

1 else?

2 MR. CATIZONE: If truly you want to stop  
3 this practice, it's going to require significant  
4 resources and mean that there has to be resources and  
5 actions on all fronts. So that would mean from the  
6 individual consumer, when they're ordering these  
7 medications, we have to go after the credit card  
8 companies, we have to go after the shippers. At the  
9 border, we have to confiscate packages. Within the  
10 U.S., anything facilitating those suppliers also needs  
11 to be prosecuted as well as in the foreign countries  
12 where they're originating.

13 Again, it's amazing to us that we -- that  
14 the industry was able to shut down the life-  
15 threatening sharing of music files through Napster,  
16 but we can't stop importation. So it's -- if you want  
17 to stop it, it involves resources and going after the  
18 individuals.

19 MR. SACHDEV: Well, my question wasn't  
20 really about stopping them. It was really to  
21 understand what you're suggesting in terms of how you  
22 do it.

23 MR. CATIZONE: Well, it's difficult to  
24 control product by product, because I would say  
25 controlled substances are the most dangerous products  
26 at this point that are being ordered over the

1 internet.

2 We've seen a proliferation of e-mails and  
3 products crossing the border that I'm not sure anybody  
4 could stop at this point. So if you put together a  
5 list of products, patients are not going to adhere to  
6 that list. They're going to find other sources for  
7 the medications they want.

8 MS. WINCKLER: That's why the list only  
9 works if you're talking about a commercial importation  
10 system. So the person only stopped at the border  
11 through the credit card and the couriers and all of  
12 those mechanisms. And if it's through commercial, you  
13 would have to license those who are outside the  
14 country, providing to those inside the country, and  
15 then you have an access point or something to go after  
16 with -- on both sides of the border.

17 SURGEON GENERAL CARMONA: Okay. It seems  
18 that most of you -- all of you are in agreement that  
19 under certain conditions this could be a possible  
20 short-term remedy for the problem. But as Ms.  
21 Winckler pointed out earlier, and those of you who  
22 spoke also alluded to, that the problem is much bigger  
23 than just importation.

24 It seems to me, though, that in all of  
25 your comments what we're talking about here is  
26 developing an adjunct or additive regulatory

1       investigative oversight authority complementary to  
2       FDA, to Customs, to DEA, to be able to do their jobs  
3       in a broader fashion than they do now, which incurs a  
4       huge cost, more resources.

5               So at what point does that cost-benefit  
6       analysis fall the other way and we say, "Well, all  
7       this is, really, is a shell game. We're shifting the  
8       cost over here, and ultimately government, then, is  
9       subsidizing this one way -- either directly or  
10      indirectly."

11             DR. SHEPHERD:     Right.     You're right.  
12      You're absolutely right.   You'd have to do some kind  
13      of analysis or some kind of a sensitivity analysis on  
14      what costs -- let me put it this way.   What costs can  
15      we afford to invest in such a system?   And then figure  
16      out what everything is going to cost.   Do we have that  
17      money to invest in it?   And then I'm not too sure  
18      we'll get our return on it.

19             SURGEON GENERAL CARMONA:   Okay.   Other  
20      questions or comments?   No.

21             Thank you so much for your patience.   I  
22      know we kept you a little longer, but that was great  
23      insight for us.   Thank you very much.

24             We're going to take a 10-minute break as  
25      we switch over to the last panel.   Thank you.

26             (Whereupon, the proceedings in the

1                   foregoing matter went off the record at  
2                   3:13 p.m. and went back on the record at  
3                   3:27 p.m.)

4                   SURGEON GENERAL CARMONA:       Ladies and  
5 gentlemen, we'll reconvene. Please take your seats.

6                   We'll begin with the third and final  
7 panel, and our first speaker, Ms. Deanna Williams,  
8 Ontario College of Pharmacists.

9                   Thank you.

10                  MS. WILLIAMS: Thank you. Dr. Carmona and  
11 members of the task force, thank you very much for  
12 having me today.

13                  My name is Deanna Williams, and I am the  
14 Registrar for the Ontario College of Pharmacists. And  
15 the Ontario College of Pharmacists is the largest  
16 regulatory and licensing body for the profession of  
17 pharmacy in Canada. We currently have 10,000 members  
18 on our register, which means that we regulate  
19 approximately 40 percent of pharmacists in Canada.

20                  And in addition to our pharmacist members,  
21 we also regulate 3,000 community pharmacies, and  
22 according to operational standards of practice, and we  
23 also regulate the sale of drugs from Ontario.

24                  It's our position that the college has had  
25 high quality, cognitive standards of practice for  
26 pharmacists, and operational standards for pharmacies

1 must be met regardless of where patients who obtain  
2 their pharmacy services from Ontario reside. And our  
3 standards include the pharmacist establishing a  
4 professional relationship with their patients, and  
5 taking reasonable steps to enter into a dialogue on  
6 their drug therapy.

7 In all situations where drugs are  
8 delivered to patients, the college's standards for  
9 packaging, shipping, and delivery, and that includes  
10 Canada customs rules and regulations for delivery  
11 outside of Canada, have to be met.

12 The college's Point of Care symbol, which  
13 I've included in your package and I'm showing you now,  
14 must also, as a standard of accreditation, be  
15 prominently displayed in all accredited community  
16 pharmacies and also on their related websites.

17 In Ontario, our legislation does not  
18 contemplate virtual pharmacies. So all Ontario  
19 pharmacies are brick-and-mortar pharmacies that are  
20 accredited and inspected routinely by our college  
21 inspectors once every three years to ensure compliance  
22 with our standards.

23 We have 3,000 pharmacies currently that we  
24 issue certificates of accreditation to, and of those  
25 our records show that under 300 of them, and at last  
26 count there were about 271 that indicate that they do

1 operate websites that are available to the public.

2 Now, the majority of the pharmacies in  
3 Ontario that operate websites simply use their  
4 websites as a manner of communicating with members.  
5 So the same way they would use faxes, telephones, and  
6 so on.

7 The exact number of pharmacies that are  
8 actually providing internet services to the U.S.  
9 patients is not certain. But what we do know is that  
10 the practice does primarily -- it is directed to  
11 patients that are residing outside of Canada. And we  
12 do investigate each and every such operation as they  
13 become known to us through various means.

14 Although this practice gives rise to  
15 issues and to potential issues, as a regulator that is  
16 charged with protection of the public our position  
17 remains grounded in knowing that Ontario has a safe  
18 and effective self-regulatory system that protects the  
19 public, whether they reside in Ontario or not.

20 And that system that we have in place  
21 protects against practitioners -- in our case  
22 pharmacists -- but in Ontario the College of  
23 Physicians and Surgeons would say also prescribers,  
24 and pharmacies that fall below our standards of  
25 practice.

26 We have processed complaints and

1 investigated complaints that we have received from  
2 U.S. patients, and we'll continue to do so. We  
3 believe that this is also true to be across Canada and  
4 would suggest that the American public is not at risk  
5 if they obtain their pharmacy services from legitimate  
6 licensed and accredited pharmacists and pharmacies in  
7 Canada.

8 Our primary issue of concern is increasing  
9 inability of us as regulators to protect the public  
10 against internet sites that purport to be but are not  
11 legitimate. An increasing number of websites are  
12 cropping up with a Canadian flag on them that promote  
13 themselves as pharmacies located in Canada when in  
14 fact they are not.

15 In the spring of 2002, our college, acting  
16 under the authority of the Provincial Offenses Act,  
17 closed down an illegal operation that was selling  
18 drugs to the American public under the name  
19 TheCanadianDrugstore.com. We laid a total of 15  
20 charges under the POA against the operation, its owner  
21 and operator, who is not a pharmacist, including using  
22 the name "drugstore," which in Ontario is a protected  
23 title and can only be used by accredited pharmacies.

24 We also laid charges against an Ontario  
25 pharmacist, their pharmacy, a physician, and a  
26 Canadian drug wholesaler for their roles in aiding and

1 abetting this illegal operation. The case was  
2 successfully prosecuted, and there are copies attached  
3 I believe in your package of the press releases  
4 outlining the results.

5 Our prosecutorial actions against  
6 TheCanadianDrugstore.com were necessary, but they were  
7 extremely resource-heavy. And I think it really  
8 underscores the need and the importance of a  
9 cooperative and coordinated approach in pursuing rogue  
10 internet prescription drug sites.

11 We also believe that focusing our  
12 attention on the procurement of prescription drugs  
13 from bona fide regulated and safe pharmacists and  
14 pharmacies that are based in Canada -- in our opinion,  
15 this is not helpful, and it actually diminishes our  
16 effectiveness in protecting the public against  
17 potentially dangerous drugs obtained through the  
18 unregulated sites.

