

UNITED STATES OF AMERICA

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HEALTH AND HUMAN SERVICES

IMPORTATION TASK FORCE

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STAKEHOLDER MEETING

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FRIDAY,

MAY 14, 2004

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The Task Force met in Conference Rooms D and E in the Parklawn Building, 5600 Fishers Lane, Rockville, Maryland, at 1:00 p.m., VADM Richard Carmona, Chairman, presiding.

TASK FORCE MEMBERS PRESENT:

VADM RICHARD CARMONA, Chairman

MR. JAYSON AHERN

MR. ALEX AZAR

DR. LESTER CRAWFORD

MS. TRACEY HARDIN

DR. WILLIAM RAUB

MR. AMIT SACHDEV

MS. ELIZABETH WILLIS

PRESENTERS:

Panel 1:

DR. RANDALL MAXEY, President, National Medical

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Association

- DR. REBECCA PATCHIN, Trustee, American Medical Association
- MS. KAREN COLLISHAW, Associate Executive Vice President of the American College of Cardiology (representing the Alliance of Specialty Medicine)
- MS. SUSAN HILDEBRANDT, Assistant Director of Government Relations, American Academy of Family Physicians
- DR. CAROLE JENNINGS, Legislative Liaison, American Academy of Nurse Practitioners

Panel 2:

- MR. CARMEN CATIZONE, Executive Director/Secretary, National Association of Boards of Pharmacy
- MS. SUSAN WINCKLER, Vice President, Policy and Communications, Staff Counsel, American Pharmacists Association
- MR. DOUGLAS SCHECKELHOFF, Director, Section of Pharmacy Practice Managers and Director, Pharmacy Practice Sections, American Society of Health-System Pharmacists
- DR. MARV SHEPHERD, Director, Center for Pharmacoeconomic Studies, College of Pharmacy, The University of Texas at Austin (representing the Academy of Managed Care Pharmacy)
- MR. ROBERT McNELLIS, Director, Clinical Affairs and Education, American Academy of Physician Assistants

Panel 3:

- MS. DEANNA WILLIAMS, Registrar, Ontario College of Pharmacists
- MR. DONALD MacARTHUR, Secretary General, The European Association of Euro-Pharmaceutical Companies
- MR. DAVID McKAY, Executive Director, Canadian International Pharmacy Association
- MR. NATHAN JACOBSON, President & CEO, MagenDavidMeds.com

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

1:11 p.m.

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2
3 SURGEON GENERAL CARMONA: Good afternoon,
4 ladies and gentlemen. Thank you for being with us
5 again for this Task Force Meeting on Drug Importation.

6 We were stalling a couple of minutes to see if the
7 other Panel Members would come, so we'd have a full
8 Panel when we begin, but we don't want to
9 inconvenience anybody that's here already, so we'll
10 get started and work in the other Panel Members as
11 they arrive.

12 I'd ask the speakers to please be
13 cognizant of the clock. Again, we've requested that
14 you keep your remarks to five minutes or less and
15 we'll just go in succession across the table to all of
16 the speakers and then the Task Force Members will be
17 able to ask you questions at that point.

18 Otherwise, we'll conduct the meeting as we
19 have the previous meetings, so there will be no
20 changes.

21 Once again, thank you all for being with
22 us, so Dr. Maxey is not here, so why don't we go ahead
23 with Dr. Rebecca Patchin from the American Medical
24 Association.

25 DR. PATCHIN: Thank you, Dr. Carmona. My
26 name is Rebecca Patchin. I am an anesthesiologist, a

1 practicing pain management specialist and a member of
2 the American Medical Association's Board of Trustees.

3 I'm in solo practice in Riverside,
4 California where I've had a number of patients cross
5 the border into Mexico to attempt to buy more cheaply
6 the prescription medication that I have prescribed for
7 them.

8 Am I concerned about this? Absolutely.
9 In fact, this is a concern shared by the AMA and
10 practicing physicians across the U.S. We are
11 concerned because when patients go outside of this
12 country to purchase their drugs, there is no way for
13 physicians to be certain that the drugs they prescribe
14 for them are the drugs they are going to receive.
15 Whenever patients get their prescription drugs from
16 Mexico, Canada or the European Union, the concerns
17 remain the same, that our patients are getting the
18 right drug, the right dose, and in the right way.

19 What the right way means is that the drugs
20 come from manufacturers, wholesalers, retailers,
21 whether internet or brick and mortar pharmacies; that
22 it can assure quality while at the same time balancing
23 against the needs for patients to get their
24 prescriptions at the lowest possible price. But when
25 it comes to drug importation, patient safety is the
26 AMA's number one priority.

1 At its 2003 Annual House of Delegates
2 Meeting, the AMA chose not to adopt a resolution
3 supporting prescription drug importation. Concerns
4 over patient safety were at the center of AMA's
5 debate. On the legislative front, the AMA also
6 opposed H.R. 2427, the Pharmaceutical Market Access
7 Act of 2003, primarily because the bill lacked a
8 provision that required the Secretary of HHS to
9 certify the safety of imported drugs.

10 The only way to assure the safety of
11 imported drugs is to make certain that all drugs for
12 sale for patients in the U.S. are FDA approved. That
13 means, among other requirements, that the drug has
14 been approved by the FDA for safety and efficacy, that
15 the drug manufacturer has met all U.S. laws and
16 regulations for good manufacturing practices, that the
17 FDA has the authority to inspect all manufacturing
18 facilities, that the drug has met all FDA labeling and
19 packaging requirements, and finally, that the drug's
20 chain of custody can be assured and traced.

21 Admittedly, these requirements would
22 demand significant federal resources, but if we are to
23 allow drug importation, these measures are necessary
24 to protect the American people and to preserve our
25 stringent and very effective approval process.

26 Another AMA concern is drug

1 counterfeiting. In a recent FDA report, drug
2 counterfeiting outside the U.S. was described as
3 widespread and affecting the drug supply of both
4 developing and developed countries. In some
5 instances, counterfeit drugs accounted for more than
6 half of a country's drug supply.

7 The AMA has concerns that if prescription
8 drugs are allowed to be imported from foreign
9 countries, counterfeit drugs will more likely enter
10 our system, a system that is now well protected for
11 its drug distribution. If we allow importation, the
12 distribution system must be closed and all drugs must
13 be subject to reliable, electronic track and trace
14 methodology to secure the integrity of our drug supply
15 chain and to prevent the importation of counterfeit
16 drugs.

17 The AMA is also concerned with whether or
18 not individual patients will be allowed to import
19 drugs directly via the internet. This is largely an
20 unregulated area with an increasing number of rogue
21 websites already selling prescription drugs of unknown
22 quality and often without a valid prescription. The
23 problem is likely to increase, if direct importation
24 by patients is legalized.

25 Without the safeguards I have described,
26 the American people cannot be certain that the

1 imported drugs they are taking are safe, effective and
2 of high quality. These may seem like high standards
3 to demand, especially when many patients struggle to
4 pay the high cost of their prescription drugs.
5 However, if we permit unsafe, ineffective,
6 adulterated, misbranded, expired or counterfeit drugs
7 to reach our patients, it may result in patient harm,
8 even death.

9 To use an example from my field of pain
10 management, if a subpotent or counterfeit drug means
11 the difference between a scale of 6 on a 1 to 10
12 scale, and a scale of 9, I'm sure you can appreciate
13 the difference that would be to you, if you were in
14 that severe pain.

15 These and other patient safety issues must
16 be weighed carefully before any decision should be
17 made on drug importation.

18 Thank you for the opportunity to address
19 you. I'll be happy to answer your questions.

20 SURGEON GENERAL CARMONA: Thanks very
21 much. Our next speaker, Ms. Karen Collishaw.

22 MS. COLLISHAW: Thank you, Dr. Carmona.
23 Thank you for offering health care providers the
24 opportunity to comment on the important public policy
25 issue of prescription drug importation.

26 My name is Karen Collishaw and I am the

1 Division Vice President for Science and Advocacy at
2 the American College of Cardiology. I am here today
3 representing the Alliance of Specialty Medicine.
4 Founded in 2001, the Alliance brings together 14
5 medical specialty societies representing over 200,000
6 physicians throughout the U.S. The Alliance is
7 dedicated to being a strong voice for specialty
8 medicine and the patients who need access to specialty
9 care.

10 The escalating cost of many prescription
11 drugs affects the most vulnerable patients, the
12 elderly, the uninsured, and those with chronic health
13 conditions. As is widely known, these patients often
14 present with advanced and co-morbid conditions leading
15 to complex decision making for physicians.
16 Unfortunately, this decision making process must
17 include consideration of whether the patient can
18 afford the most appropriate drug or in many cases
19 multiple drugs for treatment. The effectiveness of
20 any disease management regimen will be seriously
21 reduced if a patient skips doses to stretch medication
22 or is forced to make the difficult decision not to
23 fill a prescription because of a lack of financial
24 resources.

25 The Alliance is most concerned that our
26 nation's prescription drug importation policy be

1 designed to provide a safe and reliable source of
2 these medications for patients. There are undoubtedly
3 many safety and procedural issues associated with
4 prescription drug importation that must be addressed
5 by the FDA and other relevant agencies.

6 The Alliance supports the necessary
7 authority and funding for these agencies to design and
8 implement a monitoring system with controls to ensure
9 the safety of imported drugs consistent with the
10 provisions of current law. Specifically, the
11 safeguards in any and all importation policies must
12 ensure that prescription drugs brought into our
13 country are safe and effective for their intended use.

14 As you know, there are always
15 opportunities for prescription errors, whether in the
16 United States or any other country. No system can be
17 guaranteed 100 percent effective and sanitized against
18 human error. However, the protections specified under
19 current law on this subject, in addition to innovation
20 such as bar coding and tamper resistant packaging
21 should help reduce the risks to patients for drug
22 importation.

23 The Alliance recognizes that prescription
24 drug importation is not the solution to address all
25 problems that patients have with access to care.
26 However, the Alliance believes that importation of

1 prescription drugs, done safely, may be in the step in
2 the direction of reducing cost barriers and providing
3 much needed financial relief for patients.

4 On behalf of the Alliance, thank you for
5 the opportunity to share our views.

6 SURGEON GENERAL CARMONA: Thanks very
7 much. Ms. Susan Hildebrandt.

8 MS. HILDEBRANDT: Thank you. Good
9 afternoon. I apologize for being late.

10 I'm Susan Hildebrandt and I'm Assistant
11 Director of the Division of Government Relations with
12 the American Academy of Family Physicians. I've an
13 extremely brief statement because perhaps like many of
14 the groups, we are just beginning to look at this
15 issue more thoroughly and we have really decided to
16 look at the issue of drug importation really through
17 the prism of drug coverage.

18 Frankly, we looked at this for the first
19 time only about a year ago in May of 2003 and came up
20 with a recommendation. The key points in this
21 recommendation were as follows: first, the Academy
22 believes that the re-importation or importation of
23 pharmaceutical drugs from Canada and other countries
24 is really symptomatic of a larger problem, namely, the
25 lack of affordable prescription drugs. Secondly,
26 prescription drug costs and the lack of coverage

1 really limits their availability in the United States.

2 And thirdly, the Academy really believes that
3 Congress should address this issue and make sure that
4 these drugs are available to patients at affordable
5 prices.

6 Parenthetically, the Academy also believes
7 that other issues such as internet drug -- the people
8 getting drugs through the internet is also part of
9 this larger high cost problem.

10 Next week, our Academy's Commission on
11 Legislation is going to be looking at this issue again
12 and I don't know if our policy will be revised, but we
13 are certainly looking at the two most recent pieces of
14 legislation in Congress, namely, the bipartisan bill
15 that was recently introduced and then the bill that
16 was introduced by the Senate Finance Committee
17 Chairman Grassley and at that point we may revise
18 these comments. But at this point, I appreciate the
19 Academy's, you allow the Academy to present this
20 statement. Thanks.

