  
2 could affirm to be safe.

3 The category two drugs, however,  
4 present the greatest challenge for assurance of  
5 safety and effectiveness. Confidence enjoyed by  
6 Americans with our domestically manufactured and  
7 approved drugs would be possible were we to  
8 require the foreign source marketing  
9 organizations to meet all of the basic  
10 requirements -- formulation, chemistry,  
11 bioequivalence -- but, of course, that's  
12 requiring a brand new drug application.  
13 Indirectly, conceivably, we could enter into  
14 arrangements with competent foreign regulatory  
15 authorities. In any case, implementation of such  
16 an expansion of FDA involvement for collaboration  
17 with a foreign regulatory agency would be  
18 daunting, massive and complex and expensive.

19 I end with two implications for your  
20 consideration that might accompany relaxing these  
21 import restrictions. The first concerns an  
22 unintended potential increase in counterfeit  
23 drugs. This problem of counterfeit drugs has  
24 already been mentioned by Drs. Wood and  
25 Reidenberg. Permitting category one drugs to be  
26 reimported freely may quickly result in a huge  
27 seller's market across U.S. borders, strongly

1 luring counterfeiters to join the bonanza market  
2 that is created. Compliance efforts to counter  
3 this threat would be costly and possibly  
4 imperfect, leading to the risk of entry of unsafe  
5 or ineffective products.

6 The second concern relates to the  
7 effect on FDA resources but with respect to the  
8 manpower drain if tasked to provide increased  
9 enforcement activities. The full financial  
10 forecast is advised along with consideration of  
11 perhaps collecting user fees from foreign  
12 distributors and manufacturers who become part of  
13 the drug importation process to support the  
14 increased FDA resource requirements. Thank you.

15 CHAIRMAN CARMONA: Thanks, Dr. Peck.  
16 And our last speaker, Dr. Elena Rios. Dr. Rios,  
17 welcome, thank you.

18 DR. RIOS: Thank you. Sirs, General  
19 Carmona and Task Force members, it's an honor to  
20 be here today representing the National Hispanic  
21 Medical Association and the Hispanic-Serving  
22 Health Profession Schools, both non-profit  
23 associations dedicated to improving the health of  
24 Hispanics and other underserved in the U.S.

25 According to the census, we're now the  
26 largest group in the country, ethnic group, and  
27 exist in nearly all major areas of the country.

1 Besides being the group with the least access to  
2 health insurance and access to health care by  
3 many parameters, we also face many barriers to  
4 health care services based on language, culture  
5 and the severe lack of Hispanics in all levels of  
6 the health workforce. Indeed, in the IOM 2002  
7 Unequal Treatment report, this report discussed  
8 specific recommendations to facilitate the  
9 inclusion of more populations with cultural  
10 backgrounds. Furthermore, the IOM report  
11 reported on quality, have pointed to the need for  
12 a patient-centered approach in health policy in  
13 2004.

14 Both Senator Frist and Senator Daschle  
15 have introduced legislation that show us various  
16 pathways to eliminate health disparities in our  
17 health system, and they include enhancing  
18 minority research and data collection, promoting  
19 programs to increase minority health  
20 professionals and strengthening the leadership of  
21 the Office of Minority Health and cultural  
22 competence and curriculum development. I  
23 recommend that your deliberations include these  
24 recommendations.

25 Drug importation discussions, we feel,  
26 require a review of the public safety and  
27 feasibility as well as the cost-benefit analysis

1 for the pharmaceutical distribution chain, as you  
2 are doing. However, we are interested in  
3 educating physicians and health providers about  
4 the inclusion of cultural principles into any new  
5 public health activities. You can provide an  
6 imported drug to a regional wholesaler, but the  
7 eventual distribution to the local pharmacy in  
8 the Hispanic neighborhood and moreover the  
9 awareness of that new service to the community  
10 requires its own protocols of outreach and  
11 education and information sharing.

12 As the Unequal Treatment report  
13 demonstrates, a major effort is needed on the  
14 part of both private and public partners to  
15 develop linguistically and culturally appropriate  
16 services in a drug importation process. At the  
17 federal level, we feel that the FDA should  
18 partner with the Office of Minority Health and  
19 its regional minority health consultants to  
20 develop those culturally appropriate messages,  
21 marketing and product protocols.

22 We recognize the importance of the  
23 Center for Linguistic and Cultural Competence at  
24 the OMH, which has developed class standards and  
25 other projects. Just to mention, NCQA, Kaiser  
26 Permanente, JCAHO, lots of institutions in the  
27 country have adopted these principles on their

1 own and voluntarily. There's a momentum that  
2 this Task Force cannot ignore on the recognition  
3 that quality care is needed for our diverse  
4 communities in order to improve the health of all  
5 America.

6 And we feel strongly that there should  
7 be demonstration projects and research done by  
8 Hispanics with the community that they live in  
9 that demonstrates the effectiveness of any new  
10 interventions that impact on health care  
11 delivery. Lastly, you must consider including  
12 more diversity in the leadership bodies created  
13 as critical to making any new program a success.