19 Also, as regulators, we can't totally  
20 solve the problem unless we have an effective public  
21 education and communications system on both sides of  
22 the border. We can't protect the public against  
23 themselves, and the public needs to understand the  
24 dangers that exist if they go in and put in personal  
25 information and personal health information into sites  
26 that are not bona fide.

1           The VIPPS program established by the  
2 National Association of Boards of Pharmacy, which is  
3 just starting to come into play in Canada, the  
4 college's Point of Care Program, are examples of  
5 programs that offer assurances to the American public  
6 that pharmacy sites from which they seek their  
7 prescription services are both legitimate and subject  
8 to regulation.

9           These programs are just a good start,  
10 though. And it's our view that much more needs to be  
11 done to inform the public of the importance of  
12 verifying the legitimacy of their health care  
13 providers.

14           Thank you.

15           SURGEON GENERAL CARMONA:     Thank you,  
16 ma'am.

17           Our next speaker, Mr. Donald MacArthur,  
18 from the European Association of Euro-Pharmaceutical  
19 Companies. Thank you, sir.

20           MR. MacARTHUR:   Mr. Chairman, task force  
21 members, thank you very much for inviting the European  
22 Association of Euro-Pharmaceutical Companies to submit  
23 its views.   With over 70 firms from 16 European  
24 countries as members, the EAEPCC is the professional  
25 representative body of pharmaceutical parallel  
26 importers and exporters -- we call them collectively

1 parallel traders -- in Europe.

2 Ours is an industry that in its best ever  
3 year, 2002, shipped 140 million packs of prescription  
4 medicine safely and efficiently across national  
5 borders within the EU's internal market. Here is an  
6 example of a repackaged pack sourced in -- a product  
7 that was sourced in Italy and sold in Denmark.

8 Parallel trade exists because of  
9 interstate price differences, but it simply would not  
10 happen if, after meeting its costs, a parallel trader  
11 did not pass on a significant part of the price  
12 difference to the payer. In Europe, the payer is  
13 predominantly the social health insurance system.

14 Direct savings to such systems and  
15 consumers in 2002 in just five EU countries were  
16 independently quantified in excess of \$745 million,  
17 with indirect savings through parallel trade's  
18 competitive effect in an otherwise monopolistic market  
19 likely to be even higher, the study found.

20 Twenty plus years' experience in Europe  
21 has conclusively shown that pharmaceutical parallel  
22 trade is safe. It can be strictly limited to genuine  
23 products that have been approved for marketing to  
24 common high European standards and produced by the  
25 same original brand manufacturers as the domestic  
26 version. There has never been one confirmed case of a

1 counterfeit drug reaching a patient in Europe as a  
2 parallel import.

3 Parallel trade would fit very well into  
4 the U.S. free market principles. One of the reasons  
5 why governments in the UK and Germany, the two largest  
6 markets for incoming parallel trade, have been able to  
7 avoid introducing manufacturer price controls with new  
8 innovative drugs, is that use of parallel trade by  
9 pharmacists is officially encouraged there.

10 Parallel trade, as found in Europe, is  
11 very different from personal importation, whether by  
12 mail order, internet, or on foot. That has been the  
13 basis of U.S. experience to date. Ours is a mature,  
14 highly regulated, business-to-business activity. We  
15 have no direct dealings with the public, and instead  
16 supply only authorized wholesalers and/or registered  
17 pharmacies.

18 It is the community hospital pharmacist's  
19 professional decision whether parallel trade is  
20 dispensed to the patient or not. With parallel trade,  
21 the product's origin, quality, and storage conditions  
22 could be assured. The chain is a closed one. Only  
23 authorized products are purchased from authorized  
24 wholesalers in one EU country and sold to authorized  
25 distributors in another EU country by parallel  
26 traders, which are themselves authorized by no less

1 than four different controls.

2           Pharmacists purchase parallel trade  
3 because it gives them and their patients a choice. It  
4 also is financially rewarding to pharmacists.  
5 Parallel trade supports rather than threatens the  
6 local distribution -- sorry, the local pharmacy  
7 infrastructure. It is also suitable for all types of  
8 products, not just including -- not just repeats of  
9 chronic medication.

10           As I mentioned, 2002 was our peak year.  
11 Growth in the major markets was flat last year, and  
12 this year there is likely to be negative growth. This  
13 is not because the demand for parallel trade is  
14 lessening, or because interstate price differences are  
15 narrowing, it is simply because of counter strategies  
16 by manufacturers.

17           The main problem has been the introduction  
18 over the past two to three years of supply quota  
19 systems by an increasing number of major multi-  
20 national manufacturers. SRPA stock that was one  
21 traded has been eliminated in Europe.

22           As well as hitting parallel trade, quotas  
23 have damaged the business of wholesalers and also led  
24 to product shortages, which have, of course, public  
25 health implications. The EAEPC, its members, and I'm  
26 very pleased to say the European Association of Full

1 Line Pharmaceutical Wholesalers, GRP, G-R-P, allege  
2 quotas breach EU competition rules.

3           Around 50 complaints against a total of 15  
4 manufacturers are believed to be currently pending  
5 before European and national competition authorities.

6           We are constantly reminded that we have the support  
7 of the European Commission. Only this January, the  
8 Commission issued a communication reaffirming the  
9 legality of parallel trade in medicines.

10           However, antitrust investigations have to  
11 be very thorough to withstand robust examination in  
12 the courts. And with manufacturers making full use of  
13 their appeal rights, a case can drag on for a decade  
14 or more.

15           In conclusion, Mr. Chairman, while EAEP  
16 strongly supports all those who advocate parallel  
17 importation of prescription drugs into the U.S.,  
18 Europe unfortunately is not currently the solution or  
19 an alternative to supply shortages in Canada. We have  
20 the know-how and the expertise certainly. I don't  
21 think anybody else in the world has better know-how  
22 and expertise.

23           And I would like you and your colleagues,  
24 please, to come and visit us in Europe to see it for  
25 yourself. But we have supply shortages of our own.  
26 We, therefore, urge U.S. lawmakers to ensure future

1 importation legislation contains effective measures to  
2 penalize manufacturers that obstruct free trade into  
3 the U.S., especially artificial volume restrictions in  
4 the countries they are supplying.

5 I understand this indeed is the case with  
6 two bills tabled recently in the Senate. This is a  
7 very encouraging development.

8 Thank you.

9 SURGEON GENERAL CARMONA: Thank you, sir.

10 Our next speaker, Mr. David MacKay, the  
11 Canadian International Pharmacy Association. Thank  
12 you, sir.

13 MR. MacKAY: Good afternoon. I'd like to  
14 thank you, Dr. Carmona, as well as the Health and  
15 Human Services Task Force, for the opportunity to  
16 present a Canadian perspective on drug importation or  
17 what I term the "supplier's view."

18 I'd like to start by telling you a little  
19 bit about CIPA, or the Canadian International Pharmacy  
20 Association. We represent the views of the vast  
21 majority of the leading Canadian mail order pharmacies  
22 that provide prescription services to American  
23 patients. CIPA members provide roughly more than 80  
24 percent of the mail order prescriptions to now more  
25 than two million Americans.

26 Our members have been dispensing safe and

1 affordable medications to American citizens for over  
2 three years now, and each of the members adheres to  
3 all legal and regulatory requirements imposed by the  
4 Canadian government as well as the provinces and the  
5 regulatory authorities in the provinces that they  
6 dispense medications in.

7           Again, also like Mr. MacArthur, I would  
8 like to invite all officials, interested members of  
9 Congress, and members of the task force, to actually  
10 visit our Canadian pharmacies in action. I think  
11 you'll get a very interesting perspective once you  
12 actually see what it is that you'd like to study. And  
13 a lot of your questions could be answered from there.

14           CIPA strongly supports U.S. congressional  
15 legislation that would allow for the safe and legal  
16 importation of personal mail order pharmacy products  
17 from Canada by Americans. CIPA believes that the  
18 Canadian mail order program should simply be an option  
19 for Americans that complements other available drug  
20 benefit programs, like the Medicare drug benefit as  
21 well as the discount cards.

22           CIPA applauds the initiatives undertaken  
23 by the American government to provide more support for  
24 seniors and the poor who need lower cost  
25 pharmaceuticals. The American government can  
26 implement a viable, safe, and secure Canadian mail

1 order option.

2 We have some recommendations. For  
3 Americans to benefit from pharmaceuticals from Canada,  
4 CIPA urges the task force and the American government  
5 to consider a program that will do the following. I  
6 have three key recommendations. The first two are  
7 actually off safety. I'll talk about safety in the  
8 third and would be happy to take more questions about  
9 regulation and standards of practice for CIPA members  
10 in the Q&A.