21 SURGEON GENERAL CARMONA: Thank you. Next
22 speaker, Dr. Carole Jennings.

23 DR. JENNINGS: Dr. Carmona, it's good to
24 see you again. I think you started your professional
25 life in health care as a nurse.

26 SURGEON GENERAL CARMONA: Yes ma'am.

1 DR. JENNINGS: So it is nice to be here.
2 I am representing the American Academy of Nurse
3 Practitioners. We represent over 97,000 advanced
4 practice nurse practitioners throughout the U.S. and
5 we're very acutely aware of the high cost of
6 prescription drugs.

7 As primary care clinicians who prescribe
8 medications for their patients on a regular basis,
9 nurse practitioners are reminded daily of the negative
10 impact those costs have on the health of their
11 patients. Patients often do not fill their
12 prescriptions or partially fill prescriptions because
13 their cost of prohibited or they may take a medication
14 that is prescribed daily two or three times a week.
15 They often make the medication last longer or they
16 take medication temporarily until the next paycheck or
17 pension check is available. The result is poor
18 management of illnesses, poor quality of life and
19 increased need for hospitalizations and emergency room
20 care.

21 The inability of patients to pay for
22 prescription drugs actually increases the cost of
23 medical care and the cost of chronic disease
24 management which we know is now a very big priority
25 with the Medicare Program.

26 When medications cannot be taken as

1 directed, the risk for increased hospitalization and
2 ER visits multiplies. It is in the best interests of
3 the American public that affordable ways to obtain
4 medication be developed.

5 And we have three principles or areas that
6 we are particularly concerned about. The first is
7 safety, as my colleagues have also mentioned. If
8 drugs are to be imported, it's important to know that
9 they are safe, that they don't have variable doses
10 from tablet to tablet or capsule to capsule and that
11 their composition consist of the correct therapeutic
12 ingredients.

13 Consumer friendly. If drugs are to be
14 imported, it should be done so that patients can have
15 access in a timely and uncomplicated manner. If too
16 many restrictions are placed on patients so that it
17 becomes impossible to obtain drugs more cost
18 effectively through this mechanism, then the purpose
19 for drug importation is lost.

20 The last one, limiting access to provider
21 groups. If the implementation consists of identifying
22 providers who can prescribe these drugs that have been
23 brought over from Canada, we just ask that you include
24 nurse practitioners because like our primary physician
25 counterparts, it is a huge problem for us and for our
26 patients.

1 So in conclusion, nurse practitioners
2 remain acutely aware of the burden high cost
3 prescription drugs places on patients and providers.
4 The Academy believes that steps do need to be taken to
5 reduce the financial burden of these high cost
6 prescription drugs. We are so delighted that you
7 asked us to participate. We look forward to working
8 with you as you implement the Medicare prescription
9 drug legislation.

10 Thank you.

11 SURGEON GENERAL CARMONA: Thank you very
12 much. I think what we'll do now is Dr. Maxey has not
13 arrived yet, oh, there he is. I'm sorry. Perfect
14 timing. Dr. Maxey, right on cue. Right there, sir.
15 Thank you for joining us.

16 DR. MAXEY: Thank you. How are you, sir?

17 SURGEON GENERAL CARMONA: Dr. Maxey is
18 from the National Medical Association and the floor is
19 yours, sir.

20 DR. MAXEY: Thank you, sir. Just one
21 second.

22 Good afternoon, Surgeon General Carmona
23 and Members of the Secretary's Task Force on Drug,
24 Food and Drug Importation. The National Medical
25 Association, the conscience of American medicine is
26 America's premiere membership association of

1 physicians of African descent. As such, the NMA
2 represents over 25,000 medical practitioners and the
3 patients they serve. Many of our patients are from
4 underrepresented and underserved minority groups and
5 are therefore representative of the most vulnerable
6 populations seeking services from our nation's health
7 care system. These populations are also the victims
8 of disparities in health care based upon race and
9 ethnicity in their every day lives and communities
10 across our nation.

11 Consequently, the outcomes of this inquiry
12 process relating to drug re-importation is directly
13 relevant to the practice of medicine for African
14 Americans, in particular, and for the U.S. population
15 as a whole. We are appreciative, therefore, for this
16 forum and we thank the Health and Human Services Task
17 Force on Drug Importation for inviting us to
18 participate. We're hopeful that our input, in
19 addition to the input of all the other stakeholders
20 will bring us to a viable commonsense strategy for
21 dealing with this thorny issue.

22 Fundamentally, the NMA, the National
23 Medical Association, is of the opinion that the
24 quality and safety of the drugs to be imported must be
25 our paramount concern. If any doctor or physician in
26 America writes a prescription for a patient and cannot

1 be confident that the prescription will be correctly
2 filled, then the patient may as well have written the
3 prescription. It stands to reason then that the Food
4 and Drug Administration's role in this process will be
5 critical.

6 To this end, the following recommendations
7 are been proffered by the NMA in response to the
8 specific solicitation from the Task Force. We have
9 listed our responses in sequential order.

10 The first question, to assess the scope,
11 volume and safety of unapproved drugs including
12 controlled substances entering the United States via
13 mail shipment. The FDA should concern itself with
14 determining which countries of the world have
15 equivalent regulatory and approval processes for
16 bringing pharmaceuticals to market. There is also a
17 need for determining the safety of said
18 pharmaceuticals if they are to be imported into the
19 U.S. If the drugs are safely produced, we need to be
20 certain that they are safely shipped as well. The FDA
21 could develop standard protocols that can be enforced
22 at our nation's ports of entry. These protocols could
23 be signed affidavits from the issuing pharmacist that
24 demonstrates that the products being inspected meet
25 U.S. quality and safety standards and therefore merit
26 allowance into the U.S. The burden of proof could

1 then be placed on the individual or individuals
2 seeking to do the importing, thus minimizing the
3 administrative/regulatory burden placed upon the
4 resources of the FDA.

5 Volume requirements should be reasonable.

6 If an individual U.S. citizen or resident attempts to
7 bring drugs into the U.S., it should be up to them to
8 demonstrate that the products are only for a specified
9 period to treat a specific condition. This
10 information may be included as a line item on the
11 aforementioned affidavit which should also be signed
12 by the intended user or designee.

13 If the affidavit is bar coded, it could be
14 tracked for data collection and for enforcement
15 purposes if any questions of legality later arise.
16 Any attempt to mislead the U.S. government in this
17 process should be treated as a felony with the
18 appropriate penalties. Commercial shippers and mail
19 carriers should be required to ask if packages contain
20 prescription drugs and if so, require that customers
21 present the aforementioned affidavits.

22 The second question: to assess
23 pharmaceutical distribution chain and the need for and
24 feasibility of modifications in order to assure the
25 safety of imported products. If a prescription drug
26 shipment goes through an intermediary before it gets

1 to the intended consumer, then the intermediary should
2 also be required to certify that the shipment is
3 delivered to the intended recipient in the safest and
4 timeliest possible fashion. This would include
5 relevant information such as meeting refrigeration and
6 packaging requirements, for example. This
7 certification should be numerically linked to the
8 aforementioned affidavit, probably as an addendum or
9 Part B of the document. Intermediaries of the supply
10 chain should be restricted to certain categories of
11 persons. It is possibly safest if each category of
12 intermediaries has a pharmacist designated for this
13 purpose in order to improve the probability, the
14 integrity of the product is maintained pending
15 delivery to the customer.

16 The third question. To determine the
17 extent to which foreign health agencies are willing
18 and able to ensure the safety of drugs being imported
19 from their countries to the U.S. This determination
20 requires a collaboration of other U.S. government
21 entities such as the Department of Commerce. To the
22 extent that international trade agreements affect
23 these arrangements, the FDA should be given the
24 prerogative in setting the pharmaceutical requirements
25 necessary to protect the interest of the American
26 consumer. The protocols of foreign health agencies

1 with regarding to exploiting their pharmaceuticals to
2 the U.S. should be considered in light of what works
3 best for our nation's taxpayers.

4 Fourth, to identify the limitations
5 including limitations on resources and current legal
6 authorities that may inhibit the Secretary's ability
7 to certify the safety of imported drugs. The NMA has
8 no specific input on this question at this time. But
9 the current relationship between the FDA and the U.S.
10 Customs is worth investigating. It is probably worth
11 the time and resources necessary to develop compatible
12 documentation mechanisms for these two entities for
13 the purpose of regulating drug importation.

14 Fifth, to estimate Agency resources
15 including additional field personnel needed to
16 adequately inspect the current amount of
17 pharmaceuticals entering the country. The NMA has no
18 specific comments on this question at this time.

19 Sixth, to identify ways in which
20 importation could violate U.S. and international
21 intellectual property and describe the additional
22 legal protections and agency resources that would be
23 needed to protect those rights. Foreign pharmacies
24 should be prohibited from exploiting pharmaceuticals
25 that do not pass U.S. safety and quality standards to
26 the extent that the FDA can ensure compliance.

1 All American manufacturers should be held
2 to the same standard, whether or not they manufacture
3 generics. The NMA is strongly committed to the
4 principle that the best therapy should be sought for
5 each patient irrespective of whether the drug is
6 generic or brand name or for that matter whether the
7 patent was issued in the U.S. or elsewhere.

8 Seventh, to estimate the cost borne by
9 entities within the distribution chain to utilize
10 anti-counterfeiting technologies that may be required
11 to provide import security. The NMA has no comments
12 on this question.

13 Eighth, to assess the potential of short
14 and long-term impacts on drug prices and prices for
15 consumers associated with importing drugs from other
16 countries. An HHS entity such as the Agency for
17 Health Care Research and Quality or the National
18 Center for Health Statistics should be definitively
19 involved in answering this vital question. The
20 findings would particularly be useful to the Centers
21 for Medicare and Medicaid Services which, as we know,
22 is America's most significant purchaser of
23 pharmaceutical services. The population served by CMS
24 happened to significantly overlap with NMA's key
25 constituencies, so we would be very interested to
26 answer this question if as a nation we decide we can

1 successfully import safe, top quality drugs, then it
2 means viable competition for America's drug
3 manufacturers, and therefore greater bargaining powers
4 for purchasers such as CMS. This should translate
5 into lower out of pocket costs for the most vulnerable
6 consumers who are currently forced to choose between
7 medications and other essential goods and services.
8 HHS should commission a study on this question as soon
9 as possible.

10 SURGEON GENERAL CARMONA: Dr. Maxey, could
11 you sum it up, please?

12 DR. MAXEY: Yes sir.

13 GENERAL CARMONA: Thank you.

14 DR. MAXEY: The pharmaceutical industry
15 should -- we do need to collect data to find out the
16 best ways to approach this and NMA would support any
17 efforts to do the research that are required to make
18 sure that our patient's receive the best quality
19 medications regardless of their conditions, whether
20 they're imported or not. Safety is the most important
21 thing for the NMA.

22 Thank you.

23 SURGEON GENERAL CARMONA: Thank you, sir.

24 At this time, I'd like to open the floor to questions
25 from the Task Force Members.

26 Dr. Crawford?

1 DR. CRAWFORD: Yes. Thank you, Dr. Maxey,
2 for your excellent testimony. We appreciate it very
3 much.

4 You had talked about some safe harbors for
5 importation of drugs. I have basically a two-part
6 question. One is if, in fact, we go forward with
7 legislation which I believe you mentioned indirectly,
8 I assume you would hope that they would require, that
9 is, if there's a new law, to make this legal, country
10 of origin labeling and if so, how prominent would you
11 like that to be?