14 Just a few examples of looking through  
15 the literature on prescription drugs and  
16 Hispanics, and of course these come from the  
17 other border, the U.S.-Mexico border. For  
18 example, there was a study done in Los Angeles  
19 140 miles from the U.S.-Mexico border. Fourteen  
20 percent of the respondents had crossed the border  
21 to seek medical care, 80 percent of these  
22 respondents were uninsured, 23 percent reported  
23 purchasing medications, antibiotics and pain  
24 medications being the highest. Other studies  
25 have shown in Texas, in El Paso, a study on  
26 purchasing prescription medications in Mexico  
27 that more than 80 percent of the patients had

1 purchased drugs available in the U.S. as  
2 prescription drugs without a prescription.

3 In Los Angeles, in terms of issues of  
4 licensure, in our Hispanic communities right now,  
5 the Department of Health, Accounting Department  
6 of Health created a new office that increased  
7 law enforcement to curb sale of -- illegal sale  
8 of pharmaceuticals by unlicensed vendors, which  
9 included clinics run by foreign doctors without  
10 licenses as well as pharmacies providing  
11 medications without prescription. They found 280  
12 investigations, 121 arrests and \$4.5 million of  
13 drugs in the first 20 months of its operation.  
14 The Department has also started an educational  
15 program in those communities most affected by  
16 this behavior.

17 And some of the answers to some of  
18 your questions include in terms of scope and  
19 volume of imported drugs, we really feel that  
20 products need to be subject to the same level of  
21 labeling, research and critical debate as was  
22 mentioned here, and that we don't feel there  
23 should be drugs divided in two groups, one that  
24 has lesser risk and could be more acceptable to  
25 the public. The fear is that the lesser  
26 regulated product will be faster to be given to  
27 the poor and minority groups.

1           Just a couple more points. Foreign  
2 health agencies' role, I think, again, just to  
3 consider for the Hispanic community that PAHO  
4 needs to be involved for this hemisphere. And  
5 the limitations that may inhibit the Secretary's  
6 ability to certify the safety of imported drugs,  
7 I think that there is a definite inability to  
8 limit what we consider an underground trade in  
9 our Hispanic communities that would develop even  
10 faster when new distribution patterns are started  
11 by the importation of these drugs. Better to  
12 have checks and balances in the registration and  
13 inspection and recordkeeping and redundancies  
14 with oversight linked to the federal government  
15 infrastructure and its contracting institutions.

16           And, of course, there needs to be a  
17 rapid feedback system linked to the CDC with new  
18 information systems to relay information back to  
19 our providers in our communities on a timely  
20 basis as well as to connect with international  
21 points of contact.

22           In terms of new costs, we just --  
23 again, just to emphasize that we would need to  
24 see language and culturally appropriate services.

25           And in terms of impact on drug research and  
26 development, there really is a need to continue  
27 R&D in the United States and to increase the

1 focus not only on drug development but the impact  
2 on Hispanics and Hispanic research subjects and  
3 also the need to develop more physician practice  
4 networks in Hispanic communities working with  
5 pharmacies. Thank you.

6 CHAIRMAN CARMONA: Thank you, Dr.  
7 Rios. Panel members, questions, comments? Dr.  
8 Crawford?

9 DR. CRAWFORD: I appreciate all the  
10 testimony. It was very helpful to the Committee.

11 I'd like to propose sort of an alternative  
12 scenario. I believe everyone here and all of you  
13 and all the respondents we've heard from so far  
14 assume that there will be some sort of  
15 accommodation at some point. We have drugs  
16 coming in from Canada, we have a lot of political  
17 interest, we have the templates for solving those  
18 problems laid forth in the form of at least two  
19 bills and perhaps several more in the making, all  
20 of which would make us believe that there will be  
21 some kind of accommodation, some kind of  
22 facilitation of exportation from Canada.

23 What if the opposite happened? What  
24 if there was a bill or there was some sort of  
25 action within the administration that absolutely  
26 prohibited any more importation from Canada, if  
27 the borders were sealed? What harm or what good

1 would accrue from that? Would it be necessarily  
2 a bad thing or is it something that is  
3 unthinkable or what?

4 DR. SHEININ: Are you saying that  
5 there would be no importation even if it was an  
6 approved product by the FDA?

7 DR. CRAWFORD: Yes. Right now  
8 products allegedly go to Canada and then --

9 DR. SHEININ: No, no. I'm saying  
10 right now we might approve a -- sorry, I used to  
11 be -- I still say we -- FDA might approve a  
12 product by a Canadian company for importation to  
13 the U.S.

14 DR. CRAWFORD: Yes, yes.

15 DR. SHEININ: That would be excluded  
16 from your plan?

17 DR. CRAWFORD: Yes.

18 DR. SHEININ: Okay.

19 DR. CRAWFORD: I'm talking about the  
20 current package while we're here.

21 DR. SHEININ: If all the other  
22 importation was excluded, I don't see from a  
23 safety and efficacy or quality standpoint that  
24 that would be a problem. I think it would go a  
25 long way towards assuring that the products that  
26 patients were receiving were of the highest  
27 quality and were safe and effective.