11 But the first two are interesting because  
12 they're very critical and are as important as safety  
13 is to the success of the program. So the first  
14 recommendation -- limit importation to personal mail  
15 order only.

16 As the supplier with close ties to Health  
17 Canada and firsthand knowledge of the Canadian market,  
18 CIPA assures all stakeholders that implementation of  
19 any importation program, based on commercial,  
20 wholesale, or bulk channel of trade, will quickly lead  
21 to the complete collapse of this program.

22 Without adequate supply, the Canadian  
23 system will not be able to sustain the huge demand  
24 that would be placed on it by the bulk cross-border  
25 transfer of drugs. This massive diversion of supply  
26 would result in wide-scale drug shortages for

1 Canadians. The Canadian government will not tolerate  
2 any program that jeopardizes the health and welfare of  
3 Canadians, and thus will be forced to close down the  
4 border to this trade.

5 There has been a misinterpretation that  
6 Canadian companies can import products on a wholesale  
7 basis from foreign countries for purposes of exporting  
8 to other countries like the United States, under  
9 Section 37 of our Food and Drug Act.

10 According to Health Canada -- and I have  
11 some further evidence here specifically stating this  
12 -- according to Health Canada, it is illegal for  
13 Canadian suppliers to import pharmaceutical products  
14 from other nations and resell it to any country,  
15 including the United States. Therefore, Canada truly  
16 has a very limited supply.

17 For Section 37 to be invoked, you would  
18 actually have to manufacture the products in Canada.

19 This is a common misnomer and misinterpretation by a  
20 number of officials.

21 Of equal concern would be the opening of  
22 the supply chain to the increased likelihood of  
23 counterfeit penetration due to the integration of a  
24 vast wholesale network that permits repackaging and  
25 re-labeling. In Q&A, I'd like to comment on the  
26 difference between the wholesale versions between the

1 United States and Canada. It's a significant point.  
2 There's inherent safeguards in the Canadian system  
3 that should be considered.

4 Although legislation may contain  
5 prohibitions and incentives to reduce the likelihood  
6 of manufacturers cutting the supply to Canada, just  
7 the very threat of wholesale distribution could force  
8 the Canadian government to intervene by halting cross-  
9 border trade.

10 If American access to Canadian supply  
11 disappears, Americans will seek their pharmacy  
12 products, as Mr. Catizone had mentioned, from other  
13 sources -- over the internet, sources that are less  
14 secure, less safe, and more open to counterfeit and  
15 illegal substances.

16 Secondly -- our second recommendation --  
17 Congress must impose non-discrimination language and  
18 sanctions and incentives, because today the Canadian  
19 supply is in jeopardy. Recent restrictive trade terms  
20 that have been imposed on Canadian pharmacies and  
21 wholesalers by several manufacturers, resulting in a  
22 supply crisis -- for example, Pfizer, Eli Lilly, Astra  
23 Zeneca, Wyeth, Novartis, Glaxo, and Boehringer  
24 Ingelheim, have all successfully cut off supply of  
25 their drugs through Canadian mail order pharmacies by  
26 engaging in a harsh distribution tactic known as

1 blacklisting.

2           This has resulted in a complete lack of  
3 availability of select products, which casts patients  
4 into a dangerous scenario of non-compliance with their  
5 prescribed therapies. From a caregiver perspective,  
6 this is unacceptable and begs the urgent assistance of  
7 U.S. legislators to intervene on behalf of American  
8 patients.

9           Although attractive prices from Canada can  
10 be guaranteed, the supply cannot. Since the  
11 manufacturers seem determined to pursue an insensitive  
12 and unyielding course of prohibition of Canadian  
13 product, it will be up to Congress, and perhaps this  
14 task force, to ensure that strong and meaningful non-  
15 discrimination provisions be cemented into any  
16 proposed importation legislation. Without adequate  
17 supply, this choice for seniors and others becomes an  
18 exercise in futility.

19           If the Canadian option is shut out,  
20 millions of Americans will seek lower-cost  
21 pharmaceuticals from other countries and suppliers  
22 that don't meet the same strict regulatory  
23 requirements as in Canada. These people may be  
24 inadvertently forced into the hands of counterfeiters  
25 and black marketers -- the so-called buyer beware  
26 environment or the wild, wild west that's often

1 referred to.

2 Our third recommendation is to integrate  
3 FDA and HHS standards into CIPA safety standards from  
4 Canada. CIPA certified pharmacies are among the  
5 safest and most highly regulated practices in the  
6 world. Each of them are licensed and inspected by  
7 provincial regulatory authorities and sell only Health  
8 Canada or what's known as TPD -- Therapeutic Products  
9 Directorate -- approved products that were made in  
10 licensed manufacturing facilities under GMPs, good  
11 manufacturing practices.

12 Many of these facilities are licensed by  
13 the FDA in their sharing of mutual recognition  
14 agreements between these facilities and the  
15 governments associated with them, as well as CIPA-  
16 certified pharmacies comply with additional standards  
17 of practice set specifically for international mail  
18 order services.

19 In most cases, imported Canadian drugs are  
20 mailed directly to the U.S. patients in the original  
21 manufacturer's container, with tamper-evident seals  
22 intact. We only break the product when we have to in  
23 terms of quantity -- for a bottle of 250, for example.

24 SURGEON GENERAL CARMONA: Mr. MacKay,  
25 we'll need you to sum up now, sir.

26 MR. MacKAY: Sure.

1 SURGEON GENERAL CARMONA: Thank you.

2 MR. MacKAY: Counterfeit penetration of  
3 the Canadian wholesale system is negligible because of  
4 the system itself. CIPA-certified pharmacies will  
5 welcome any further regulatory oversight that is  
6 deemed necessary by Congress or this task force.

7 As an expert in international mail order  
8 systems, CIPA would want to work with the FDA and HHS  
9 to develop appropriate standards that will satisfy all  
10 stakeholders and ensure safe and affordable drug  
11 access for American citizens.

12 Thank you.

13 SURGEON GENERAL CARMONA: Thank you, sir.

14 Our next speaker, Mr. Nathan Jacobson,  
15 from MagenDavidMeds.com, from Israel. Thank you for  
16 being with us, sir.

17 MR. JACOBSON: Thank you. I appreciate  
18 the opportunity to appear before you today. My name  
19 is Nathan Jacobson, and I am the President and CEO of  
20 MagenDavidMeds.com.

21 Sitting here and listening to the task  
22 force members and the stakeholders speak has truly  
23 convinced me that it was worthwhile to board my flight  
24 in Tel Aviv at 1:00 this morning. And I thank you.

25 MagenDavidMeds.com is an internet pharmacy  
26 operating out of Israel. For time zone, language, and

1 cultural reasons, we have established a call center in  
2 North America. We began operating in January of this  
3 year after three years of planning and have been very  
4 pleased at the interest we have received and the  
5 growing number of orders that we are filling.

6 In our various publications, we often  
7 refer to the Gutenberg printing press. We do so  
8 because we see an analogy with today's internet  
9 pharmacies. The Gutenberg press was a new technology  
10 that made the printed word more accessible to the  
11 masses in a format and at a cost that the masses could  
12 more readily absorb.

13 The Gutenberg press was a catalyst for an  
14 exponential increase in literacy and general learning  
15 that played a role in the industrial revolution and  
16 the spread of democracy across Europe. Nevertheless,  
17 the Gutenberg press was reviled by the vested  
18 interests in society who previously exercised a  
19 monopoly on information and used that monopoly to  
20 maintain political, social, and economic control.

21 In exactly the same way the internet, as  
22 the new technology, has been a social and economic  
23 leveler, with all its faults has brought political,  
24 economic, and social empowerment to every corner of  
25 the globe.

26 Internet pharmacies such as

1 MagenDavidMeds.com are a subcomponent of the internet  
2 revolution. We aim to provide a low cost, but  
3 entirely safe, alternative to the multi-national  
4 pharmaceutical companies and the conventional supply  
5 chain. As happened with Gutenberg, we have been  
6 reviled by the vested interests in the drug business  
7 whose market dominance and profits may be threatened.

8 If I were one of those vested interests, I  
9 would be concerned, too, because obviously a gap has  
10 developed between what U.S. consumers want and what  
11 U.S. pharmaceuticals are prepared to give. An  
12 overwhelming number of Americans take prescription  
13 drugs or have a family member who does. The high cost  
14 of prescription drugs in the United States is driving  
15 more and more people to internet pharmacies and cross-  
16 border purchases and has made the internet pharmacies  
17 an overnight success.