12 You talk about FDA should determine what
13 countries should be eligible to import or export to
14 the United States under some new sort of scheme.
15 Normally, where the product is manufactured, if it's a
16 U.S. product which is all we have to deal with now is
17 sort of list it in very small print.

18 We've had these debates in the food area
19 and in other areas that FDA regulates and it becomes a
20 very big sticking point as to whether or not you want
21 to clearly identify, some color coding scheme or
22 something like that.

23 Do you have any thoughts on that?

24 DR. MAXEY: Yes. We do know that some
25 countries are very sophisticated in terms of how they
26 judge the quality of their drugs and we know that many

1 of these drugs are manufactured by the same companies
2 that manufacture here.

3 Where we do lose control, even in the
4 United States, is when we get to our wholesalers and
5 get to the people who distribute and we know even here
6 we don't have total control over the quality there.
7 So we do think that FDA standards, our high quality
8 standards should be applied to some of the more
9 sophisticated foreign countries and those should be
10 probably the countries that we would limit where drugs
11 would be imported from, if that's possible.

12 Clearly, there's some countries that are
13 not up to snuff, where you couldn't certify anything
14 and I think those would have to be a long time in
15 coming. So we're concerned with the safety of drugs
16 we have now because we know once they leave the
17 manufacturer, get to the wholesaler and distributor,
18 we lose all control. But to the extent that we can
19 put controls in there, as well as in the more
20 sophisticated foreign countries, then we are for
21 bringing in things that can approach the treatment of
22 our patients at a price they can afford.

23 DR. CRAWFORD: And a follow-up, if I may?

24 SURGEON GENERAL CARMONA: Please.

25 DR. CRAWFORD: The next thing generally
26 this takes us to is if, in fact, FDA or some other

1 entity certifies that another country has the same
2 kinds of standards, equivalent standards, would you
3 countenance or what would be your opinion about some
4 sort of labeling system which would say not FDA
5 approved, let's say approved in Canada, for example.
6 Or would you want some sort of formal declaration of
7 FDA approval? See, we could do it a couple of ways
8 and I'm not sure how to do it at this point. But
9 these are some of the kinds of questions that your
10 testimony engender in my mind.

11 DR. MAXEY: I don't claim to be an expert,
12 but we do want to know that our FDA can have some sort
13 of oversight of that process to the extent possible.
14 Somewhat of what you asked is a legal question and
15 there's a liability question so if you certify
16 something that you don't have total control of, you
17 don't want to take that liability either. But to the
18 extent that we have control of our own system, we
19 should try to have those countries that wish to
20 cooperate with re-importation to have some standards
21 that we can approve of. That's as far as I could
22 really say and be safe.

23 DR. CRAWFORD: Thank you.

24 SURGEON GENERAL CARMONA: Other questions?

25 Amit?

26 MR. SACHDEV: This question is for Mr.

1 Maxey and actually others, if they have comments, are
2 free also to provide their input.

3 In all the discussions that we've had,
4 your testimony was certainly the most complete and I
5 appreciate the fact that you actually went through
6 each of the questions that we are grappling with and
7 try to provide us with information about those because
8 in some cases, we've gotten testimony on certain
9 questions, but not all of them. And I think that's
10 very appreciated.

11 One thing that you mentioned right up
12 front that I want to ask you about is the comment that
13 you made about equivalence and the need for the FDA,
14 if Congress considers legalization of importation, to
15 assure that any imported drugs are equivalent to U.S.
16 drugs.

17 Can you help us with how you would define
18 equivalence? And in particular, some legislation
19 that's pending has looked at that issue and said that
20 some products can be like FDA products, but not
21 necessarily the same as FDA products, differing in
22 things like labeling, differing in terms of
23 bioavailability and as we have thought about that
24 issue and are trying to respond to the questions that
25 Congress has given us, we struggled with trying to
26 understand how much product exists outside of the

1 United States that is truly the same as U.S. approved
2 products or is, in fact, equivalent, but not quite the
3 same as U.S. approved product.

4 DR. MAXEY: Boy, I almost feel like I'm
5 back in medical school.

6 Most of our major pharmaceutical firms are
7 multi-national anyway and most scientists tend to be
8 multi-national in terms of their training and their
9 travels. So it shouldn't really be a hard reach to
10 find bioequivalence and speaking the same language and
11 find that.

12 We also, there's some differences even in
13 generics and brand names in terms of bioequivalence
14 whether it's Digoxin or other drugs that we know and
15 bioequivalence is something that you determine in a
16 laboratory of what meets what standard. And that
17 should not be a hard scientific question to answer.
18 It will require some real time testing of products.
19 Just because something bears the same name and label,
20 does not mean it has the same bioequivalency. That's
21 something that we would have to devise standards for
22 that the scientists of each company would have to meet
23 approval of their country, and of course, our FDA.

24 So that's not a hard question.
25 Bioequivalence is something you determine by actual
26 testing.

1 MR. SACHDEV: And what you're suggesting
2 then is that you would be interested in seeing an
3 importation scheme, if Congress put one in place, that
4 had basically drugs that were meeting the same
5 standards that are in the United States?

6 DR. MAXEY: Absolutely. Are labeled
7 appropriately, just so you know what you're getting if
8 you're going to take an aspirin from here and one
9 comes from England, you should know that one is half
10 the equivalent of the other or something. That
11 doesn't seem like a very hard technical challenge.
12 Most of our companies work every place in the world.
13 They produce drugs here. They produce drugs in
14 Africa. They produce them in Europe and so there
15 shouldn't be really a problem if the same companies
16 are dealing with these drugs.

17 SURGEON GENERAL CARMONA: Others on the
18 Panel who want to comment on that?

19 MR. SACHDEV: I have one follow-up
20 question as well.

21 SURGEON GENERAL CARMONA: Please.

22 MR. SACHDEV: Another one of the questions
23 that we're grappling with has to do with the extent to
24 which there are certain categories of products, either
25 by virtue of their -- the way they're manufactured,
26 the way they have to be handled and stored, the types

1 of doctor-patient or medical professional-patient
 2 interaction that's required when they're prescribed.
 3 And in fact, in some cases, the type of labeling
 4 that's on them, there are a lot of these products out
 5 there that vary tremendously.

6 And the question for us is in thinking
 7 about importation, how do we address the fact that you
 8 have these various types of products, which have
 9 differing risk profiles? And in the context of
 10 importation, are there certain categories of products
 11 that the witnesses today believe simply aren't
 12 appropriate for importation because of particular
 13 characteristics? Or would pose more risk if, in fact,
 14 Congress were to legalize importation because of the
 15 characteristics?

16 And again, it's open to anyone on the
 17 Panel.

18 DR. MAXEY: Just to -- one answer is there
 19 are certain drugs and I don't know the cost of them,
 20 but the Coumadin or warfarin type drugs can be
 21 somewhat lethal if you didn't have some
 22 standardization of these drugs, they could cause
 23 bleeding. But simply by testing such things as LD-50
 24 and having the appropriate protocols should again
 25 avoid that. So we would want to know the appropriate
 26 testing for equivalence has gone on.

1 The one concern I do have is that many of
2 our drugs, even here in the United States, have not
3 been appropriately clinically tested on a broad range
4 of ethnic people. Many African Americans, for
5 example, have not undergone clinical trials for some
6 of the ace inhibitors. That leads to some problems.
7 So if we're going to bring in drugs from other
8 countries, again, we would want to know that
9 appropriate testing among ethnic groups and cultural
10 groups has been done so that we really know the
11 appropriateness of these drugs. So that is something
12 we have as a problem right here, right now, with our
13 own medication. So that's going to be compounded when
14 you're bringing in drugs from outside. So that should
15 also be considered that the appropriate database has
16 been obtained so that they apply to all people that
17 they're intended for.

18 SURGEON GENERAL CARMONA: Others?

19 DR. PATCHIN: I think speaking for the
20 AMA, we would view the FDA process as the gold
21 standard and one that we would want to have our
22 patients and our physicians have confidence in
23 wherever the drugs came from.

24 MR. SACHDEV: Are there particular
25 products like controlled substances or biologics or
26 injectables that you know, that folks think are

1 probably of greater concern than other products, maybe
2 fixed dose type products?

3 MS. COLLISHAW: We haven't talked about
4 that, but it strikes me individually as reasonable
5 that there would be probably be certain things that
6 people would be uncomfortable with coming from outside
7 the country.

8 Sounds reasonable that you would have to
9 make some choices.

10 SURGEON GENERAL CARMONA: Dr. Raub.

11 DR. RAUB: I had a question for all of the
12 members of the Panel that builds on the last several,
13 but it begins with my stating the obvious, that is,
14 the dilemma for this Task Force is that our citizens
15 can look across the border to Canada or across the
16 ocean to the U.K. and see people able to acquire safe
17 and effective medications, and at least for some of
18 the non-generic varieties at a substantial reduction
19 in price.

20 If we were able to create a mechanism
21 whereby drugs approved by those national authorities
22 for distribution within their own countries could, in
23 fact, be brought here through a certified distribution
24 mechanism, and made available in our distribution
25 system and then to our pharmacies, what would be wrong
26 with that?

1 DR. PATCHIN: I'll start with that.
2 Again, if they meet our FDA standard and they meet all
3 of the items I said in my prior testimony, I think
4 that we have a trial under way of that very subject of
5 the cost to pharmaceuticals in this country and it was
6 released about a week and a half ago when the Medicare
7 website went up that compared the cost of
8 pharmaceuticals. I think we've done a service to our
9 elderly and as someone not eligible for Medicare, I
10 too, have benefited by the cost comparison that has
11 been obtained by looking at that website. When we get
12 the drug cards and we get the ability to negotiate
13 prices in this country, we may see that market forces
14 affect the cost of pharmaceuticals in this country,
15 but whatever we bring in, we need to make sure it
16 meets our existing standards so that patients can
17 understand that it is safe and that the physicians can
18 know that it is safe when they write that
19 prescription.

20 DR. MAXEY: From the National Medical
21 Association, one, we're going to pretty much ditto
22 what the American Medical Association says with the
23 proviso that even though we have very safe drugs, many
24 of my patients can't buy them, can't afford them and
25 that's a major problem. If you have the safest, best
26 thing in the world, but you can't get it, it's of no

1 consequence. So it's very important to us that we
2 solve this dilemma by having both safety, but also
3 availability.

4 DR. RAUB: But the mechanism I was
5 describing would bring drugs, safe and effective, for
6 Canadians --

7 DR. MAXEY: That we support.

8 DR. RAUB: Or Brits, but at a lower cost.

9 DR. MAXEY: We support that.

10 MS. COLLISHAW: If you have a system for
11 certifying that they're safe and effective, it's hard
12 to argue with that, right.

13 SURGEON GENERAL CARMONA: Other questions
14 from the Task Force Members?

15 I have one for all of you. You have
16 spoken all eloquently about safety, about cost, about
17 quality. We've heard testimony earlier, if we're
18 looking at importation as an option that those who
19 have expertise in the safety aspects, all of the
20 technology that's available today and we posed a
21 question to them in hypothetical, assuming that cost
22 is not an issue, do we have the technology available
23 today to be able to ensure the safety of importation
24 of all drugs and the testimony we heard was that the
25 technology wasn't there.

26 So what do we do in that case if we're

1 looking at importation as an option and the experts
2 who deal in this field tell us probably can't do it,
3 at least for a few years. We don't have the
4 technology, not only to look at the bulk packaging
5 which is similar, but when we get down to the
6 repackaging as you said, Dr. Maxey and the
7 distribution and warehouses and the breakdown and
8 repackaging and getting down to every single pill or
9 every single ounce of medication, how do we ensure
10 that that's safe? Then what do we do? What are our
11 options then?