1 DR. WOOD: Well, I think one of the  
2 issues is that we've failed to explain to the  
3 American people why the amount of money they're  
4 spending of drugs has increased. And we've  
5 allowed people to demonize the FDA, to demonize  
6 pharmaceutical companies, and some of them have  
7 done a pretty good job of helping that, and we've  
8 failed to really grapple with the issues, which,  
9 as I tried to illustrate to you, are that the  
10 amount of money we spend out of our pocket on  
11 drugs is going to increase in the future. You  
12 know, if you were designing the ideal medical  
13 model today, you wouldn't have surgeons, you  
14 wouldn't have all these things going on, you'd  
15 have pills that treated people. If you watch  
16 Star Trek, people didn't have surgery, they had  
17 pills that they got to treat what ailed them.

18 So I mean the future model is going to  
19 shift hopefully towards more and more medications  
20 and less and less of more primitive forms of  
21 therapy. We need to do a better job of  
22 articulating that to both the public and to  
23 legislators.

24 Now, I'm originally from Scotland. I  
25 don't like to spend money anymore than the next  
26 guy, but, clearly, patients will not tolerate  
27 vast differences in prices of any product.

1 Ferragamo shoes cost about the same in Florence  
2 as they do in New York City, and the reason for  
3 that is that they long ago recognized that they  
4 if didn't, people would buy them there and not in  
5 New York. So we cannot, I think, sustain a  
6 system that has vast differences in drug prices.

7 Now, what are we going to do about it?

8 Well, one of the groups that control this that  
9 have not been talked about very much are the drug  
10 companies who do allow their products to be sold  
11 at less than they're being sold for in this  
12 country. And, of course, drugs are unique  
13 amongst all products practically that we sell  
14 because the incremental cost of making one more  
15 pill is almost trivial. Most of the cost of drug  
16 production comes from development and research  
17 and regulatory issues. That's hard to explain to  
18 people. They think of a car being built of steel  
19 and chairs and so on and engines. Drugs are  
20 different, and we're going to have to explain  
21 that better to people, I think. I don't think  
22 something terrible will befall if people have to  
23 get all their medications from within the United  
24 States borders, I mean that's clearly what most  
25 of us do right now.

26 DR. REIDENBERG: Basically, what  
27 you're describing is theoretically the status

1       quo, and that's fine.

2                   DR. CRAWFORD:   Well, no.   The status  
3       quo -- we do have a reimportation problem now.

4                   DR.   REIDENBERG:       Well, a certain  
5       amount, yes.       But you're saying that drug  
6       products actually made in a plant in Switzerland  
7       by Ciba Geigy that are designed for the American  
8       market and who've been approved, that would  
9       continue to be imported.   We don't say it can  
10      only be made within the continental United  
11      States.

12                   DR. CRAWFORD:   That's right.

13                   DR.       REIDENBERG:               So       that,  
14      conceptually, that's fine.   I'd like to comment  
15      that when we talk about the prices that people  
16      know, we're talking about the list prices, not  
17      the discounted prices.   And that if one really  
18      wanted to say that the total revenue for a drug  
19      from the United States market should be stable,  
20      then if one reduced the list prices and raised  
21      the discounted prices, one could even the playing  
22      field within this country and with the  
23      circumstances of just having it here.   I've  
24      written a paper on this, and I'll submit it for  
25      the docket when I get home.

26                   CHAIRMAN CARMONA:   Thank you.   Other  
27      comments?   Questions from panel?   Any others?

1 No? Yes, please, Dr. O'Grady?

2 DR. O'GRADY: I guess I'd just like to  
3 -- because of Dr. Crawford's question, I'd just  
4 like to flip it around to a certain degree what  
5 happens if Congress does pass a bill that says we  
6 will allow reimportation under certain  
7 circumstances, and what would be your position in  
8 terms of just -- I mean I think that Dr. Rios did  
9 talk about sort of some of the things that would  
10 be involved in implementation, but to the other  
11 members of the panel in terms of thinking about  
12 what that suddenly mean in terms of reality.  
13 There is a bill passed, it's to be implemented,  
14 it's to be done so while maximizing safety and  
15 efficacy or safety anyway in this case, and can  
16 you talk a little bit about the implications of  
17 that and what would be necessary steps?

18 DR. WOOD: Well, I actually address  
19 some of that in my written comments. Clearly,  
20 one of the first things we need to know is the  
21 providence of the drug that's being imported, so  
22 there needs to be some kind of system to track  
23 the medication from manufacturer to final point  
24 of sale by smart tags or radiofrequency and  
25 tagging or something. And some of these could  
26 also track the storage conditions, as Carl talked  
27 about earlier on. So, clearly, knowing that

1 you're getting what you think you're getting is  
2 critical.

3 Now, is that enough? I don't know.  
4 It depends on how innovative people who try to  
5 game the system could be. And so it's hard to  
6 imagine, perhaps with the exception of aircraft  
7 or something like that, something in which it's  
8 more important to be able to track the  
9 medications that are coming into this country.  
10 Now, nobody today that I've heard has actually  
11 talked about importing controlled substances,  
12 opiates and drugs of abuse and so on. It seems  
13 to me that that's a different issue and one that  
14 should not be on the table.