18 Internet pharmacies are responding to an  
19 enormous pent-up demand. Recent polls conducted in  
20 this country indicate that nearly a third of Americans  
21 say that paying for prescription drugs is a problem  
22 for their families, and many are cutting dosages or  
23 going without as a consequence.

24 In another poll, nearly two-thirds of  
25 respondents said American government should make it  
26 easier to buy cheaper drugs from Canada and other

1 countries. Eighty percent of Americans in another  
2 poll believe that the high cost of prescription drugs  
3 will be an issue in the campaigns for your elections  
4 this November. Almost half of those polls said that  
5 it would be a very important issue.

6 The high cost of prescription drugs  
7 impacts particularly on the most vulnerable  
8 populations -- seniors, people without private  
9 insurance, the disabled, the unemployed, and the  
10 working poor. Our research has identified over 200  
11 elected officials -- from Mayors to U.S. Congressmen  
12 and Senators -- who have expressed their support for  
13 internet pharmacies on behalf of their constituents.

14 In response to the alternative presented  
15 by internet pharmacies, the vested interests and their  
16 agents have propagated a number of myths in order to  
17 try and shake the public's confidence in and support  
18 for internet pharmacies.

19 I'd like to spend some time on the -- of  
20 the time allotted to me today to address a few of  
21 those myths. One myth is that internet pharmacies,  
22 unlike the pharmaceutical giants, sell drugs that are  
23 produced outside of the United States. As such, so  
24 the myth goes, they are less safe than drugs  
25 manufactured in the United States and their purchase  
26 reduces the number of jobs and other economic spinoffs

1 that the U.S. pharmaceuticals generate in the United  
2 States.

3 The facts are these: about 86 percent of  
4 all prescription medications bought in the United  
5 States are manufactured outside of the United States.

6 The United States imports over \$40 billion in  
7 pharmaceuticals yearly. One of the largest-selling  
8 drugs in the world -- Lipitor -- is manufactured in  
9 Ireland. So is Viagra. Nexium is produced in Sweden,  
10 France, and other countries. Prevacid is produced in  
11 Japan.

12 Many of the drugs sourced through internet  
13 pharmacies are identical in every way to drugs  
14 produced by the major multi-nationals. In fact, many  
15 of them are produced by those multi-nationals.

16 Another myth is that internet pharmacies  
17 are engaged in counterfeit pharmaceuticals. Countries  
18 such as India, Pakistan, and China have been targeted  
19 by former FBI agents hired by the pharmaceutical  
20 companies as hot spots for the black market  
21 counterfeit medications. And in the past few weeks,  
22 Israel has suddenly been alleged to be one of those  
23 hot spots.

24 I cannot speak for other internet  
25 pharmacies. I can only speak from MagenDavidMeds.com.

26 In our case, the facts are: Israel's security system

1 for pharmaceuticals is second to none in the world,  
2 and the reasons are obvious. El Al is the world's  
3 most secure airline, and I'd venture to say that  
4 Israel's pharmaceutical industry is the most secure in  
5 the world.

6 Another myth is that internet pharmacies  
7 are breaking the law or at least operating on the  
8 fringes of the law. Again, in the case of  
9 MagenDavidMeds.com, we are operating in full  
10 compliance with U.S. and Israeli laws, in particular  
11 within the free trade agreement between Israel and the  
12 United States executed in 2001.

13 We only accept prescriptions from  
14 registered health care practitioners who are  
15 authorized by state law to issue prescriptions in the  
16 United States, and we have a team of Israeli-  
17 registered pharmacists who verify the authenticity of  
18 every prescription.

19 Prescriptions must be sent to us by post  
20 or facsimile. No online ordering is allowed. We do  
21 not trade in narcotics, controlled substances as  
22 defined by U.S. law, or habit-forming medications of  
23 any kind. Another myth is that those who patronize  
24 internet pharmacies are putting themselves at risk.

25 The facts in the case of  
26 MagenDavidMeds.com are these: drug safety regulations

1 is, in many respects, stricter or more effective in  
2 Israel than in the United States. Medications sold by  
3 pharmacists in North America are usually received by  
4 the pharmacist in bulk, typically in containers of  
5 250, 500, or 1,000 pills or capsules.

6 The medication is then usually manually  
7 counted through these devices by the dispensing  
8 pharmacist and repackaged into smaller containers for  
9 the patient. This is the way it's been done from time  
10 immemorial, but when medications are dispensed in this  
11 manner patient safety can be compromised.

12 Manual handling leads to sanitary  
13 concerns. The conventional approach increases the  
14 potential for counterfeiting and dispensing of stale,  
15 dated medication, because expiring date and lot  
16 numbers from the original container do not make their  
17 way through to consumers.

18 Under our system, all medications sold by  
19 MagenDavidMeds.com are sourced from FDA-approved  
20 facilities. All medications purchased by our  
21 customers are delivered in the original manufacturer's  
22 packaging, including sealed, foil blister packs,  
23 typically 30 pills per sheet.

24 Consumers also receive the medical profile  
25 and any warnings for the medication written in  
26 English, Hebrew, and Arabic.

1 SURGEON GENERAL CARMONA: Mr. Jacobson,  
2 would you please sum up now?

3 MR. JACOBSON: Okay.

4 SURGEON GENERAL CARMONA: Thank you.

5 MR. JACOBSON: In fact, Israel is  
6 internationally recognized as a pharmaceutical center  
7 of excellence. Israel leads the world in the number  
8 of scientists and technicians in the workforce -- 145  
9 per 10,000, as opposed to 85 per 10,000 in the United  
10 States.

11 In price terms, we are simply benefiting  
12 from the lower prices of pharmaceuticals that apply  
13 governing outside the U.S. and the discounts we  
14 receive through the government.

15 We would like to work with the United  
16 States. We welcome members of the United States  
17 authorities to visit our pharmacies within Israel, and  
18 we believe that the United States -- the FDA -- has a  
19 lot to learn from the way medications are dispensed in  
20 Israel in order to guarantee the security of the  
21 American population.

22 Thank you very much.

23 SURGEON GENERAL CARMONA: Thank you, sir.

24 Let's open the floor, then, to task force  
25 members for questions, comments. Yes, Ms. Hardin.

26 MS. HARDIN: This is a question for Ms.

1 Williams and Mr. MacKay, and this was something that  
2 was alluded to in one of our earlier panels. We've  
3 heard a little bit of conflicting information about  
4 the legality and regulation of trans-shipment of drugs  
5 in Canada. And I was wondering if you could address  
6 that for us.

7 MS. WILLIAMS: I would concur with what  
8 was said earlier, and that is that we would consider  
9 that any drug that is not approved for sale by Health  
10 Canada to for -- in Canada is an illegal entity. And  
11 in Ontario, we would use every resource that's  
12 available to us to enforce that.

13 MR. MacKAY: In terms of the CIPA members,  
14 I can speak for them. On the shelves of all CIPA  
15 members will only be products with a drug  
16 identification or a DIN number equal to your NDC  
17 number. Any violation other than that, because of the  
18 fact that we receive surprise inspections from both  
19 Health Canada as well as provincial regulatory  
20 authorities, would be an extremely foolish move,  
21 something that would be found very easily and very  
22 quickly.

23 None of our members trans-ship products.  
24 There may be products coming in porously through the  
25 border for consumption in Canada, but they are not  
26 ending up on the shelves of the Canadian mail order

1 pharmacies, and thus re-exported to the United States.

2 That is not occurring.

3 MS. HARDIN: And just to follow up, if you  
4 could just outline for us, to the extent you can, what  
5 recourse provincial authorities or federal authorities  
6 have against pharmacies that may be illegally trans-  
7 shipping.

8 MR. MacKAY: If a registrar were to find  
9 that there was a violation of the Food and Drug Act,  
10 that would be reported to Health Canada. Health  
11 Canada could take action to work with the provincial  
12 government to remove the license for that pharmacy,  
13 and thus effectively put the pharmacy out of business  
14 if they -- they may be warned.

15 I won't speak for Health Canada or the  
16 provincial regulatory authorities. But on an  
17 inspection report, that would be typical -- a warning  
18 and potentially closing down the pharmacy by removing  
19 the license.

20 MS. WILLIAMS: Just to add to that -- we  
21 could -- as a regulator, if we found that that was  
22 happening, we have the authority to prosecute through  
23 our own internal disciplinary system. Both the holder  
24 of the certificate of accreditation, who is a  
25 pharmacist, because in Ontario pharmacists own  
26 pharmacies -- as well as take away the accreditation

1 certificate for the operation of the pharmacy itself.