12 DR. MAXEY: Well, I understand that we
13 have a very safe situation, but we know that it's not
14 safe down to the pill, as I've said before. So we can
15 get as close to what we have now with the effort to
16 make it as perfect as possible. I think that's the
17 best we can do. We have to err somewhere between a
18 perfect system that nobody can afford and an imperfect
19 system where you have death and destruction. So we do
20 have to get these drugs to people. So I think we have
21 to make best efforts to develop that technology.

22 We do have the knowledge and we know how
23 to certify those, but we have to have the will to do
24 it, which does mean putting some of the finance and
25 development into getting that system up and running.

26 DR. JENNINGS: I haven't heard anybody

1 talk about the process that the Canadians go through
2 to assure the safety of their medications, but I think
3 it would be important that we just don't reinvent the
4 wheel, that they may have a very good process. I've
5 heard patients and colleagues in Canada feel that they
6 have a very successful prescription drug system and I
7 would somebody suggested that maybe the FDA should be
8 involved with doing research on what the regulations
9 and the mechanisms for patient safety and medications
10 are, I guess at this point, you know, to start with,
11 Canada. But I just don't think -- we're not the only
12 ones who can assure that patients receive safe
13 medications and I think other countries have done a
14 good job in that area.

15 SURGEON GENERAL CARMONA: Other comments?

16 MR. SACHDEV: I'd like to follow up on
17 that line of questioning. I think -- I'd like to get
18 opinions from you all or thoughts. Concerns have been
19 raised in the past in these listening sessions that
20 follows on Dr. Carmona's question and it relates to
21 the extent to which there is an effort to legalize
22 importation. And we are able to address some of the
23 safety concerns. We've had raised questions about --
24 and I know most of you are medical professionals,
25 doctors, and so you have a special relationship with
26 lawyers, but in particular, there's been questions

1 about the extent to which there would be adequate
2 legal recourse for patients who might be harmed by
3 products that are imported into this country from
4 overseas or from Canada or from anywhere where the
5 U.S. regulatory entities including the federal Food
6 and Drug Administration, but also the state pharmacy
7 regulators do not currently have the ability to reach.

8 Do you have comments, any of you, on how
9 that issue would need to be addressed or how it could
10 be addressed or if you think it's a significant
11 concern?

12 DR. PATCHIN: Well, we have 19 states in
13 this country in crisis with medical liability. We
14 have only five or six that are not on the tipping
15 point to become one of the 19 that have been
16 identified by the AMA. And anything that potentially
17 would harm patients has potential to impact on the
18 medical liability system.

19 I'd like to just share with you a personal
20 story. Dr. Carmona practiced in what I call one of
21 the other border states which I do, living in southern
22 California, and I won't say which patient it was, but
23 it is a patient that I see in a county hospital who
24 pays for his own medications. And he had told me
25 about his friend. And I don't know whether it was him
26 or his friend who had gone to Mexico and purchased the

1 prescription medication that I had written for him to
2 fill in this country at a much lower cost. And he
3 asked me if it was okay to take. And I went into I
4 have no idea, you know. I don't know what the FDA
5 does in that country. He says but it looks exactly
6 the same. The bottle looks exactly the same. And I
7 said well, I still don't know what is actually inside
8 that pill.

9 The next month he came back in and told me
10 that his friend had opened one of those pills and that
11 his friend had found common dirt inside of the
12 tablets, not any medication. And I said how did you
13 know it was dirt? And he said my friend analyzed it.

14 It was just dirt. And that is what we're dealing
15 with, whether it be counterfeit meds from wherever
16 they come, is whether that patient took that
17 medication. Dirt probably wouldn't harm him, but if
18 it was something else, he could have come to harm with
19 either a drug to drug interaction or a lack of
20 effectiveness. And it is the patient is why we're
21 here, so thank you.

22 SURGEON GENERAL CARMONA: Thank you.

23 Another issue, you know, the issue -- we spend a lot
24 of time, of course, speaking about Canada as maybe
25 being representative when certainly a northern border
26 it is, but we have the southern border with Mexico as

1 well as many other countries that will potentially
2 import drugs in.

3 Dr. Jennings, you had mentioned looking at
4 the Canadian system. We have and certainly Dr.
5 Crawford and others are expert in that. And I think
6 that we all agree that pharmacy by pharmacy and their
7 pharmacies are like ours and they have a very adequate
8 system, maybe as good as ours. But even in the
9 Canadian government has told us that they don't
10 sanction, nor can they certify the drugs that come
11 through their country not for use by their citizens.
12 So basically there are those we have found in our
13 investigation that take advantage of that and just use
14 the country of Canada as a through put to send the
15 drugs out. And so with that in mind, I take to heart
16 your comments, but when the Canadian government has
17 told us, we can't guarantee the safety because these
18 drugs aren't being used for our people and others take
19 advantage of that, how do we handle that? Because as
20 we've seen through various investigations here from
21 Customs from DEA from others when they do their
22 investigations, a great many internet sites as well as
23 proprietors put up information of Canadian drugs
24 giving the false impression that these are secure when
25 really the Canadian government or their FDA equipment,
26 their health ministry have had nothing to do with

1 that.

2 DR. JENNINGS: Well, I think for years
3 many patients have gone to Canada and purchased their
4 drugs and brought them back and I guess it would be
5 interesting to look at that history and see if, in
6 fact, they had adverse reactions or they found that
7 the medication was ineffective, the medication that
8 came somewhere else other than the U.S.

9 MR. SACHDEV: I have a follow-up.

10 SURGEON GENERAL CARMONA: Please.

11 MR. SACHDEV: I thought the distinction
12 that Dr. Carmona was trying to draw was between the
13 licensed Canadian pharmacist that the person who
14 drives across the border goes to and what we're seeing
15 now which is operations in Canada that are being
16 created solely or primarily for the purpose of export
17 to the United States. And in that situation, I think
18 that's the situation you were describing, was it not?

19 SURGEON GENERAL CARMONA: Yes.

20 MR. SACHDEV: Where the Canadian
21 regulators really in their laws don't focus on those
22 products getting exported, similar to how the U.S.
23 treats our products when we have products that flow
24 through our country for exportation. In that context,
25 I guess that was the question. How do we handle that
26 or what is the -- are the recommendations from this

1 Panel as to what to do about that trans-shipment
2 problem.

3 SURGEON GENERAL CARMONA: Exactly. I
4 think that we've seen enough information that for the
5 average person who goes across the border to fill a
6 prescription in a licensed pharmacy in Canada is not
7 an issue. But the issue is much broader, much bigger
8 than that because of the importation into Canada, the
9 redistribution and repackaging of medications and
10 really nobody really having oversight of that and then
11 how do we protect the consumer and what recourse does
12 the consumer have when and if there's an adverse
13 reaction to the medication?

14 So those are the complex issues that have
15 surfaced during this investigation. Do any of you
16 have any comments on any of that?

17 Any other questions or comments from our
18 Panel?

19 Yes, Dr. Crawford.

20 DR. CRAWFORD: Just to follow up a little
21 bit with that. We are aware and all of you are I'm
22 sure aware through pressure ports and others that
23 companies and others around the world have taken note
24 of the fact that we have a porous border with Canada,
25 that we have this issue that has gained a lot of
26 national and international attention and in effect,

1 Canada is reaffirming this week that they have no
2 control over these products that are so-called trans-
3 shipped. And essentially, these are products that are
4 brought in as, Mr. Sachdev and the Surgeon General
5 have said, they're called import for export products.

6 So they're brought in either in bulk to be repackaged
7 or they're brought in already packaged for export and
8 then if you will, smuggled into the United States.

9 Our problem with declaring countries of
10 origin would be very, very great indeed. It would be
11 far larger than just say if we certified Canada, for
12 example, we would have to also figure out a way for
13 them to join us or us to get some independent
14 international body to make sure that the products that
15 have come in from other countries that might even be
16 labeled Canadian, we have some supervision over
17 because with every product we regulate, whether it's
18 food products or whatever, we can't stand at the
19 northern border and stop them. We've got to have some
20 system, as all of you have correctly pointed out in
21 your testimony, to deal with it.

22 But the utilization of the current non-
23 system by people in countries and companies bent on
24 getting the product here at all costs is something I
25 have to tell you is a major concern of ours, as is the
26 possibility of terrorism.

1 DR. JENNINGS: I just have one question.
2 Is the Panel considering perhaps only approving a very
3 limited number of drugs for importation to begin with,
4 rather than open it to the whole area of prescription
5 drugs?

6 SURGEON GENERAL CARMONA: Dr. Jennings, at
7 this point we are considering everything. The door is
8 open. In fact, we've had some who have contributed to
9 the docket and haven't spoken and others who have
10 spoken who have made recommendations similar to what
11 you're suggesting, a limited group of drugs and a
12 limited amount of pharmacies and so on and certainly,
13 that will be considered. We haven't reached an
14 opinion yet, and obviously, we still have a great deal
15 of deliberations to consider. But that is one of the
16 options that has been presented to us.

17 DR. MAXEY: I'm wondering if anyone has
18 dealt with the basic question is with the
19 pharmaceutical companies why don't we charge them like
20 the Canadians or other countries charge them so that
21 from the beginning they come to us at a reasonable
22 price and find some other way to support the research
23 that they need.

24 We're basically bearing the research
25 dollar that it takes to care for the rest of the
26 world. And you wouldn't have to re-import if they

1 brought it here at the right price in the first place
2 which is a whole different consideration, which may be
3 political.

4 SURGEON GENERAL CARMONA: We've actually
5 had panel discussions just on that issue. We've had
6 economists from here and abroad who have spoken to us
7 on the global implications of importation on the
8 issues of the United States shouldering the burden of
9 all of the research and development and the rest of
10 the world, in effect, being free riders, what are the
11 possibilities to deal with those issues? We've had
12 discussions about presenting this as a trade issue in
13 negotiations for our government.

14 So we've heard all of that information and
15 we've still got to synthesize it among our
16 deliberations and come up with a recommendation for
17 the Secretary.

18 Any other comments or questions, Task
19 Force Members?

20 Thank you very much, ladies and gentlemen.

21 We appreciate you being here. We'll switch over to
22 the next Panel right now and just take a quick stretch
23 break and we should back in session in the next couple
24 of minutes. Thank you.

25 (Off the record.)

26 SURGEON GENERAL CARMONA: All right,

1 ladies and gentlemen, we'll go ahead and begin. Our
2 first speaker for Panel 2 is Mr. Carmen Catizone,
3 National Association of Boards of Pharmacy. Thank
4 you, sir.

5 MR. CATIZONE: Thank you, Dr. Carmona and
6 Members of the Task Force. I serve as the Executive
7 Director of the National Association of Boards of
8 Pharmacy whose members are the state agencies and
9 provincial authorities that regulate the practice of
10 pharmacy in the United States, Canada, Australia, New
11 Zealand and South Africa.

12 The illegal importation of drugs is one of
13 the most complex and frustrating issues for pharmacy
14 regulators. It's an issue that has the potential of
15 altering how medications are dispensed in the United
16 States and how the practice of pharmacy is regulated.

17 In fact, if illegal importation is allowed to
18 continue, the impact on patient safety, pharmacy
19 practice and the regulation of pharmacy practice will
20 be devastating.

21 Patients illegally importing drugs are
22 bypassing the drug approval system of the FDA and the
23 safety of U.S. licensed pharmacies and placing their
24 health and well-being in the hands of the country,
25 territory or back room with the seemingly lowest
26 priced pharmaceuticals.

1 NABP does not oppose importation within
2 the safe and secure regulatory framework of the FDA
3 and the State Boards of Pharmacy. NABP does oppose
4 the illegal importation of medications which is
5 presently occurring.