15 DR. SHEININ: As I indicated, I still  
16 would feel there would be a problem of  
17 demonstration that the product being imported is  
18 bioequivalent. Does the same amount get into the  
19 blood over the same period of time? There's  
20 other issues as well. The synthetic route for  
21 the active ingredient may be different, which in  
22 most cases then would introduce different  
23 impurity profiles, as I believe it was mentioned  
24 earlier. You don't know what the safety of those  
25 impurities are, and you would not have any  
26 procedure for the control of those impurities if  
27 there was a problem with the drug. Unless you

1 knew what the impurities were, it would be very  
2 difficult to develop an analytical procedure to  
3 test that product that caused a problem that may  
4 or may not be due to a trace impurity.

5 Now, granted, the probability of a  
6 very low level of an impurity causing a safety  
7 problem is small, but there are well known  
8 examples of cases where it was an impurity at a  
9 very, very low level that did cause a safety  
10 problem that had not been seen prior to something  
11 being introduced into the U.S. market.

12 DR. WOOD: Sorry. I thought your  
13 question related to identical product -- the same  
14 product produced by the same manufacturer on the  
15 same machine.

16 DR. O'GRADY: Well, I think that we  
17 don't know is what a particular piece of  
18 legislation might or might not have in it. And I  
19 think you've brought up the problems here, but in  
20 terms of the reality of implementation, if  
21 something came in and you are faced with that  
22 sort of thing and you were the Commissioner of  
23 the FDA or the Secretary of HHS and you had to  
24 implement, I mean the implications of what you're  
25 saying are, are we talking about a doubling of  
26 the resources of the Food and Drug Administration  
27 to be able to do that sort of testing, to be able

1 to check for those sort of impurities to all of a  
2 sudden -- I mean how would you -- I mean I'm  
3 trying to think through the reality.

4 I mean you've been persuasive in terms  
5 of you're not thrilled with this idea, but at the  
6 same time the reality is is that often Congress  
7 will do what it thinks is the right thing to do  
8 for the American people, and if they move  
9 forward, part of what we have to think about is,  
10 well, then what are the implications of that?  
11 Are we talking massive amounts of resources? Are  
12 we talking about large sets of labs at the border  
13 and at major, sort of, airport hubs and things  
14 like that? And that's what I was hoping for to  
15 get in terms of your response.

16 DR. WOOD: I don't think we can  
17 possibly put enough resources in to do what  
18 you're talking about. If you're talking about  
19 drugs that are made that we know nothing about,  
20 they're coming from XYZ Pharmaceutical Company in  
21 God knows where, then measuring the content of  
22 the active compound in the pill at the border is  
23 almost valueless. So we cannot determine whether  
24 that pill is equivalent to the pill on the market  
25 in the U.S. from simplistic tests like that.

26 If we're talking about drugs that are  
27 made on the same machine, that's a different

1 issue, and that's what I was talking about.

2 DR. SHEININ: I agree. It would be a  
3 monumental task to try and control the quality of  
4 all those products. One aspect that could go a  
5 ways towards helping with that, you could have  
6 reduced amount of testing of some type if there  
7 was a USP monograph for that product, in which  
8 case you would have at least a standard that you  
9 know that the product has to meet. The problem  
10 is there is somewhere on the order of 1,200 to  
11 1,300 that are marketed in the U.S. that do not  
12 have a USP monograph today. This is because we  
13 rely on companies to provide us with that  
14 information. It's not releasable from FDA as to  
15 how a company controls the product, and in most  
16 cases a company will not provide that information  
17 until it gets close to patent expiring. So there  
18 are no monographs for many of the newer, quote,  
19 unquote, "miracle drugs," that are on the market  
20 today that are so expensive. But there could be  
21 at least some sort of screening if there was a  
22 USP monograph, and anybody importing those drugs  
23 knew that it had to meet the quality set forth in  
24 the monograph.

25 CHAIRMAN CARMONA: Dr. Reidenberg?

26 DR. REIDENBERG: Yes. If I can  
27 comment on the world that I live in. My son is

1 an academic, he's on sabbatical leave in France.

2 His family is with him. When they've gotten  
3 sick this year, they've bought medicines in  
4 French pharmacies, and I've had no concerns about  
5 their quality.

6 I think there are very clearly a  
7 number of countries that one could name that have  
8 regulatory procedures and implementations  
9 essentially equivalent to ours. And drug  
10 products that are acceptable for their market  
11 that can be tracked so we know what comes into  
12 this country are those drugs products and not a  
13 counterfeiters that got into the distribution  
14 system I would have no worries about because if  
15 my family's abroad or I'm abroad in these  
16 countries, we buy them, we take them, we're  
17 content. And I think that to me the biggest  
18 issue here is making sure that the origin of the  
19 product is from a jurisdiction that is equivalent  
20 to the United States and that it's this  
21 particular product that gets into our  
22 distribution system so that it's not a  
23 counterfeit.

24 And then from a medical standpoint, I  
25 don't perceive a problem when my patients  
26 purchase their medicine when they're abroad in  
27 these places, when my family does, and I don't

1 perceive a problem if I were to purchase this  
2 medicine here.

3 CHAIRMAN CARMONA: Dr. Peck?

4 DR. PECK: I'm not quite as confident  
5 as my friend Marcus is with regards to any other  
6 regulatory agency. We have standards here, for  
7 example, for the dyes in tablets and capsules  
8 that are not shared by virtually any other even  
9 Western advanced regulatory agency. In other  
10 words, dyes are included in their tablets that  
11 are on the carcinogenicity list in the NCTR. So  
12 it's not so simple. Perhaps casual use of a  
13 French drug might not be so bad, but I don't  
14 think I would actually be comfortable with my  
15 family using any drug other than a generic or  
16 brand name U.S.-approved manufactured drug.