2 MS. HARDIN: Is that similar across the  
3 provinces, or does it vary some?

4 MS. WILLIAMS: It's similar across the  
5 country.

6 MR. MacKAY: It's regulated by the Food  
7 and Drug Act federally.

8 SURGEON GENERAL CARMONA: Other questions  
9 for the -- Mr. Sachdev?

10 MR. SACHDEV: This one is for Mr.  
11 MacArthur. In a listening session about three weeks  
12 ago, actually the public listening session, we had  
13 testimony from Dr. Kanavos I believe, from the London  
14 School of Economics, and he provided us with some very  
15 interesting data that we hadn't seen before about the  
16 savings that are being achieved in Europe as a result  
17 of parallel trading.

18 And in particular, the statistic that we  
19 were interested to learn was about the extent to which  
20 the savings were being passed on to purchasers. In  
21 his testimony, he said less -- between one and three  
22 percent of savings that could be realized by parallel  
23 trading in Europe were being passed on to purchasers,  
24 and he speculated that -- and he said that a large  
25 proportion of the savings were actually being achieved  
26 by the wholesalers. And he speculated about why he

1 thought that was.

2 Is that data that you would agree with?  
3 And do you have a sense of why that is, in fact, the  
4 case in Europe?

5 MR. MacARTHUR: Well, Dr. Kanavos' study  
6 is completely flawed. It's widely recognized in  
7 Europe. It is not used by European industry to  
8 support its arguments.

9 We issued a three-page press release. I  
10 can go through some of the main points if you'd like,  
11 or I can send it to you. I mean, for a start, he  
12 looked at 19 drugs. The average parallel importer  
13 will have 1,000 products.

14 The penetration of parallel trade in those  
15 19 drugs -- in Denmark, for example, -- ranges from  
16 naught -- naught percent to 0.2 percent I think from  
17 memory. You know, he didn't look at the products that  
18 were parallel traded.

19 Another glaring fault is that he assumed  
20 that parallel traders could source at the lowest price  
21 in Europe when, in fact, because of the quotas our  
22 members have to source from eight, 10, even sometimes  
23 more countries. And of course this has huge cost  
24 implications as well.

25 He expressed savings as a percentage of  
26 pharmacy purchase price, whereas of course the payers

1 in Europe pay the full reimbursement price, which  
2 includes the pharmacy margin, the wholesale, and value  
3 added tax, which can be 50 percent on top of the  
4 pharmacy purchase price.

5 What other serious flaws -- I mean, you  
6 know, I can go on. The study is flawed.

7 MR. SACHDEV: Well, actually, my question  
8 was is, do you have your own opinion about the extent  
9 to which there are savings being realized by consumers  
10 or purchasers --

11 MR. MacARTHUR: Yes.

12 MR. SACHDEV: -- in Europe versus savings  
13 that are being realized back into the system by  
14 wholesales?

15 MR. MacARTHUR: Yes, yes. Well, as I said  
16 in my testimony, we -- Johnson & Johnson sponsored the  
17 LSE -- or London School of Economics study led by Dr.  
18 Kanavos. We sponsored -- it was not a secret --  
19 another study, an earlier study, which probably  
20 provoked Big Farmer to sponsor its study. We  
21 sponsored one from the University of York, which has  
22 one of the oldest, most reputable center of health  
23 economics in the world.

24 And that is the figure of \$745 million  
25 equivalent that I quoted -- came from that study in  
26 five countries of direct savings. Also, it's a study

1 which we can happily -- it's on our website. It's on  
2 the York website. It includes lots of charts showing  
3 the competitive effect of parallel trade. Where  
4 prices have been stable, parallel trade enters and the  
5 parallel trader provokes a response -- pricing  
6 response.

7           There is a price war that results. Very  
8 often the parallel trader is forced off the market,  
9 but in Europe you can't invariably increase prices, so  
10 that low price that's being produced by parallel trade  
11 continues. So, you know, just a threat of parallel  
12 trade is enough to provoke sometimes a response from  
13 Big Farmer.

14           So we think it has a very important  
15 competitive effect. There were discussions earlier  
16 today I heard about the sort of short-term nature of  
17 importation. Well, parallel trade, as I say, in  
18 Europe has been going on for 20, 30 years. It is  
19 consistently realizing savings.

20           You have to have competition. Otherwise,  
21 you know, you have a monopoly situation, and prices  
22 only go one way. To keep prices down you need  
23 continual parallel trade.

24           As I say, I am very happy to send you --

25           MR. SACHDEV: I think that would be very  
26 helpful. I would have loved to have had you at the

1 public meeting when Dr. Kanavos was here --

2 (Laughter.)

3 -- so you could have spoken together. But  
4 we would have -- we would very much appreciate  
5 additional information, in particular about because  
6 there is widespread speculation about the extent to  
7 which any savings that might be realized under  
8 legalized importation --

9 MR. MacARTHUR: Yes, yes. But it's common  
10 sense.

11 MR. SACHDEV: -- would be realized by the  
12 purchaser.

13 MR. MacARTHUR: If there were no savings,  
14 why would anybody prescribe, dispense, or purchase,  
15 you know, parallel trade. It's the same product,  
16 exactly the same product. There is no benefit to  
17 anyone.

18 MR. SACHDEV: Right. But what we as a  
19 task force are trying to determine -- and I think this  
20 is an important question -- is the extent to which the  
21 experience in Europe would apply in the U.S. and the  
22 extent to which it wouldn't. And that's a factual  
23 question that I think we would very much appreciate  
24 further information about.

25 MR. MacARTHUR: I'll certainly make sure  
26 you get it.

1 MR. SACHDEV: I have some more --

2 SURGEON GENERAL CARMONA: Please. Go  
3 ahead.

4 MR. SACHDEV: This is for Mr. MacKay. I  
5 want to be clear, because this is also something that  
6 we've heard recently in the press -- we're read  
7 recently about the -- because of limitations on supply  
8 in Canada and potential shortages that are resulting  
9 because of the actions of the pharmaceutical  
10 companies, that some of the pharmaceutical cross-  
11 border pharmacies in Canada are beginning -- are  
12 looking at contracts with European or UK sources.

13 Are those pharmacies the ones that are  
14 your members, or do you -- under your -- the  
15 guidelines that you laid out, would they not be  
16 allowed, as a condition of membership, to source from  
17 Europe?

18 MR. MacKAY: The ones that I know that are  
19 doing it are members of CIPA, and we boldly support  
20 what they're doing. What's unacceptable is facing a  
21 patient with noncompliance. What we first do is offer  
22 them to consult with their physician for a therapeutic  
23 alternative, but that sometimes is not optimal. You  
24 may not want to switch into this -- into a product  
25 that's in the same class.

26 Failing that, we do -- when I say "we,"

1 three or four pharmacies to date have successfully  
2 engaged in partnerships with British pharmacies, not  
3 wholesalers, not parallel traders, but pharmacies.  
4 And what would happen is the patient would be referred  
5 to -- there is no trans-shipment involved -- as an  
6 option with a signed declaration of consent to be  
7 referred to a British pharmacy.

8 If they agreed to -- and they get a lot of  
9 information on the MHRA and the regulatory authority  
10 in Britain. And if they agree, the product is  
11 directly mailed from Great Britain to their location  
12 in the United States. And we do support that.

13 MR. SACHDEV: That's a question that has  
14 come up at several of these listening sessions. And  
15 it was Barbara Wells from NAPRA and -- as well as the  
16 Quebec and Manitoba pharmacy regulatory authorities  
17 that indicated that whether it was shipped directly  
18 from Europe to the U.S. consumer, or through Canada to  
19 the U.S. consumer, they determined -- they believed  
20 that both of those activities were unapproved under  
21 their provincial authorities.

22 Is that your understanding as well?

23 MR. MacKAY: Not at all. I've spoken to  
24 Health Canada several times, just left Ottawa a couple  
25 of days ago. They have no issue with this so far.  
26 It's not breaking any Canadian laws. We're not

1 jeopardizing safety insofar as we're taking regulatory  
2 from Canada and now shifting it to Great Britain,  
3 where I would have no issue whatsoever. But that's an  
4 individual choice to make about the personal decision  
5 to go with Great Britain with the regulatory controls  
6 there.

7 But I can tell you that I fundamentally  
8 and categorically would deny that Health Canada feels  
9 this is illegal.

10 MR. SACHDEV: Okay. That's helpful,  
11 because this is -- we now have actually a factual  
12 inconsistency between prior testimony. It would be  
13 very helpful to us because Health Canada was unable or  
14 chose not to come to this forum to get more clarity  
15 there.

16 Ms. Williams, do you have an opinion on  
17 this question?

18 MS. WILLIAMS: Well, I mean, we have  
19 always taken the position that a drug that is not  
20 approved by Health Canada for sale in Canada is not a  
21 legal entity, and we do have issues with that.