6 At our recently concluded annual meeting,
7 the states and provinces passed a resolution which
8 resolved that NABP continue to oppose illegal
9 importation of medications and expressed to the FDA
10 the concerns of member states and strongly urged the
11 FDA or appropriate legal authority to pursue actions
12 against state and local governments for endorsing,
13 promoting or engaging in the illegal importation of
14 medication.

15 At its worse, the illegal importation of
16 drugs creates the opportunity for unknowing and
17 unsuspecting patients to suffer harm. Counterfeit and
18 dangerous drugs contaminate the U.S. medication
19 distribution system and a thalidomide-like disaster to
20 reoccur.

21 NABP cannot accept the premise that people
22 must die from the illegal importation of drugs before
23 the existing laws ensuring the safety of patients are
24 complied with and enforced. The "show us the body
25 strategy" proposed by some legislators, governors,
26 mayors and other public officials is irresponsible.

1 NABP acknowledges that appropriate
2 safeguards exist within Canada's federal and
3 provincial regulatory systems to ensure that the
4 dispensing of medications in Canada to Canadian
5 patients is safe. Unfortunately, the same safeguards
6 do not exist for U.S. patients purchasing and
7 importing drugs from Canada and other countries. The
8 regulatory void and breach of the safety net for U.S.
9 patients is significant and unknown to the
10 overwhelming majority of patients ordering drugs from
11 other countries.

12 NABP has learned that medications shipped
13 from locations purportedly to be in Canada have
14 originated in Slovenia, Pakistan and Vietnam. Each
15 progression to extend the distribution source to
16 unknown borders further away from the FDA drug
17 approval process and the state regulation of pharmacy
18 practice makes the situation more dangerous. The
19 extension of importation to countries lacking
20 effective drug approval processes, regulatory systems
21 or practice standards further the erosion and
22 destruction of the entire regulatory system for the
23 practice of pharmacy.

24 The U.S. system, based with the states and
25 the FDA, has been exemplary in protecting the citizens
26 of the various states and providing patients and

1 health care practitioners with the assurances and
2 confidence that the medications prescribed and
3 dispensed are safe and effective products. NABP
4 recognizes that a solution resolving the conflict of
5 affordable access to medications versus safety must be
6 developed to address the needs of U.S. patients and
7 prevent irreparable damage to, if not the elimination
8 of, the regulatory systems in the U.S.

9 NABP is in discussions with a variety of
10 regulatory agencies and affected stakeholders to
11 develop the necessary framework to regulate the Inter-
12 Board of Practice of Pharmacy in the dispensing of
13 medications to patients in the U.S. and Canada. The
14 framework would provide similar protections as those
15 afforded U.S. patients to utilize pharmacies engaged
16 in the interstate practice of pharmacy and would focus
17 on identifying and monitoring the source of
18 medications.

19 The framework will coordinate the
20 regulatory efforts and resources of the Canadian
21 provinces and the U.S. State Boards of Pharmacy.

22 In closing, NABP respectfully requests the
23 Task Force recognize that allowing and encouraging the
24 purchase and importation of medications from other
25 countries without the appropriate regulatory
26 safeguards is a serious threat to our regulatory

1 foundation and patient safety. NABP requests further
2 the Task Force assistance in preserving the sanctity
3 of current regulations so as to prevent any patient
4 from being seriously injured by the illegal
5 importation of medications from other countries where
6 U.S. laws and regulations are being ignored or the
7 laws of that country or territory do not equate to
8 U.S. laws and regulations.

9 NABP does not believe that even one
10 patient should suffer or be harmed as a consequence of
11 disregarding federal and state laws that ensure the
12 dispensing of safe and effective medications to U.S.
13 patients. Thank you.

14 SURGEON GENERAL CARMONA: Thank you very
15 much, sir. Our next speaker, Ms. Susan Winckler.
16 Nice to see you again.

17 MS. WINCKLER: Good to see you, Dr.
18 Carmona and Members of the Task Force, thank you for
19 inviting the American Pharmacists Association to
20 present today.

21 I'm Susan Winckler. I'm a pharmacist and
22 an attorney and serve as APhA's Vice President for
23 Policy and Communications.

24 It's important to note that APhA was
25 founded in 1852 because of problems with the
26 medications supply and recognizing that if drugs don't

1 contain what they should or contain things that they
2 should not, we have a problem.

3 It's interesting that in 2004, APhA's
4 mission is to help improve medication use and advance
5 patient care. I think the problems facing the Task
6 Force today get at both why APhA was founded and what
7 we do today. And that's trying to assure that
8 patients have access to medications that are what they
9 say they are as well as trying to assure that if we
10 provide broader access to medications, that that
11 doesn't pose a problem with coordination of care here
12 in the United States. Those are the two things I'll
13 talk about this afternoon.

14 The first, talking about product
15 integrity. We are concerned that opening the door to
16 importation, although we try to put in limits, will
17 open the door to those who want to corrupt our system
18 and to introduce counterfeits and we're very concerned
19 about that. We're particularly concerned about that
20 reality in the context of personal importation. And
21 in that idea that if we open the door and allow anyone
22 to import medications, how could we set up a system to
23 try and make sure that it is only the limited,
24 legitimate medications that we want to see.

25 The second challenge in the product
26 integrity area is that differences in products do

1 matter and this is the difference between the U.S.
2 approved products and what we would see in foreign
3 versions of approved products. It's important as the
4 AMA representative noted that consumers get what their
5 doctor or their physician assistant ordered. And
6 differences matter. It matters if it's a tablet
7 versus a capsule. Differences in names matter when
8 we're trying to make sure that we don't have
9 medication errors. Differences in strengths matter.
10 Differences in salts and esters matter when we're
11 trying to adjust doses and make sure that consumers
12 indeed get what they're looking for.

13 To address this issue, we frankly would
14 recommend that any importation be limited to FDA-
15 approved products. We recognize that's a very, very
16 narrow range of what's on the international market, at
17 least from our understanding, but you, at least know
18 what it is your pharmacist and your physicians will
19 know what it is that they're dealing with and
20 consumers will know what it is that they're dealing
21 with.

22 This is where most discussions stop. We
23 stop and we forget that medication use and good
24 pharmacy practice goes beyond getting patients the
25 right drug at the right time. We forget that good
26 medication use requires doctors, pharmacists and

1 patients knowing how to make the best use of that
2 medication. Getting the right drug doesn't mean that
3 the tablets leap out of the bottle and into our bodies
4 and we use them correctly, or that we know how to use
5 inhalers correctly. There's something beyond that.

6 And importation poorly constructed, can create
7 significant problems there and that's in our
8 coordination of care.

9 What we're concerned about here is because
10 of the stigma involved in importing medications and
11 what happens today, many patients don't tell their
12 doctors or their pharmacists that they're importing
13 medications, that they're securing those products from
14 outside the U.S. It's understandable and dangerous,
15 because unless the patient provides that information
16 to the pharmacist, they really cannot watch for drug
17 to drug interactions. They cannot help the patient
18 make the best use of that medication if they don't
19 know what it is they're taking.

20 Limiting a system to a commercial
21 importation helps with some of this challenge because
22 you at least use the distribution systems that are
23 present here in the United States, but we just have to
24 understand that it's more than making sure we have an
25 okay product. We also have to make sure that the
26 doctors and the pharmacists and the consumers who use

1 that product understand how to use it and know to make
2 the best use of it.

3 The bottom line of what APhA is very
4 concerned about is the recognition and we know the
5 task force has considered this, but I must underscore
6 it, that medications are different. And that it
7 matters what's in the tablet, but it also matters that
8 the consumer knows how to use that.

9 If we are going to move to a system to
10 legalize importation, as Mr. Catizone mentioned, we
11 have to make sure that it has appropriate protections,
12 not only in statute and regulation, but in
13 enforcement.

14 I do also have to note that it's
15 unfortunate that Congress failed to establish a task
16 force to address the broader issue that's driving
17 these discussions and that's improving access to
18 necessary medications. The current international
19 pricing structure is flawed and U.S. consumers bear
20 the brunt of that flaw. We want new technology to
21 help us, but we have to bear the disproportionate
22 price for the world.

23 I regret that we're not here today to talk
24 about how to improve consumer access to medications
25 and to pharmacist services to help them make the best
26 use of their medications. That discussion has

1 promise.

2 Thank you.

3 SURGEON GENERAL CARMONA: Thanks very
4 much. Our next speaker, Mr. Douglas Scheckelhoff.

5 MR. SCHECKELHOFF: Thank you and good
6 afternoon.

7 I'm Douglas Scheckelhoff and I'm the
8 Director of Pharmacy Practice Sections at the American
9 Society of Health-System Pharmacists. ASHP is a
10 30,000 member national professional association that
11 represents pharmacists that practice in health systems
12 including hospitals, ambulatory clinics, HMOs, long
13 term care and home care. I'm pleased to provide you
14 with ASHP's views on the importation of prescription
15 drugs into the United States.

16 For more than 50 years, the U.S. could
17 boast the safest, most tightly regulated system for
18 approving and distributing prescription drugs. Today,
19 however, there are challenges facing our system. The
20 growing illegal drug trade, including counterfeit
21 medications, rogue internet sites and efforts to open
22 U.S. markets to medications imported from abroad have
23 all raised questions regarding the FDA's ability to
24 respond to those challenges.

25 First, regarding the impact of unapproved
26 drugs. Pharmacists who work in hospitals are

1 confronted with the issue of purchasing quality
2 pharmaceuticals at the lowest cost on a daily basis.
3 ASHP has received numerous phone calls from pharmacy
4 directors whose hospital administrators have asked
5 them to purchase drugs from Canada at lower prices
6 rather than from U.S. sources. We have referred them
7 to FDA regulations that prohibit that kind of
8 importation, but the pressure to find lower cost,
9 alternate sources remains.

10 The scope and volume of unapproved drugs
11 entering the United States has raised the concern of
12 ASHP members. That's why our House of Delegates will
13 vote next month to reaffirm the following policy: to
14 oppose importation of pharmaceuticals except in cases
15 in which the Food and Drug Administration determines
16 it would be necessary for the health and welfare of
17 United States citizens.

18 The issue of safety in our nation's drug
19 supply has been obscured by the issue of allowing
20 individual citizens to purchase prescription drugs at
21 lower prices from non-U.S. locations. While there are
22 no hard data to indicate serious patient harm caused
23 by these imported drugs, and it make take years to
24 identify clusters of problems caused by imported
25 medications, the safety perspective must be the
26 highest priority.

1 There's another factor of the importation
2 issue that has not been addressed adequately and it
3 relates to foreign terrorism in our nation's counter-
4 terrorism activities. The integrity of the drug
5 supply and the health of consumers is at significant
6 risk if terrorists utilize more lenient importation
7 rules to introduce harmful agents into the United
8 States.

9 Regarding FDA's ability to assure safety.

10 The FDA's regulatory system has been the world's gold
11 standard of drug approval. To assure the safety of
12 imported products, the FDA will need significantly
13 greater resources to examine those products for
14 quality, purity, safety and effectiveness, since a
15 significant amount of imported drugs are ordered via
16 the internet, the Agency should consider ensuring the
17 adequate regulation of internet pharmacy sites.

18 Regarding regulatory and legislative
19 issues, the FDA must have the authority to assure the
20 same level of safety for imported drugs as consumers
21 expect from drugs purchased from a state-licensed
22 pharmacy. Consumers are ill-equipped to make these
23 types of risk-benefit decision and there is no added
24 level of risk beyond today's safety standards that
25 ASHP members would consider acceptable.

26 Regarding technology. The FDA's efforts

1 to encourage manufacturers to include electronic track
2 and trace technology into their product packaging for
3 anti-counterfeiting measures should work well to also
4 prevent the importation of unapproved drugs and to
5 prevent the reintroduction of diverted drug products.