17 On the other hand, I think as  
18 highlighted in my testimony, I think the category  
19 one drugs offer an opportunity, assuming that the  
20 economic challenges can be overcome. Those are  
21 drugs that are approved by FDA, manufactured in  
22 the United States or in an FDA-approved  
23 manufacturing source in another country and are  
24 either reimported or they come across the border  
25 from the manufacturing. So for all intents and  
26 purposes they are the same drugs that we  
27 distribute and approve for distribution in this

1 country.

2           The conditions for full confidence in  
3 those would include having an absolutely bullet-  
4 proof record of the pedigree and transportation  
5 and storage conditions of that. And I think that  
6 would do it. If there were deviations from the  
7 specs, then in vitro, on-human dissolution  
8 testing might be a pass-through test, an  
9 occasional random sampling with mass spec  
10 evaluations to see if there are any impurities  
11 out of sync. So I think we could limit ourselves  
12 to a particular reliable sourcing of FDA-approved  
13 drugs that could run around the world, actually,  
14 and come back to us. That doesn't solve the  
15 economic challenges that accompany this, but I  
16 think from a safety and effectiveness point of  
17 view, if one limited it.

18           And I think the resource requirements  
19 for that are attractable. I don't think it would  
20 require doubling of the FDA resources. FDA  
21 regulates 25 cents on every consumer dollar, and  
22 that includes foods and medical devices and  
23 animal drugs and a lot of other things, and so it  
24 would require an increase in the field and  
25 compliance resources, and it should be modeled.  
26 Our opinions, I think, are worthless. There  
27 should be some econometricians actually getting

1 out their spreadsheets and checking this out to  
2 see what the resource implications are.

3 CHAIRMAN CARMONA: Thank you, Dr.  
4 Peck. Dr. Reidenberg, regarding your comment, I  
5 guess we've all had the experience of being stuck  
6 someplace where it was not home, in another  
7 country and had to purchase a medication for some  
8 reason or other. And I think we have found  
9 ourselves, and those of us who have been  
10 discussing this before the panel and after, as  
11 Dr. O'Grady mentioned with the Medicare  
12 transformation or modernization and the new  
13 pharmacy guidelines for our seniors, we had the  
14 anecdotes all the time. But I went to Canada and  
15 nothing happened to me. My friend went to Mexico  
16 and bought it and nothing happened. We've heard  
17 it from a dozen countries. But yet, as you know,  
18 the absence of a complication doesn't necessarily  
19 dictate a good system, one that's robust and will  
20 protect the American public. And so we're  
21 obviously trying to get beyond the anecdote of  
22 survival for any of us to one of how do we deal  
23 with this as a national policy issue?

24 Prior to this panel and previous  
25 panel, we've had experts in security from some of  
26 the large drug manufacturers, others who came and  
27 suggested that if importation was considered,

1 there would be really no way to ensure safety and  
2 efficacy. And in fact the state of technology  
3 today is -- they could not guarantee that we  
4 would be safe from subpotent or knock-offs or any  
5 of the other classifications of drug that may get  
6 into our pipeline. So although we don't have the  
7 exact cost, I think that the experts who talked  
8 to us said they'd be hard pressed even giving  
9 almost an unlimited budget with the technology  
10 they have to be able to guarantee.

11 So I want to throw that out to all of  
12 you, but, also, Dr. Reidenberg, I understand your  
13 comment regarding your son in Paris, but I guess  
14 I'm trying to go beyond the anecdote really and  
15 look at national policy.

16 DR. REIDENBERG: Sure. If I can  
17 respond to that. A couple of qualifications I  
18 had in the written testimony is that the drugs  
19 being manufactured in countries that have the  
20 same laws and regulatory implementation as we do,  
21 and I think that we can identify some advanced  
22 industrialized countries that one would have to  
23 acknowledge that they're as careful and as  
24 conscientious as we are. I don't know anything  
25 about the technology of assuring security so that  
26 the product that is in the pharmacy in New York  
27 City is the specific product that was made in

1 England or in Australia and brought in. If that  
2 can't be done, then there's no way to assure  
3 safety. But if we're dealing with products that  
4 are prepared under these particular  
5 jurisdictions, then it would be very difficult  
6 for me to argue that there is a greater  
7 likelihood that they will either be more  
8 hazardous or less effective than products made  
9 under FDA jurisdiction where these others  
10 essentially are equivalent to ours.

11 CHAIRMAN CARMONA: Another just brief  
12 comment on that, and then I'll ask all of you to  
13 comment also. Assuming that we could identify a  
14 dozen countries internationally that had the same  
15 requirements that we do, let's say an equivalent  
16 FDA that was regulating and we felt safe, the  
17 other question then bespeaks what we've heard  
18 with the last panel of economists and what are  
19 the long-term implications of the health policy  
20 that has us shopping worldwide as far as research  
21 and development as well as many other factors  
22 that we've spoken about? And is that something  
23 that we would recommend as policy, either short  
24 term or long term, considering the significant  
25 input we've had already from economists and what  
26 we know from the literature?