22 I should tell you, we were at a meeting  
23 last week. All of the medical regulators, pharmacy  
24 regulators, and members of Health Canada were at a  
25 meeting last week in Ottawa. And, you know, we talked  
26 -- all of these issues were put on the table, so while

1 I can't speak for Health Canada, I would encourage you  
2 to do so.

3 You know, certainly, these are issues that  
4 are very right up in the forefront right now, and that  
5 are going to require some decision, so that the  
6 legitimate pharmacy operations that are trying to do a  
7 right -- the right thing with respect to serving the  
8 patients that they serve, you know, do need guidance.

9 MR. SACHDEV: That would be -- we would  
10 love to speak to Health Canada. We've certainly  
11 tried. And we would -- we'll continue to try. In the  
12 meantime, if there's anything from those proceedings  
13 that you mentioned that would be illustrative or  
14 useful for us, we'd very much appreciate that because  
15 we do have on the record for us now testimony that's  
16 different than what you all provided today, and we'll  
17 have to try to reconcile that with the Canadian  
18 officials.

19 MR. MacKAY: Sir, could I add one point?  
20 I apologize.

21 MR. SACHDEV: Yes.

22 MR. MacKAY: Health Canada I think has a  
23 view -- I don't entirely speak for them, but because  
24 the product is not touching down in Canada, because it  
25 is not Health Canada or TPD-approved with a DIN number  
26 on it, there is a perception that that is not a Health

1 Canada issue in terms of mandate for supervision and  
2 regulatory control.

3 It's a British product that's being  
4 ordered by an American patient. It really takes  
5 Canada right out of the picture. The Canadian  
6 Pharmacies Act is a broker for that transaction. They  
7 don't even receive payment. The payments are being  
8 received in Britain. We're simply guiding the  
9 American patient to a British pharmacy.

10 MR. SACHDEV: And that's the question we  
11 asked the Canadian provincial regulators the last  
12 time, and they all three said that they believed that  
13 was the -- the unapproved dispensing of a product.  
14 And that -- and I think it was Barbara Wells who said  
15 she had heard directly from Health Canada that that  
16 was unapproved.

17 That's what has resulted in our having  
18 some confusion here that we'd like to get --

19 MR. MacKAY: I would suggest that it's  
20 unapproved because it's outside of their realm and  
21 mandate of jurisdiction.

22 MR. SACHDEV: Outside the provincial  
23 authorities.

24 MR. MacKAY: Right, it's outside their  
25 authority. It wouldn't be approved. They can't  
26 approve it, because it's outside their jurisdiction.

1 MR. SACHDEV: And so a pharmacy in Canada  
2 that was engaging in that practice would be violating  
3 provincial authority?

4 MR. MacKAY: Not in my view. I'm saying  
5 that it's -- how can I put it? If it's unapproved --  
6 they can't possibly approve or unapprove it, because  
7 it's outside their jurisdiction.

8 MR. SACHDEV: Okay. And so as to a cross-  
9 border pharmacy that exists in that province, you're  
10 saying they don't have authority over the cross-border  
11 pharmacy for that product?

12 MR. MacKAY: In the case of a product  
13 coming from Great Britain, that's exactly what I'm  
14 suggesting.

15 MR. SACHDEV: Okay. So that would be  
16 outside of -- that's an important point, too, for us.  
17 So that would be outside of the scope of the  
18 provincial regulatory authority.

19 MR. MacKAY: That's my whole point.  
20 Exactly.

21 MR. SACHDEV: Okay.

22 MS. WILLIAMS: I was just going to add --  
23 I think there is maybe two practices going on. One is  
24 where our pharmacies actually are providing the  
25 product where the product is coming into the pharmacy  
26 that's in our provincial authority over which we do

1 have regulatory authority, and then shipping to the  
2 U.S., and that is illegal.

3 And I would suggest there's a different  
4 practice that is being suggested here, which has to do  
5 more with facilitating the procurement of a drug where  
6 it's not actually coming in through Canada or so --

7 MR. SACHDEV: That's fine.

8 MS. WILLIAMS: I'm thinking that their --  
9 I'm not sure that what our -- my colleague said was --  
10 like they may have been reacting to one thing and not  
11 the other. I don't know if it was clarified. So we  
12 have to just -- I'd just be wanting to clarify that.

13 MR. SACHDEV: That would be great, because  
14 we did ask specifically both questions separately.  
15 And I'd like to -- we'd love to hear back from both  
16 the provincial level and the Health Canada level.

17 I had some more questions, but I can wait  
18 if there are others who want to go.

19 SURGEON GENERAL CARMONA: Okay. Why don't  
20 you go ahead and finish up. Thank you.

21 MR. SACHDEV: Okay. Good.

22 Mr. MacKay, we talked earlier with the  
23 prior panel about the Canadian pharmacies that were  
24 cross-border pharmacies that were working with states  
25 like Minnesota. And I asked, I think it was Mr.  
26 Catizone, about -- and the other members about why

1 they thought there were deficiencies from -- with the  
2 majority of those pharmacies.

3 I want to give you the same opportunity to  
4 comment --

5 MR. MacKAY: Sure.

6 MR. SACHDEV: -- in the event that any of  
7 those were your members.

8 MR. MacKAY: Appreciate that. Actually,  
9 all of them were my members, and it's my understanding  
10 it was actually eight instead of nine, but that may be  
11 a moot point.

12 Of the eight that were inspected, two were  
13 approved, four were from the province of Manitoba,  
14 which were instantly disqualified due to an issue that  
15 the provincial regulatory authority had with cross-  
16 border between Manitoba and Minnesota due to the fact  
17 that the state board in Minnesota has not licensed  
18 Manitoba.

19 It's a technicality that has since been  
20 somewhat ironed out. Therefore, four were instantly  
21 disqualified, which leaves two that had issues.

22 Now, I will point out that some of the  
23 deficiencies are actually differences in the  
24 regulatory standards between Minnesota and Manitoba.  
25 However, I don't want to look like we're trying to  
26 skirt this. One particular pharmacy was the vast

1 majority of the transgressions and discrepancies.

2 And I have in front of me right here a  
3 response to the Minnesota report from that pharmacy.  
4 It's ADV Care. It's -- I believe it's out of Toronto,  
5 and it goes through point by point. I'd like to  
6 submit it to you --

7 MR. SACHDEV: Thank you.

8 MR. MacKAY: -- to actually see the -- not  
9 so much the rebuttal, but we're accepting the fact  
10 that there were some issues. And I think the spirit  
11 of any report should be that we have the opportunity  
12 to improve and effect change. And that's exactly what  
13 happened in the case of this pharmacy.

14 We'll take ownership for the fact there  
15 were problems. But after a period of time, this  
16 pharmacy took the necessary steps to make sure that  
17 the improvements were put in place.

18 MR. SACHDEV: At a broader level, where  
19 you have basically a cross-border pharmacy that is  
20 trying to comply with 50 different U.S. state pharmacy  
21 regimes, how do you -- how do we reconcile the issue  
22 of, while there were problems with Minnesota because  
23 they may have different requirements than the  
24 provincial authority in which your pharmacies operate,  
25 you might have different problems with North Dakota or  
26 different problems with Wyoming, how do you handle

1 that?

2 MR. MacKAY: Well, truly, I don't think  
3 you can apply the state -- one by one, the state  
4 regulatory standards versus Canada, because you will  
5 have a nightmare on your hands in trying to match them  
6 up.

7 I think you need to come up with a  
8 national set of standards. I'm not suggesting that  
9 the National Board of Pharmacy shouldn't be involved.  
10 We'll welcome anybody, whether it's the FDA, HHS,  
11 whether you liaise with Health Canada, or whether the  
12 state boards -- national state board is involved.

13 We have nothing to hide. We'll take all  
14 comers. Whoever wants to come see our pharmacies, and  
15 approve the standards of practice, we welcome them.

16 MR. SACHDEV: But without that -- and  
17 that's a good point. And without that national  
18 standard, is there really any way for your members to,  
19 on a state-by-state basis, comply with these types of  
20 inspections?

21 MR. MacKAY: That would be chaotic,  
22 because you'd have to go through them one at a time  
23 with a fine tooth comb, and it would -- I think it  
24 would be overwhelming and just impractical.

25 MR. SACHDEV: Governor Pawlenty was here  
26 -- I think it was last week or the week before -- and

1 he testified that there had been subsequent trips up  
2 by the Minnesota pharmacists to evaluate additional  
3 facilities.