6 Other anti-counterfeiting technologies will improve
7 safety, but will have less impact than that of an
8 effective track and trace system.

9 Regarding the financial impact. The FDA
10 must thoroughly study the financial impact of
11 importation and determine whether it would actually
12 lower the cost of drugs for American consumers.
13 Regulations put in place to implement Section 1121 of
14 the Medicare Prescription Drug Improvement and
15 Modernization Act of 2003 must not be burdensome to
16 pharmacists or wholesalers. If pharmacists or
17 wholesalers are required to conduct testing or
18 authentication of imported drugs, the additional cost
19 of doing so would largely eliminate the anticipated
20 cost savings for consumers.

21 In conclusion, ASHP appreciates the
22 opportunity to comment to the FDA on this significant
23 issue. We are ready to assist the Department of
24 Health and Human Services in any way that we can in
25 implementing policies related to the importation of
26 prescription drugs.

1 Thank you.

2 SURGEON GENERAL CARMONA: Thank you, sir.

3 Our next speaker is Dr. Marv Shepherd.

4 DR. SHEPHERD: How are you all doing?

5 SURGEON GENERAL CARMONA: Doing fine.

6 DR. SHEPHERD: Mr. Chairman Carmona and
7 Members of the Task Force, the Academy of Managed Care
8 Pharmacy appreciates the opportunity to participate as
9 you receive testimony on the issues related to the
10 importation of prescription drugs.

11 My name is Marv Shepherd and probably as
12 you can tell from my greeting, I'm from Texas and I'm
13 the Director of the Center for Pharmacoeconomic
14 Studies at the University of Texas. I have been
15 studying the issue of drug importation for over 10
16 years, especially Mexican drugs coming across the
17 border and now the last three years, Canadian drugs.

18 The Academy of Managed Care Pharmacy, who
19 I speak for this afternoon, is an association of
20 pharmacists and professionals who serve the patients
21 and the public through managed care principles. The
22 Academy has over 4800 pharmacist members who provide
23 comprehensive coverage in pharmacy service to over 200
24 million Americans.

25 The Academy is opposed to proposals that
26 would allow personal importation of prescription

1 drugs. There is no system for double checks on
2 accuracy. There is no counseling on the
3 pharmaceuticals. There's no one to call if you've got
4 a question as a consumer. The potential for problems
5 is particularly serious when individuals are ordering
6 their prescriptions on-line. The prescription order
7 via the internet, from what seems to be a Canadian
8 pharmacy, may in fact, may not be a Canadian pharmacy.

9 In addition, when patients received their medications
10 through individual importation, there's no pharmacist
11 involved who can verify that the patient even
12 understands how to take the pharmaceutical correctly.

13 Personal importation of pharmaceuticals is
14 growing enormously. In my opinion, it is way out of
15 control as FDA has documented in many documents,
16 approximately 200 million packages coming in last
17 year.

18 There's no guarantee that legislators,
19 regulators and pharmacists can provide the information
20 necessary to consumers, letting them know whether the
21 imported prescription drugs they are receiving are
22 adulterated, counterfeit or approved for use in the
23 United States and there's also no way for local
24 pharmacists to determine whether the medication is
25 safe and effective.

26 The Academy also has concerns of proposals

1 that would allow the importation of prescription drugs
2 by U.S. pharmacists and wholesalers. The Academy
3 understands the plight of individuals unable to afford
4 much needed prescription drugs and supports the goal
5 of lowering drug costs for American consumers.
6 However, the anticipated savings, as mentioned
7 already, developed by importation may generate
8 uncertainty between the factors involved in
9 importation and basically the differential in price
10 for specific drugs isn't that great.

11 The availability of the product for
12 importation is it going to be a consistent
13 availability? You don't want to move from one source
14 to another source.

15 What are the additional overhead charges
16 for the importation problems?

17 One negative consequences of the program
18 and I don't believe anybody has ever mentioned this in
19 front of your group, is that I'm a hypothesis believer
20 that it may permit pharmacies and wholesalers to
21 import prescription drugs and the development of a
22 two-tiered drug system in the United States, two-
23 tiered based on cost. If states base reimbursement to
24 pharmacists on the importation base acquisition cost,
25 pharmacies would have to establish a dual inventory
26 system, one system for U.S.-made drugs and one system

1 for imported drugs. That brings all kinds of
2 ramification of control and cost control and patient
3 controls.

4 I'll be glad to entertain any questions
5 you have on that.

6 Mostly importantly, prudent importation
7 legislation must ensure maintenance of quality
8 assurance as others have stated throughout the
9 international drug distribution system. In order to
10 guarantee patient safety, agencies such as FDA and
11 U.S. Customs Service must have technological and
12 financial resources to address these safety concerns.

13 I'm telling you, after being at the border
14 of Mexico and monitoring the drugs from across the
15 border, they are in dire need of technology to monitor
16 the pharmaceuticals, dire need. Pen and paper and
17 pencil just doesn't make it.

18 All of us are aware of the potential for
19 drug counterfeiting and drug counterfeiting is a
20 world-wide problem. No country is immune to drug
21 counterfeiting. However, drug importation, especially
22 personal importation, only opens the door wider for
23 counterfeits in the United States. Counterfeits go
24 where the money is and the United States has the
25 market and an excellent target where the money is.

26 You will find pharmaceutical fraud,

1 deception and counterfeiting, if we continue with
2 importation. The recent FDA report on combating
3 counterfeit drugs puts forth an excellent strategy for
4 combating drug fraud and ensuring drug integrity for
5 Americans, but at the same time, we have governmental
6 agencies allowing U.S. residents to import
7 substandard, inferior and sometimes counterfeit drug
8 products. We have been fortunate, as already has been
9 mentioned, that we have been fortunate that people
10 haven't been hurt or killed by these products. And I
11 have said and I will continue to say it's only a
12 matter of time before a horrific tragedy involving
13 imported pharmaceuticals will occur.

14 The Academy believes that until more
15 conclusive data are available as to likely impact the
16 importation on the cost of drugs and the risk imposed
17 to American citizens, we will oppose proposals that
18 allow importation of prescription drugs for sale to
19 U.S. citizens.

20 Thank you again, for this opportunity and
21 I look forward to answering any questions you may
22 have.

23 SURGEON GENERAL CARMONA: Thank you, sir.

24 Our next speaker, Mr. Robert McNellis, American
25 Academy of Physician Assistants, thank you for being
26 with us.

1 MR. McNELLIS: Thank you, Dr. Carmona.
2 Good afternoon, Dr. Carmona, and the rest of the Task
3 Force. I thank you on behalf of the American Academy
4 of Physician Assistants and the 51,000 clinically
5 practicing PAs to provide some testimony today about
6 the perspective, in particular, of PAs and how they're
7 looking at this particular problem.

8 What PAs have in common, even though they
9 work in every specialty and every state dealing with
10 patients of all ages is a commitment to providing
11 quality, cost effective, accessible healthcare. That
12 is, in fact, our mission statement. And that's really
13 the guidance that I have from our Academy's policies
14 as to what I say today. We don't have a policy on
15 drug importation per se, but we use that to guide it.

16 For PAs, the focus is really on the
17 patient and it's not to imply that other organizations
18 don't have that perspective as well, and certainly I
19 know that that's in your interest as the patient, but
20 that's all we do is do patient care. And we
21 understand the concerns of consumers, as well as
22 states, that they need to bring in affordable drugs.
23 We understand that the pharmaceutical industry and
24 distributors want to maintain safety as well as
25 incentives for future drug development. But in the
26 world of our members, kind of outside of the beltway,

1 they see this as a balancing act between safety and
2 affordability. Those are the two things that resonate
3 with our members. And that ensuring a safe and
4 genuine drug supply is critical, but so is ensuring an
5 accessible one.

6 As Dr. Maxey said, safe drugs that are
7 unaffordable aren't really of any benefit to those who
8 need them the most. And I know it's cliché and it's
9 anecdotal as well, but I still get stories from our
10 members about their patients who have to choose
11 between their groceries and their drugs, so it still
12 is a problem.

13 I'm spoken a lot recently with PAs who are
14 in Maine, Seattle, Detroit and other many of the
15 border states and they tell stories about their older
16 patients getting on buses, the things you've heard
17 probably over and over again during the last five or
18 six listening sessions. But it certainly is
19 happening. And one of our members though described it
20 this way, you know, who is going to Canada to buy
21 their drugs? Is it the insured person who has got a
22 pharmacy card for \$20 they can go and pick up their
23 Lipitor? No, probably not. It's the person on low
24 fixed income or the uninsured who are going to
25 essentially pay cash, out of pocket to get less
26 expensive drugs so they can afford them. And then I'm

1 sure the PAs in Texas and California, they certainly
2 have similar stories about Mexico.

3 But for the most part, our patients seem
4 to be buying brand name drugs, the brand ones are the
5 ones that are the most expensive. They're not going
6 across the border to buy the more affordable generic
7 drugs. And these brand name drugs are essentially
8 manufactured to the same standards, same packaging as
9 drugs sold in the U.S. and there's a sense that the
10 Canadians aren't really suffering any increased
11 consequences due to the unsafe drugs in their system.

12 Now clearly safety is an issue to
13 consider. Unsafe counterfeit drugs seem to enter the
14 system when the traditional distribution system breaks
15 down, when retailers or distributors buy drugs through
16 other channels or consumers purchase their drugs
17 through internet pharmacies, that's when the supply is
18 most at risk.

19 PAs, I know, as a profession, don't
20 generally recommend that their patients buy drugs over
21 the internet, unless of course, that particular site
22 might have a reputation for providing quality
23 products. But again, it begs the question, who's
24 going to be buying drugs over the internet? And once
25 again, it seems like it's the most vulnerable who are
26 likely to be scammed or given counterfeit drugs, the

1 patients who are looking for alternative sources to
2 try to afford their drugs, and that demand for less
3 expensive sources of medication seems to have
4 paralleled in some ways as well as other things, the
5 growth of the number of uninsured which the IOM, of
6 course, estimates now at 43 million.

7 And we appreciate the efforts of
8 pharmaceutical companies to make available discounted
9 drugs to the patients who need them. I note that the
10 process is still a little burdensome, I think. We're
11 also optimistic that the new Medicare discount card
12 will provide our seniors some of the drugs that they
13 can -- more affordable.

14 We appreciate the viewpoints of Governors
15 that Canada or even Europe might offer solutions to
16 immediate crisis, but unfortunately, unaffordable
17 drugs seems to be just one system of the broader
18 health care problems. And I know it's out of the
19 scope of the Task Force, in particular, but I think
20 this problem is within the context of kind of broader
21 problems with an ailing health care system.

22 Really, our view of best is that Canada,
23 allowing importation of Canada or other countries is
24 really a limited solution to some of these broader
25 problems. There need to be more permanent solutions
26 to the inequities of drug pricing, especially since

1 from the perspective of PAs, the people who are paying
2 most for their medications are the ones who can least
3 afford it.

4 Certainly, there are some potential fixes
5 out there. You've heard from lots of experts whether
6 consumers be billed directly from wholesalers or
7 states could negotiate more Canada-like prices, but
8 that's not what we know. What we know is patient care
9 and PAs feel strongly about their role as patient
10 advocates and they know that really affordable drugs
11 is just kind of one part of the whole health care
12 system. They don't have to be either safety or
13 affordable. They need to be both safe and affordable
14 and we need to find ways to diminish that.

15 So thank you very much for allowing me to
16 express the viewpoints of physician assistants in this
17 very complex debate before you.

18 SURGEON GENERAL CARMONA: Thanks very
19 much, appreciate it. Now we'll open the floor for my
20 fellow Task Force Members, questions.