27 DR. REIDENBERG: I think that the

1 economic issues that were raised and discussed  
2 are very important ones. I was addressing  
3 specifically the clinical issue of efficacy and  
4 safety, and I think that it will be difficult to  
5 argue efficacy and safety when we're really  
6 thinking about support for long-term research.  
7 They're two different subplots.

8 CHAIRMAN CARMONA: Thank you, sir.  
9 Other comments? Okay. Dr. Peck?

10 DR. PECK: What you've just challenged  
11 us with stimulates me to think about a different  
12 world that I think we're actually seeing begin to  
13 evolve in Europe. If you look at the history of  
14 drug regulation in Europe over the last 20 years,  
15 you will understand that 20 years ago there was a  
16 separate regulatory agency in each country that  
17 did not recognize a drug approval in the  
18 neighboring country. And in the course of the  
19 last two decades that has shifted now to a common  
20 regulatory agency surrounded by individual  
21 country regulatory agencies and two pathways for  
22 approval of a new drug in Europe. Increasingly,  
23 manufacturers are taking the route of going  
24 through the EMEA, the European Medications  
25 Evaluation Agency, which when they meet the  
26 standards of testing and safety and effectiveness  
27 for that, they get all at once approval for

1 marketing in all 18 or 40 countries, depending  
2 upon what the current status is.

3           So that has obviously huge economic  
4 implications. As far as I know, the individual  
5 countries still determine the pricing policies  
6 for those, so it's not perfected in terms of a  
7 global economic solution, but the prospect of  
8 having mutual recognition or common drug approval  
9 across countries would relax much in the area of  
10 safety and effectiveness, and then the economic  
11 thing has still got to be solved, but that could  
12 become an incentive to drug companies.

13           CHAIRMAN CARMONA: Thank you, sir.  
14 Let's see, Dr. Sheinin and then Dr. Wood.

15           DR. SHEININ: Let me preface what I'm  
16 going to say by saying if you don't have good  
17 quality and you don't know what the quality is,  
18 you can't really say anything about safety and  
19 efficacy. You must know the quality of the  
20 products. And we've been talking -- I was  
21 talking earlier about doing testing to look at  
22 the quality, but you cannot test quality into a  
23 product. Quality is part of the overall scheme.

24           There also has to be knowledge that the products  
25 are made under good manufacturing practices.

26           Several years ago there was an effort  
27 to put into place a mutual recognition agreement

1 with Europe, with the European Union in terms of  
2 inspections, FDA and the European Union. And as  
3 far as I know, that has never come to fruition  
4 because of the fact that in the opinion of FDA  
5 not every country in the European Union was  
6 equivalent in terms of how they inspected to  
7 GMPs. So that would have to play into any sort  
8 of a scheme that was put into place to allow  
9 mutual recognition of the review and approval of  
10 a product from another country. What country  
11 actually did the inspection? Is it the country  
12 where it's manufactured or was it an investigator  
13 from another country within the European Union,  
14 and that would just complicate the whole picture  
15 all together.

16 In my opinion, and a conclusion, I  
17 don't believe that there is a better regulatory  
18 authority in the world than FDA. I worked there  
19 for 30 years, I'm proud it, and I think they are  
20 the best that there is anywhere in the world.  
21 Given that, to do what we're asking, they would  
22 have to tremendously increase their resources.  
23 They don't have the resources today to inspect  
24 every facility every two years as the law  
25 requires, and if you added additional sources of  
26 drugs coming in, not only is it the testing, it's  
27 also the inspection of the facilities.

1 DR. CRAWFORD: Would you consider  
2 coming back to the Food and Drug Administration?

3 DR. SHEININ: No. I'm enjoying what  
4 I'm doing at USP, but I really did enjoy it, and  
5 I thought it was a very worthwhile part of my  
6 career, a major part of my career.

7 CHAIRMAN CARMONA: Thank you, Dr.  
8 Sheinin. Dr. Wood, did you have a comment?

9 THE WITNESS: Yes. I think it's  
10 important that we remember what we're talking  
11 about here. The only drugs that people are going  
12 to be tempted to import are ones that are  
13 currently under patent for protection. So the  
14 idea that people are going to be out formulating  
15 their own drugs somewhere else means either that  
16 we're going to abrogate patents, which I think  
17 nobody is proposing, or that we're going to allow  
18 counterfeit drugs in, which we're certainly  
19 against.

20 So the universe of drugs that we're  
21 talking about that people are going to be tempted  
22 to import are those that are currently expensive  
23 and almost by definition are ones that are  
24 currently under patent protection. These drugs  
25 are currently being produced by multinational  
26 pharmaceutical companies, frequently on the same  
27 machines and in the same factory for use in

1 multiple different countries. So controlling the  
2 quality there is less of a problem than we might  
3 like to think.

4 But I want to pick up your second  
5 point, which was what will the effect be on  
6 innovation, and I think that's really important.

7 You know, we don't have treatments for some of  
8 the major diseases in this country and anywhere,  
9 I mean not just in this country. If we don't  
10 encourage innovation, we're not going to have  
11 treatments for most of these diseases in my  
12 lifetime, given the lifetime it takes to develop  
13 a drug.