4 MR. MacARTHUR: Right.

5 MR. SACHDEV: Were your members involved  
6 in that?

7 MR. MacARTHUR: Yes. The reason why they  
8 did a second trip is, Minnesota being geographically  
9 close to Manitoba, they tend to really prefer Manitoba  
10 pharmacies, because they've always sent their busses  
11 there. So they wanted to put some Manitoba pharmacies  
12 on their website.

13 The reason they couldn't do it the first  
14 time is because of that technicality I referred to  
15 that had to do with the Manitoba Pharmaceutical  
16 Association having an issue with the State Board of  
17 Minnesota licensing any pharmacies for that website.

18 Now, they've since ironed it out, and they  
19 are asking Cody Wyberg from Department of Human  
20 Services to go pick some more Manitoba pharmacies this  
21 time, because they were noticeably absent in the first  
22 round.

23 MR. SACHDEV: And have they already done  
24 that?

25 MR. MacKAY: Yes. They've made the  
26 inspections. I'm sure recommendations will be made

1       shortly to Kevin Goodnull, and I'm sure you'll see  
2       Manitoba pharmacies up on that website shortly.

3               MR. SACHDEV: That's great. Are there any  
4       drugs -- we've heard -- this is a comment we've asked  
5       all of the panels. Are there any drugs or other  
6       products, like controlled substances, injectables,  
7       that you believe should not be eligible for  
8       importation at this time?

9               MR. MacKAY: Absolutely.

10              MR. SACHDEV: That's open to anyone on the  
11      panel.

12              MR. MacKAY: Well, I don't want to hog the  
13      mike here, but we've gone through this process with a  
14      number of states already, because, as you know, four  
15      or five states have actually put up a website. So we  
16      go through this a lot.

17              Definitely narcotics, anything that is a  
18      scheduled product, Schedule 5, painkillers, any  
19      controlled substances, any habit-forming drugs,  
20      benzodiazepenes, dealing with a complicated dosing  
21      schedule, anything that is just going to be trouble in  
22      terms of making sure it's well monitored -- lifestyle  
23      drugs -- Viagra, Cialis.

24              Biologics are tricky. We tend to prefer  
25      to avoid them -- any of the injectibles -- because on  
26      a mail order basis sometimes you may not guarantee

1 they will be picked up in time. Although the majority  
2 of these products are stable at room temperature, they  
3 should be refrigerated as a precaution.

4 Therefore, our advice to our members is to  
5 stay away from the injectibles. You could eliminate  
6 them if you felt they were going to be trouble.

7 There is also issues of whether a generic  
8 -- for example, Zocor -- is genericized in Canada, is  
9 not genericized in the U.S. You do not have a  
10 situation of exact equivalence there. You may want to  
11 avoid those.

12 Interesting to point out, this gets down  
13 to sort of the practicality of it. I did an analysis  
14 of the top 100 drugs that we sell to Americans. As  
15 you know, they're mostly chronic and maintenance  
16 medications. When you get down to the issue about  
17 whether there would be some problems about  
18 interpreting like different names -- Peratin in Canada  
19 is Aciphex here. Prilosec here is Losec in Canada.  
20 Name differences or dosing differences.

21 Do you know how many actually occurred of  
22 the top 100 that would potentially come into  
23 problematic viewpoint here? Six. That is all we're  
24 talking about.

25 I could easily walk this task force  
26 through in half an hour the top 100. We could come to

1 agreements on the bioequivalence of every single one  
2 of those drugs. We would only have to argue about six  
3 of them.

4 MR. SACHDEV: And so hearkening back to a  
5 conversation we had from the other panels, where they  
6 were discussing whether or not importation, if it were  
7 legalized, should or should not be limited to a number  
8 of drugs, is that something that you would suggest  
9 would be acceptable?

10 MR. MacKAY: Absolutely. You know, we  
11 want to do this in a practical, workable manner. We  
12 don't want to encourage problems. We know what the  
13 high risk pharmaceutical products are. Let's avoid  
14 them.

15 We've been doing this for three years.  
16 We've kind of mastered what is a problem and what's  
17 not. We know what to avoid. So we could hopefully  
18 offer you some very good advice in that regard.

19 MR. SACHDEV: Thank you.

20 MR. MacARTHUR: Perhaps I could just  
21 comment on parallel importation, which is very  
22 different. We're often accused of cherry picking  
23 products. But as I said, often our members will sell  
24 1,000 products maybe out of the 8,000 on the market.  
25 We tend not to get involved in generics, simply  
26 because we cannot compete with -- you know, the

1 original brands in Europe cannot compete with a  
2 properly competitive generic price.

3 We're not involved with OTCs, but I would  
4 say almost the entire range of prescription drugs,  
5 especially under patent, as I say, are -- can be and  
6 are parallel traded in all strengths -- to say all  
7 dosage forms -- injectibles, vaccines, insulins,  
8 everything. I'm not sure about narcotics; I have to  
9 pass on that.

10 But I said the whole chain is certainly  
11 respected, and, you know, we don't know quality issues  
12 arising through parallel trade as opposed to direct  
13 importation.

14 MS. WILLIAMS: I'd have to say that I  
15 would support what was said earlier by some of my  
16 colleagues with respect to opening -- if you're going  
17 to allow -- legalize importation, that it should be  
18 open across the board, provided, you know, acceptable  
19 regulatory frameworks are in place. And that's based  
20 on our position -- mine as a pharmacist and our  
21 college position -- that it's in the patient's best  
22 interest to procure their pharmacy services from,  
23 wherever possible, one pharmacy and one provider.

24 The problem I would have with, you know,  
25 saying you can get some drugs this way, and you have  
26 to go other places to get other categories of drugs,

1 is that you lose. It becomes very fragmented -- the  
2 patient care -- and I don't believe that's in the  
3 public interest.

4 You know, the ones that are filling one  
5 category of drugs may not have access to the  
6 information as to what they're getting from somewhere  
7 else. And it may also drive, you know, the practice  
8 underground into the illegitimate sites. If they  
9 can't get certain categories from legitimate  
10 pharmacies, where are they going to be getting them  
11 from? And then, who is going to be protecting the  
12 public, and how? So I just wanted to offer that.

13 MR. SACHDEV: Thank you all for traveling  
14 to be here.

15 Thank you, Dr. Carmona.

16 SURGEON GENERAL CARMONA: Dr. Raub?

17 DR. RAUB: A question for Mr. Jacobson.  
18 You made reference to procedures to authenticate  
19 prescriptions. Would you say a bit more about that?

20 MR. JACOBSON: Sure. When we receive the  
21 prescription -- first of all, the patient fills out a  
22 patient profile, a medical profile. It arrives first  
23 at our office in Canada, where it is reviewed by a  
24 medical technician or a pharmacist. This is our  
25 customer support center.

26 We see whether there is any conflicts

1 between what the patient has filled in as their  
2 profile and what the prescription is. If there is any  
3 conflict, our person will call the doctor in the  
4 United States and verify with them that that is in  
5 fact what has happened. It is then sent off through  
6 our system to Israel. We have a paperless system.

7 In Israel, every prescription must be  
8 signed off by an Israeli doctor. Again, the Israeli  
9 doctor views the patient profile, he views the  
10 prescription, sees that there is no conflicts in that  
11 case, from which it goes to our pharmacist.

12 In Israel, all pharmacies are licensed by  
13 the Ministry of Health. Prescriptions are only  
14 allowed to be dispensed by licensed pharmacists. The  
15 pharmacist also has the patient profile, the  
16 prescription -- also, there is a third verification  
17 that there is no mistake made in it. It is then  
18 dispensed. The patient receives it back in the United  
19 States, including a copy of the original prescription.

20 DR. RAUB: Okay.

21 MR. JACOBSON: So there's three levels of  
22 security, more so than if you were to go to a  
23 Walgreens or Wal-Mart or Costco, or something like  
24 that for your prescription, where the pharmacist  
25 doesn't know you. You come in and you hand them your  
26 prescription -- that's it. Or as well the level of

1 safety, where they take a bottle, pour it into this  
2 device, count them out.

3 In Israel, they're all -- there's two  
4 levels of security as well on the actual medication  
5 that they receive. The patient receives on the box  
6 the lot number and the expiring date, and on the  
7 blister pack is the lot number and the expiring date.

8 And each pill is sealed.

9 DR. RAUB: Thank you.

10 All right. Mr. MacKay, how does the  
11 authentication procedure just described compare to  
12 what's required of CIPA members?

13 MR. MacKAY: CIPA members are like any  
14 other pharmacy in the province in Canada. All of them  
15 are, first of all, regulated by the provincial  
16 authority and licensed as such with a license number  
17 that would have to go on their website and be on all  
18 of their documentation. They receive inspections.