21 Dr. Crawford?

22 DR. CRAWFORD: Dr. Winckler, thank you
23 very much for your testimony, and thank you also for
24 your candor in establishing that re-importation is
25 only a symptom of the larger problem that we're
26 dealing with. Those may not be your words, but they

1 would be good words.

2 The thing I wanted to focus on in terms of
3 what you said though is the international pricing
4 structure is flawed and although that's a bit beyond
5 the scope of our task, I would appreciate any
6 commentary you would have about how to fix that or how
7 to address it or something like that?

8 MS. WINCKLER: Sure. I guess it's the one
9 thing that doesn't fit in either my degree in pharmacy
10 nor my degree in law, so --

11 DR. CRAWFORD: My experience with lawyers
12 in the government is you can stake out any turf you
13 like.

14 (Laughter.)

15 MS. WINCKLER: All right. I guess it
16 comes back to what other people have likely said
17 before you and the economists have pointed out, but we
18 just do have to look at the broader issue and I guess
19 what frustrates APhA and what frustrates our
20 pharmacist members is that we're talking about
21 importing the drugs when it appears what some people
22 want to do is import the price controls. And if
23 that's what you want to do, please talk about that and
24 have that discussion. And I'm not saying that we
25 support price controls, but that would at least seem
26 to be an intellectually honest conversation, rather

1 than this proxy of let's import the drugs.

2 So I guess broadly what we're looking at
3 is the need to make sure that American consumers have
4 access to the medications that they need, whether
5 that's through making sure we protect the uninsured or
6 the under insured and doing more through that. If
7 it's through direct negotiation for price controls, I
8 don't know those answers, but do know that we have to
9 tackle that broader issue. And is it seeing if this
10 new Medicare drug benefit works for that population.
11 Is it doing something else for the uninsured? Is it
12 doing -- taking other issues and part of the broader
13 issue here too is again remembering it's not only the
14 price of the medication when you get it, it's the
15 value of that medication to the patient, so in the
16 whole cost structure, if they got the right
17 medication, but they don't know how to use it, you've
18 wasted all of the money. And it doesn't matter how
19 expensive or how cheap it was.

20 So I guess I would just implore the Task
21 Force to recognize and I know you recognize this, that
22 it's a much broader issue and whatever we can do to
23 underscore those challenges, will be important in your
24 report.

25 SURGEON GENERAL CARMONA: Other questions?

26 Amit?

1 MR. SACHDEV: I have some for each and all
2 of you, but particularly for Mr. Catizone. We've
3 heard testimony from the Minnesota Governor about the
4 program that Minnesota has set up. We've heard
5 testimony from other Governors about state programs
6 that have been set up that facilitate importation by
7 creating websites that link to particular Canadian
8 pharmacies for their state citizens to use in
9 purchasing prescription drugs.

10 In Minnesota, in particular, the Minnesota
11 Board of Pharmacy issued a report when they evaluated
12 Canadian pharmacies that they wanted to link to where
13 they found seven of the nine pharmacies they looked
14 at, Canadian pharmacies they looked at were deficient
15 in some way or another and so in the end that state
16 ended up linking to two particular pharmacies as
17 opposed to more than that.

18 Can you comment on why you think there
19 were deficiencies in those Canadian mail order type
20 pharmacies and whether you think that is indicative of
21 a distinction between maybe the practice of pharmacy
22 in the U.S. and what we're seeing in terms of the
23 practice of pharmacies that are exporting products to
24 the U.S.?

25 MR. CATIZONE: What concerned us about
26 that whole process is that it operated outside of the

1 traditional regulatory framework and process, so that
2 even though members of the Minnesota Board of Pharmacy
3 were involved in that inspection, we would categorize
4 that inspection as a visit and not an inspection that
5 would normally be conducted on a traditional brick and
6 mortar pharmacy or a pharmacy based in the U.S.

7 The pharmacy was given notice of the
8 inspection or visit. The inspectors were restricted
9 to certain areas of the pharmacy. They were not
10 allowed to talk to any of the pharmacists involved in
11 that operation and instead, only spoke to the business
12 agents and the lawyers representing those pharmacies.

13 They were also restricted from asking questions about
14 certain information or requesting certain information
15 that would be part of a normal inspection.

16 So our concern with the inspections, in
17 general, and with the approaches that many of the
18 Governors have taken is that they are bypassing and
19 operating outside of the standard regulatory
20 framework. So it's not a question of the Canadian
21 system not being equivalent to, it's the system being
22 employed by these Governors in states to bypass
23 traditional regulatory safeguards. Those seven of
24 nine pharmacies that did not meet those standards had
25 serious problems with recording the source of the
26 medications, recording the patient interactions,

1 recording very important critical patient data and
2 dispensing information about those medications and
3 therefore those seven pharmacies were rejected.

4 MR. SACHDEV: My question was, and it's
5 open to anyone here, but why do you think that is?
6 Why was there an 80 percent deficiency rate for these
7 pharmacies that were looking at to participate, even
8 despite the fact that they knew people were coming and
9 looking at their facilities?

10 MS. WINCKLER: I think part of the
11 challenge comes from the challenge of trying to at
12 some level meet a different federal and different
13 state laws. Those pharmacies, I'm sure, are very good
14 at meeting the provincial law and the law that they
15 have to meet for Canada, but as I understand it, the
16 Minnesota folks were looking at how it compared with
17 the Minnesota law and rules and very challenging for
18 those individuals and entities to navigate that
19 complex system.

20 The pharmacies in the U.S. that serve
21 patients in all 50 states have extensive processes set
22 up so that they can try to meet all the different
23 requirements that we have from state to state and
24 comply with the federal system and I can't imagine
25 them trying to learn and comply with an international
26 set as well.

1 DR. SHEPHERD: One possible reason why
2 there was neglect of some of the regulations is the
3 fact that the growth of the industry. In 1999, there
4 were 10 Canadian internet pharmacies. Right now,
5 you've got 120, most of which are located in one
6 province and when you look at the news articles on
7 this one province, it's pretty lax and there's a big
8 rift between the community pharmacists and the
9 internet pharmacy operations in that province.
10 There's actually a big rift between those two.

11 The internet pharmacies are stealing them
12 out of the community pharmacies by offering higher
13 wages. There's a shortage. Internet pharmacies are
14 having troubles getting access to drugs. They're
15 buying off the independents from the communications
16 I'm getting. They can't get the drug out of the
17 wholesaler. There's a shortage, so they're buying it
18 from independents and independents have the
19 opportunity to make the money or the community
20 pharmacy, so they end up selling them under the table
21 to the internet pharmacies in order to dispense. So
22 it's kind of like a fast growth industry that the
23 Manitoba pharmacists have just started to jump on in
24 the internet section and develop it. So it could be
25 part of the growth. It may smooth out. I'm not
26 saying it won't, but I think that's probably the

1 reason.

2 SURGEON GENERAL CARMONA: Mr. Ahern -- oh,
3 do you have another one, a follow up?

4 MR. SACHDEV: I do have a follow up. And
5 this is open to all of you, we've heard a lot of
6 discussion here in listening sessions about the types
7 of drugs that are, in fact, being imported today in
8 this country from not just Canada, but elsewhere. And
9 varying points of view about the quality of those
10 drugs and in particular, their equivalency to federal
11 standards, but also the equivalency between how
12 they're dispensed in terms of foreign pharmacies
13 versus U.S.

14 Generally, do members of this panel have
15 evidence or reason to believe that the products that
16 are coming in are, in fact, more likely to be the same
17 as, equivalent or more likely to not be similar or the
18 same as U.S.-approved product based on what you know?

19 And again, it's open to the panel.

20 DR. SHEPHERD: When I visited a couple,
21 three mail operations that received the drugs back and
22 we've opened up packages, I can unequivocally say that
23 I don't think they're equivalent, the vast majority of
24 the products. They are not equivalent.

25 When you get products coming in in
26 baggies, boxes of them, and they're talking about a

1 90-day limit, quantity, I've seen boxes half the size
2 of this table addressed to personal people in
3 Southwest United States, filled with baggies filled
4 with tablets and capsules.

5 I've seen bags, envelopes, three by four
6 cartons of nothing but Viagra and sexual dysfunction
7 drugs coming in one day. Thirty thousand drug
8 packages are coming in daily right now in Miami, a
9 day. You multiply that by the 13 other sites out
10 there, you can imagine. But I cannot say that the
11 products are equivalent. They're coming from all over
12 the world, Brazil, Argentina, Chile, South Africa,
13 Nigeria, Vietnam, Cambodia. They're coming from
14 everywhere.

15 Canadian -- well, I think Mr. McNellis
16 talked about this, I think Canadians only represented
17 18 percent of the packages out of 1400 that were
18 opened coming out of Canada. But they're coming world
19 wide.

20 And I want to dispel a myth here.
21 Everybody is talking about price and use of the
22 internet. I agree with you that price is important,
23 why people do it. But I also believe access, you
24 don't need a prescription with these people, is a big
25 issue. You don't need a prescription. So you get
26 your oxycodone or any other narcotic or drug you want

1 without going to the doctor and that's the number one
2 reason why they go to Mexico, is access. I don't need
3 a prescription. The drugs are all over the counter.
4 You can walk in any pharmacy in Mexico and buy
5 anything you want, except for the controlled
6 substances, without a prescription.

7 It's hard to get that data and I've tried
8 to get that data to figure out what's the demographics
9 of people using the internet and because of the
10 patient confidentiality, you cannot get that data to
11 even survey them. But I'm -- I really believe that
12 there are a lot of elderly or a lot of seniors and a
13 lot of people who can't afford drugs using them.
14 There's no other about it. But I also believe there
15 are a lot of young people doing it because of the easy
16 access. They don't have to go see a doctor, they can
17 just fill out a form and get it wherever you want to
18 get it.

19 MR. CATIZONE: I think your question is
20 actually two questions. Are the drugs approved
21 through Health Canada's drug approval process
22 equivalent to the U.S. FDA approved drug products and
23 I think from NABP's perspective which is not as
24 scientific as the FDA, the answer would appear to be
25 yes.

26 The second part of the question is though

1 are patients in the U.S. receiving those Health Canada
2 approved products and the answer is no. In the cases
3 that we've studied where consumers have complained to
4 us, they are coming from outside that Canadian drug
5 approval process. Our colleagues in Canada
6 effectively regulate the practice of pharmacy and
7 those internet pharmacies that would allow an FDA and
8 state board inspection, would be able to provide safe,
9 effective medications to U.S. citizens.

10 Those pharmacies that you asked about in
11 your first question that have stepped forward and
12 jumped on this bandwagon, they would probably not
13 allow an FDA state board inspection and therefore they
14 probably shouldn't be operating in Canada or the U.S.

15 MR. SACHDEV: One follow up question that
16 flows from testimony that we heard from the listening
17 session two weeks ago from a woman from a key Canadian
18 equivalent, NAPRA, and the question was asked about
19 the trans shipment issue that was discussed by Dr.
20 Carmona and Dr. Crawford and whether or not under the
21 provincial authorities and they obviously vary in
22 Canada, but under the provincial authorities,
23 generally, would the trans shipment of a product from
24 Europe to Canada and then from Canada to the United
25 States or the facilitation by Canadian pharmacy of
26 shipment of a product from Europe, say the U.K. to a

1 U.S. consumer, where it didn't actually flow through
2 Canada, but still is facilitated by a Canadian
3 pharmacy through a mail order operation, they
4 testified that it was their belief in both those
5 instances under provincial pharmacy regulatory
6 authority in most of the provinces, in all of the ones
7 that testified, which I believe included Ontario,
8 Manitoba and Quebec, that it was, in fact, unapproved.