14 And I'm not talking about rare  
15 diseases or orphan diseases, we're talking about  
16 things like osteoarthritis. We have nothing that  
17 prevents osteoarthritis. We have nothing that  
18 prevents Alzheimer's which is going to be a huge  
19 problem by the time I reach that age. These are  
20 high-risk, high-cost research endeavors, and  
21 those who invest in that need to be confident  
22 that their investment is going to be protected  
23 for a time that allows them to recover their  
24 costs with some legitimate level of profit. So I  
25 think that's an issue that we can't -- a circle  
26 we can't square.

27 CHAIRMAN CARMONA: I think that, and I

1 don't know the magnitude, but I think we've heard  
2 of cases -- first, let me preface my statement  
3 with I agree with the premise that it's mostly  
4 the patented drugs and the expensive drugs, but I  
5 think we've heard of cases of generics being  
6 imported, maybe because the public doesn't  
7 understand, for instance, in Canada that our  
8 generics generally are cheaper and also from  
9 Mexico as well as other countries. So I don't  
10 know that it's just only the expensive. That may  
11 be the driver, but I think there's an  
12 undercurrent there also of maybe just  
13 misunderstanding that people still look outside  
14 the borders to get some of the less expensive  
15 drugs and those that are not controlled on  
16 patent.

17 DR. CRAWFORD: I was just in Chicago  
18 yesterday at the mail detention facility, and I  
19 spent all day looking through what's coming in.  
20 And Dr. Wood is generally correct, but there are  
21 also controlled substances, marijuana and all  
22 that kind of stuff, right there before you. But  
23 then you go from the sublime to the infinitely  
24 bizarre, because if it's anything that might  
25 increase even the muscle in your small finger,  
26 it's there, and it's always injectable because  
27 it's better if it's injectable. And the syringes

1       come with them.       And they come from Central  
2       America and all over the world.       And I'm not  
3       talking about a small volume, I'm talking about  
4       4,000 pieces a day coming right in there.       But  
5       you're right.

6                   And the point I was going to make  
7       before I got waxed so ineloquent is that there  
8       were almost no generics there, that we would call  
9       generics.

10                   CHAIRMAN CARMONA:       Thanks, Doctor.  
11       Other questions?   Yes, Dr. O'Grady?

12                   DR. O'GRADY:       I guess in terms of  
13       trying to parse through exactly where these  
14       different parameters when we try to think about  
15       this, it's a tough one in terms of as we continue  
16       here, because I think it was very compelling  
17       testimony that we heard about counterfeiting.   At  
18       the same time, while the security folks from the  
19       different manufacturers were laying that out, I  
20       was thinking reimportation or no reimportation  
21       you've got a counterfeiting problem here, guys,  
22       and you've got an Internet problem here, guys,  
23       and this all could go away tomorrow, and there's  
24       still going to be draw on resources, kind of  
25       public and private, to do that.

26                   So sort of trying to parse through  
27       what part of this challenge goes into -- I know

1 I'm struggling with it right now. I mean the  
2 doubling of FDA, I mean it seems to me that when  
3 we look at that testimony, and luckily it's  
4 something that Les has to worry about, not me,  
5 but I mean counterfeiting, Internet, that's here,  
6 that's not going away.

7 Now, I can certainly see how  
8 importation-reimportation complicates that matter  
9 even more, but I keep trying to keep in mind  
10 we've got this layer there that only looks like  
11 it's going to expand. So whatever we do with  
12 importation is -- you know, you want to be  
13 careful not to make matters worse, but it's still  
14 there for sure.

15 CHAIRMAN CARMONA: Thank you. Any  
16 other comments?

17 DR. DUKE: I just have one.

18 CHAIRMAN CARMONA: Dr. Duke, yes.

19 DR. DUKE: Just to build on two  
20 questions earlier, one Les proposed, Les and Mike  
21 took the opposite on the issue of no importation  
22 or open the doors wide. And I'd sort of like to  
23 go at, all afternoon we've been sort of going  
24 back and forth without sort of precisely defining  
25 that we're talking about two polar opposite  
26 approaches to importation. One is sort of the  
27 individual importation by the Internet or a bus

1 trip across the border. That's one form of  
2 importation. And the second form of importation  
3 is wholesale purchases which lend themselves to  
4 the possibility for regulation and testing, and  
5 I'd sort of like your comments on how we wrap our  
6 minds around a problem that presents itself with  
7 both of those extremes?

8 DR. WOOD: Can I respond?

9 CHAIRMAN CARMONA: Please, Doctor?

10 DR. WOOD: I don't see that there's a  
11 fundamental difference between the FDA approving  
12 another generic drug with all of the requirements  
13 that Eric talked about that are demanded of that  
14 and importing a drug. What I mean by that is the  
15 idea that we should allow somebody to bring in a  
16 drug that's not been approved because it's,  
17 quote, "equivalent" to another drug but the  
18 legitimate manufacturer who tried to sell a  
19 generic equivalent and through the stream of  
20 commerce in the U.S. has to go through all the  
21 requirements to get approval by the FDA seems to  
22 me just impossible to deal with. I mean you  
23 cannot have a parallel track where legitimate  
24 people are going through the FDA to get approval  
25 for a generic equivalent and simultaneously I can  
26 bring wholesale imports of a drug in from Canada  
27 without going through that approval process.