19 CIPA pharmacies, however, as members, have  
20 an extra layer of regulatory control in the form of a  
21 sworn affidavit on standards of practice that are part  
22 of the terms of license. And they are specialized to  
23 cross-border sales, with the ability for us to follow  
24 up with action if there is transgressions of the  
25 standards of practice.

26 We do do reviews of our pharmacies, and

1 beyond that we're seeking out other accreditation  
2 standards. And, again, we welcome FDA involvement or  
3 state board involvement. But we've sought out, for  
4 example, an independent third party organization  
5 commission out of Vermont called IMPAC -- the Internet  
6 Mailorder Pharmacy Accreditation Commission.

7 We felt that we didn't want to be the fox  
8 in charge of the henhouse, so we thought we seek out  
9 an independent U.S.-based commission. And a number of  
10 our pharmacies are being accredited by IMPAC.

11 If VIPPS could -- I've asked Carmen if we  
12 could come to terms with this. We'd welcome VIPPS  
13 certification if we could. Unfortunately, right now,  
14 VIPPS will not certify a Canadian pharmacy that  
15 engages in cross-border practice.

16 DR. RAUB: But specifically, what happens  
17 with the authentication of prescriptions?

18 MR. MacKAY: Oh, in terms of that, I'm  
19 sorry, yes, it's almost identical. The prescription  
20 comes in from the patient, and we -- we turn it into a  
21 digital file. The patient actually gets to talk to  
22 customer service. They can talk to a pharmacist at  
23 length if they'd like.

24 And then actually from there it goes to  
25 the cyber clinic, where we match up all of the patient  
26 medical profile information, make sure we've got a

1 complete picture of allergies, of drug interaction  
2 potentials, of the current medications that they're  
3 on.

4 We also phone back the doctor in the cyber  
5 clinic to make sure we confirm that prescription is  
6 valid and has not been altered in any way by the  
7 patient or is being put in multiple times to get  
8 multiple medications. Once we receive verification,  
9 there is actually three independent pharmacists that  
10 do a check on the prescription before it goes out the  
11 door.

12 So, in total, you've got the primary care  
13 physician writing the script from the United States.  
14 You've got a second pair of professional medical eyes  
15 insofar as the doctor in Canada who actually looks at  
16 the entire medical profile. They don't get paid to  
17 just sign off on a prescription. They're paid to  
18 conduct a review. And in some cases, many cases, they  
19 will flag drug interactions and be a life-saving  
20 element to the continuum of care.

21 We actually think that's an enhancement to  
22 the standards -- having a second doctor involved. I  
23 don't think anyone in the room here, when they go and  
24 get their prescription, has two doctors involved. And  
25 on top of that, you've got three pharmacists checking  
26 the prescription. That's a total of five medical

1 professionals versus two, if you had acquired your  
2 medication locally and bought it at a Walgreens, for  
3 example.

4 MR. SACHDEV: The term "cyber clinic," so  
5 you're saying this is an online question, that this is  
6 not --

7 MR. MacKAY: No. Sorry. A cyber clinic  
8 is the integration between the digital information we  
9 have in the patient profile and then literally  
10 manually phoning the doctor to confirm all of that  
11 information.

12 MR. JACOBSON: I'm sure what the Canadians  
13 are finding is what we're finding -- that most of the  
14 people that buy medications from us are not computer  
15 literate, and we receive more requests by telephone  
16 and we mail out the forms to them and they send them  
17 back, than people going online and doing inquiries.

18 MR. SACHDEV: Is that right?

19 MR. MacKAY: Yes.

20 SURGEON GENERAL CARMONA: Other questions  
21 or comments? None?

22 Yes, Dr. Crawford. Thank you.

23 DR. CRAWFORD: Mr. MacArthur, you  
24 mentioned -- and I didn't quite get the import of it  
25 -- shortages have occurred. Is that as a result of  
26 parallel importing? Could you elaborate on that a

1 little bit?

2 MR. MacARTHUR: No, I said the opposite.

3 DR. CRAWFORD: Okay.

4 MR. MacARTHUR: Shortages have resulted as  
5 a result of attempts to stop parallel trade. We have  
6 in Europe a very competitive wholesale sector, and a  
7 wholesaler that didn't supply his own market  
8 nationally or regionally would soon be out of  
9 business, because there are contracts between  
10 pharmacies and wholesalers. So if a pharmacist  
11 couldn't get any stock because that wholesaler has  
12 exported it, he would switch to another wholesaler,  
13 perhaps permanently.

14 This is also enforced in law in more than  
15 half of the members states in the so-called public  
16 service obligation. They are required by law -- every  
17 wholesaler -- to stock a full range or 95 percent of  
18 all the products on the market and deliver this within  
19 a certain timeframe to all of their customers.

20 And even in markets like the UK where it  
21 is not in law, there is a code of conduct for  
22 wholesalers. So wholesalers supply their local market  
23 first. Period. Parallel trade is only with certain  
24 stock, but quotas sadly have been enforced so  
25 rigorously.

26 I mean, you know, we have cases of

1 wholesalers' premises being burnt down and trying to  
2 get replacement stock and this being refused. We've  
3 had a case in Italy of a major wholesaler suffering a  
4 strike -- industrial action -- and obviously not being  
5 able to service his customers. A competitor wanting  
6 to move into that territory couldn't get any more  
7 stock -- supply.

8 In Greece, we had, after Glaxo so-called  
9 improved its distribution system by going direct,  
10 purely to obstruct parallel trade -- a lot of the  
11 islands were not supplied with essential drugs,  
12 including noticeably it picked up Lamictal, an anti-  
13 epileptic, and that had serious or potentially serious  
14 therapeutic consequences.

15 So we would argue that parallel trade --  
16 parallel exporting specifically doesn't lead to  
17 shortages, but, sadly, attempts in Greece and Spain  
18 specifically to stop parallel trade have led to  
19 shortages.

20 DR. CRAWFORD: One more.

21 Mr. MacKay, do your members export to  
22 other countries than the United States -- countries  
23 other than the United States?

24 MR. MacKAY: No, not that I'm aware of.

25 DR. CRAWFORD: Okay. Thank you.

26 SURGEON GENERAL CARMONA: Questions,

1 comments, from any of the other task force members?  
2 None?

3 Okay. Then, let me just wrap it up. I  
4 want to thank all of the presenters for being with us  
5 today. This concludes our sixth and final scheduled  
6 listening session.

7 Since Secretary Thompson announced the  
8 creation of this importation task force on March 16th,  
9 we've heard from consumer groups, individuals in the  
10 pharmaceutical industry, international and academic  
11 perspectives, health care purchasers, professional and  
12 medical groups, and members of the public.

13 According to my count, we've heard from  
14 101 presenters representing a number of views,  
15 opinions, and ideas. In addition, we have received  
16 information through our public docket.

17 Just as a reminder, any individual or  
18 organization can continue to submit information to the  
19 public docket through our website at  
20 [www.hhs.gov/importtaskforce](http://www.hhs.gov/importtaskforce) until June 1st. After all  
21 of that information is collected and compiled, the  
22 task force will engage in the challenging duty of  
23 writing the report for Secretary Thompson.

24 We've heard a number of different  
25 perspectives in this important public debate, and I  
26 believe that we have been well served by the members

1 of the community as a whole in providing us with the  
2 best information available.

3 When he created this task force, Secretary  
4 Thompson called on us to consider how and if drug  
5 importation could be conducted safely, and its  
6 potential impact on the health of American patients,  
7 including on medical costs and the development of new  
8 medicines.

9 While we share the goal of increasing  
10 access to prescription drugs for those who need them,  
11 indeed our report cannot just consider the short-term  
12 cost impact of allowing importation. We must look at  
13 the implications of any policy decision with regard to  
14 safety and efficacy of the drugs, the potential long-  
15 term benefits and consequences to research, the effect  
16 on the national, international, and global economies,  
17 all while taking into consideration the total supply  
18 of medicines.

19 The Medicare Prescription Drug Improvement  
20 and Modernization Act of 2003 requires us to report to  
21 the Secretary by the fall of this year. However,  
22 Secretary Thompson has asked that we expedite our work  
23 and share with him our findings as soon as possible.

24 I look forward to working with my  
25 colleagues on the task force in assessing the  
26 information that we have received and drafting a

1 report based on the best scientific information  
2 available that serves the public health of all  
3 Americans.

4 In closing, I would like to thank all of  
5 the members of the task force and the task force staff  
6 for their commitment and effort during their service  
7 thus far, and rest assured there will be more service  
8 to come.

9 Thanks very much.

10 We stand adjourned.

11 (Whereupon, at 4:32 p.m., the proceedings  
12 in the foregoing matter were adjourned.)  
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