1 That will just destroy our excellent drug  
2 approval process that we have in this country.  
3 So I think that's untenable. I just can't see  
4 how that can possibly be done, unless we abolish  
5 drug regulation, which I don't think anyone  
6 seriously is proposing.

7 CHAIRMAN CARMONA: Thanks, Dr. Wood.  
8 Any other comments, questions? Yes, Dr. Peck?

9 DR. PECK: Dr. Crawford can probably  
10 give more precision on this situation, but for  
11 many years FDA and I think the Customs Department  
12 have been relaxed about individual importation,  
13 so to speak, perhaps partly because it would be  
14 sort of a messy problem to control but also  
15 because it has less commercial and large-scale  
16 safety and effectiveness and may even have  
17 something to do with individual freedoms and a  
18 right to purchase.

19 But it does seem to me that at least  
20 some of the irrationality of that when that  
21 that's the case could be affected by education  
22 and programs to inform. I remember when I was at  
23 FDA I think the individual importation issue came  
24 to a head when groups of AIDS patients and their  
25 caregivers wished to import in larger quantities,  
26 and what they wanted to import was sometimes  
27 pretty irrational, but it was a desperate effort

1 and it was a message of desperation. But many of  
2 those groups I recall engaging with began  
3 advising their constituencies not to go forward  
4 when they became informed about the situation.  
5 So I think that part of it could be amenable to  
6 education and information.

7 DR. DUKE: I think that's what Les was  
8 talking about, though, with the 4,000 items a day  
9 at several major import sites in the country.  
10 And so I often find in these discussions that the  
11 conversation waxes back and forth between the  
12 sort of systemic issues around wholesale  
13 importation and the issues of the economic  
14 concerns, the clinical concerns, and then we  
15 switch sort of -- or sort of slide into the next  
16 discussion of grandma who knows that Aunt Besse  
17 up in Canada's getting her medicine cheaper.

18 And I think when we face the public,  
19 we are faced with both sets of arguments, and I  
20 think that's one of those where I think we need  
21 some intellectual rigor as we try to sort through  
22 it, because I think you're getting into -- and I  
23 thought, Dr. Peck, you made the good point --  
24 that we then find ourselves faced with the issues  
25 of privacy and an assertion of rights and so  
26 forth, despite the fact that we have laws on  
27 these matters. But this is a distinction I think

1 we need to articulate more clearly in order to be  
2 able to more clearly identify the problem so that  
3 we can put the resolutions with the right pieces  
4 of the problem.

5 CHAIRMAN CARMONA: I couldn't agree  
6 with you more. That's well said. I really  
7 appreciate Dr. O'Grady bringing up earlier today  
8 the practicalness of those of us who have to  
9 speak in public about this, that all of these  
10 very academic discussions fall by the wayside  
11 when it's that one senior citizen in front of you  
12 saying, "I want my medication. Don't confuse me  
13 with all of that stuff." But I think it's  
14 important, and hence the purpose of these  
15 hearings to get out all of the contributing  
16 factors so that we can somehow synthesize that  
17 body of information, as Dr. Duke says, to come  
18 out with a reasonable approach to policy for our  
19 country as it relates to importation and anything  
20 else that comes of this that we would put in the  
21 report, because, certainly, we're not restricted  
22 but we need to meet those minimum requirements as  
23 Congress has outlined for us.

24 Any other comments or questions from  
25 any of us? If not, let me just say I'd like to  
26 thank all of our presenters for coming here  
27 today. We had some very good and valuable

1 discussion. On that note, it's becoming  
2 especially clear that the United States  
3 government would need international cooperation  
4 in order to devise a structure to legally, safely  
5 and effectively import prescription drugs from  
6 foreign nations. To encourage that discussion  
7 the Task Force invited representatives from  
8 Health Canada and the European Association of  
9 Europharmaceutical companies to participate in  
10 today's listening session. However, both  
11 organizations were unable to accept our  
12 invitation. So with the consent of the rest of  
13 the Task Force, I would like to publicly invite  
14 these two organizations to present at either of  
15 our two remaining listening sessions on May 5 or  
16 May 14. And even the primary focus of those  
17 listening sessions may be slightly different than  
18 today's, the Task Force mission is the same no  
19 matter what the date, and I believe that these  
20 two organizations are vital to hear from.

21 We are also encouraging more input  
22 from a wide diversity of economists. We've heard  
23 some today, but we know there's more out there  
24 that have opinions, and we'd like to get them to  
25 the table also. So I would ask the Task Force to  
26 please let Health Canada and the European  
27 Association of Europharmaceutical Companies have

1 open invitations as well as any economists that  
2 have diverse input and opinions on these complex  
3 issues and any other stakeholders who we may have  
4 missed inadvertently, because I assure you we  
5 have done our due diligence to find everybody  
6 that has an opinion on this issue. If we've  
7 missed the boat on any of those, please, any of  
8 you let us know, and thank you so much for your  
9 time and helping us through this very difficult  
10 dilemma. Good night.

11 (Whereupon, at 5:19 p.m., the  
12 Stakeholder meeting was concluded.)

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