9 We've heard differences of opinion and I
10 wanted to get your opinion on that, on that practice
11 and also to have you elaborate a little bit more about
12 what your inter border regulatory proposal would do in
13 terms of assessing sort of the pharmacies. And these
14 are two questions, but the pharmacies' practices in
15 Canada versus the ones in the United States.

16 MR. CATIZONE: We would concur with the
17 testimony from Barbara Wells of NAPRA in that those
18 products are unapproved and that the provincial
19 authorities and Health Canada and I know there's a
20 representative from Ontario that will speak on the
21 third panel. As Dr. Carmona and Dr. Crawford
22 mentioned though, they are not regulated or monitored
23 by Health Canada or the provincial authorities.

24 MR. SACHDEV: Okay, so because we haven't
25 had Health Canada, they were not able to attend, all
26 we have is their public statements from the past. And

1 so what we're trying to ascertain is we want to get a
2 clear answer. I think it's very important for this
3 group, as we go and try to respond to the questions, a
4 clear answer about what folks' understanding is of the
5 trans shipment issue, but in particular, how the
6 Canadian laws at both the federal level and also at
7 the provincial level address products that are not
8 necessarily Canadian licensed, but are intended for
9 export and the intersection with U.S. law in that
10 regard.

11 Others have a comment?

12 DR. SHEPHERD: I have a comment and an
13 issue. I don't know if you're aware or not, but the
14 Canadian -- Health Canada does not visit facilities
15 outside their country for approval of drugs. I'll
16 repeat that: they do not visit that facility outside
17 of Canada for approval.

18 When you're a manufacturer in Canada --
19 and I downloaded their forms and I'm in Ecuador and I
20 want to export to Canada -- I fill out a one- or two-
21 page form that says I comply with the Canadian good
22 manufacturing processes and sign my name and I can
23 ship the drug in.

24 So they don't -- like FDA visits
25 facilities for FDA-approved drugs, Canada doesn't do
26 that. So I don't think that we're going to have the

1 equivalent approval process when you look at it for
2 the processes and the inspections of the plants
3 involved with it. And it could be the same plant
4 where you got an FDA-approved drug going through
5 Canada. That very well could be, but they don't --
6 they don't leave the country.

7 SURGEON GENERAL CARMONA: Thank you.

8 Let's see, I had Mr. Ahern first, and then
9 Dr. Raub. Thank you.

10 MR. AHERN: Dr. Shepherd, very quickly,
11 you said you've done a lot of study with importation
12 of pharmaceuticals from Mexico, and recently have now
13 started to do some studies in Canada as well.

14 DR. SHEPHERD: Right.

15 MR. AHERN: Have you seen any significant
16 -- and you also made a statement that the Canadian
17 supply is starting to be depleted or diminished. Are
18 you starting to see any shift from the Mexican supply
19 into the Canadian supply?

20 DR. SHEPHERD: Yes, I have.

21 MR. AHERN: And do you have any figures of
22 what that might be?

23 DR. SHEPHERD: I don't -- I know the types
24 of drugs -- that VancouverCanadianPharmacyTrust.com
25 site is shipping Mexican-made sexual dysfunction drugs
26 to U.S. people, and neither drug -- both drugs have

1 been approved by Health Canada or the United States.
2 That's been published, and it was published two weeks
3 ago in Scripts Reports World Health News, that U.S.
4 consumers have been reporting the product coming out
5 of Mexico and being shipped through Canada.

6 MR. AHERN: And very briefly, also, you
7 made a statement here that FDA and the Customs Service
8 should have the technological resources to address
9 some of the safety concerns. What would be some of
10 the technological resources you believe would help the
11 situation?

12 DR. SHEPHERD: Just monitoring the amount
13 of drug coming across the border, whether you're in
14 Canada or the United States, is a difficult task. You
15 can -- I'll give you an example. You stand on the
16 border of Nuevo Laredo, Mexico, and Laredo, Texas.
17 You have 25- to 30,000 people walk across that bridge
18 in one Saturday afternoon.

19 One in two people will bring back
20 pharmaceuticals. And they won't bring back just a 30-
21 day supply; they'll bring back a shopping bag full of
22 pharmaceuticals. I've seen people drop \$2- or \$3,000
23 going over there.

24 Now, when they come back through U.S.
25 Customs there, and the U.S. Customs agent has no way
26 of recording all of that information -- it's a pencil

1 and paper job, declaration form, even document to what
2 extent the drugs are coming across the border, what
3 are the products, what's the quantity, what's the
4 value?

5 They're required to fill out -- if they're
6 asked, they're required to fill out a declaration form
7 where they estimate how much they bought. Most of
8 them don't even estimate it. Most of them just stick
9 the drugs in the bag, and they just walk across the
10 border.

11 But just monitoring the process and
12 knowing exactly what they're buying and the
13 demographics, there's just no data. And it's -- to
14 me, there ought to be a way that you can
15 electronically scan the label out of Mexico,
16 electronically get the information in a sheet, and
17 just do it periodically just to keep track of what's
18 coming in and what's going out of the country. But
19 right now that doesn't exist.

20 We have tried to develop something like
21 that and tried to work with Customs on it. It's
22 difficult. That's the first thing I would do. We
23 don't -- if you can just give me the demographic
24 information of who is using the internet, that would
25 provide this task force with immense information. You
26 don't even have that.

1 MR. AHERN: Thank you.

2 SURGEON GENERAL CARMONA: Thanks. Dr.
3 Raub?

4 DR. RAUB: Thank you, Mr. Chairman.

5 I have a question for Mr. Catizone,
6 because it's keyed off the statement in your
7 testimony, but others may want to address it as well.

8 The statement is, if the illegal
9 importation of drugs into the U.S. is allowed to
10 continue, the impact on patient safety, pharmacy
11 practice, and regulation of pharmacy practice will be
12 devastating.

13 Many of our witnesses have talked about
14 the first item -- of the jeopardy for individuals.
15 Others have not addressed how the impact would be
16 adverse on either pharmacy practice or the regulation
17 thereof, and I'd appreciate it if you'd elaborate on
18 that. And others may want to comment as well.

19 MR. CATIZONE: Our specific concerns are
20 that the importation is bypassing all of the state
21 regulatory systems. So inspections or visits are
22 being conducted by personnel other than the boards of
23 pharmacy, even though the state legislatures have
24 decreed that the responsibility of those state
25 agencies.

26 State laws are being ignored and bypassed.

1 In the State of Illinois, it was interesting -- our
2 Attorney General, in dealing with the last gaming
3 license to be awarded to a land-based casino, voided
4 that license and those proceedings and said that she
5 could not worry about the state balancing its budget
6 in lieu of following state laws, but yet she allows
7 importation to occur, even though it is breaking state
8 laws and does create, in our opinion, serious patient
9 harm.

10 So from those perspectives, that's where
11 our concerns lie.

12 DR. RAUB: There's an erosion of the
13 confidence in the regulatory -- I mean, it seems like
14 it's going on outside the regulatory mechanism. I'm
15 trying to understand the link as to why the regulatory
16 infrastructure is harmed.

17 MR. CATIZONE: Once a decision is made
18 that you don't need to follow state regulation, and
19 that the governor or other public officials -- based
20 upon economic reasons -- can decide which laws to
21 follow or not, there's really no need for a State
22 Board of Pharmacy or state regulation. The governors
23 or other public officials can simply decide based upon
24 what's best for the economic structure of the state.

25 DR. RAUB: Okay. Thank you.

26 Others from the panel?

1 MS. WINCKLER: I'll start with a challenge
2 to pharmacy practice, and part of that challenge is
3 coming in when the pharmacist -- you have a patient
4 who is importing something, and then they need an
5 acute prescription. So they go to the local pharmacy
6 for a pain medication or an antibiotic or something
7 else. Ask the patient what they are taking.

8 In some situations, the consumer will not
9 tell the pharmacist and probably didn't tell the
10 physician about what they're importing, because they
11 may know it's illegal or simply may not remember to do
12 that. If they do tell them, it creates a challenge
13 for the pharmacist, because it's the consumer
14 reporting that they are importing a cholesterol-
15 lowering medication.

16 But trying to do a drug-to-drug
17 interaction check when you may not know what the
18 cholesterol-lowering medication is, or know anything
19 about the foreign version of the medication, creates
20 challenges.

21 One of the things we've talked about, if
22 importation were to be legalized and you let in things
23 other than FDA-approved products, we would have to
24 change all of the databases and clinical decision
25 support tools that pharmacists and physicians use to
26 make sure that they include not only the U.S. versions

1 but the foreign versions, so they could get
2 information about that. So you create those
3 complexities.

4 You also create a challenge that many
5 pharmacists face every day when consumers walk in with
6 those medications. And similar to the question they
7 asked to one of the previous panelists, they'll put
8 the tablets in their hand and say, "Is this okay to
9 take?" That's a question that we've observed for our
10 members they can't answer.

11 They don't know the answer to that
12 question, and then you could get into all kinds of
13 liability concerns if they were to answer -- you know,
14 if they become engaged and answer the question and
15 provide all of that advice. It's just this gray area
16 that starts to take a challenging health care
17 profession and very important work and make it even
18 more challenging.

19 DR. RAUB: Thank you.

20 MR. SCHECKELHOFF: I think as you allow
21 importation, especially if it's through internet
22 pharmacies, you start to erode a few things -- one,
23 the patient-pharmacist relationship, where the
24 pharmacist is trying to work with the patient to
25 assure that they're taking their medication properly.

26 And so the pharmacist's time really gets

1 shifted from assuring safe and effective medication
2 use to product integrity, which for many years they've
3 been able to assume that if a product is FDA-approved
4 that it has integrity and it's a safe and effective
5 drug product.

6 Now you start to shift it away to where
7 the pharmacist has to second-guess what the patient
8 has received, and you also start to remove some of the
9 checks and balances that come with the traditional
10 U.S. dispensing system, where the pharmacist is
11 reviewing the order of the physician and evaluating
12 the appropriateness of that drug, and then dispensing
13 it to the patient.

14 So, again, if you have a patient who is
15 receiving a product through an internet pharmacy, you
16 have a pharmacist who -- or you may or may not have a
17 pharmacist who is dispensing that product from that
18 internet site, wherever it's at, who typically does
19 not know all of the patient's information, what their
20 condition is, what their diagnosis is, and you lose a
21 lot of the benefits and checks and balances that come
22 through our traditional system.

23 SURGEON GENERAL CARMONA: Yes, Ms. Willis.

24 MS. WILLIS: All of you have been very
25 articulate in the dangers posed by the personal
26 importation of drugs. My question is: how do you

1 feel about a government-approved system of importing
2 of drugs, where the patient would not be responsible
3 but the government would be approving some system of
4 importation? How do you think that would affect your
5 patient care and practice of pharmacy? And also, and
6 the impact on the regulatory system?

7 DR. SHEPHERD: I'll take a shot at that.
8 Just off the top of my head, there's two issues that
9 affect pharmacy practice. And I think I'll draw a
10 picture for you here.

11 You've got a brand-name drug made in the
12 United States, high-priced premium product. Okay?
13 Let's say it just goes off patent. Now you get a
14 generic drug that comes underneath it and it's going
15 to be approximately 30 to 35 percent less. That's
16 what usually generics start at.

17 Now you're going to import a product --
18 maybe the brand-name product is going to be imported
19 -- and I am anticipating, after seeing some of the
20 figures that have come across from different
21 countries, it will be less than a generic product.
22 Imported product, it has a potential to be less in
23 price than a generic product.

24 Now I ask you: what is that going to do
25 to the generic market in the United States? If you
26 took an old product, a brand-name, the generic

1 product, and the imported product, the imported
2 product most likely -- if it's coming out of Cambodia
3 or Egypt -- will be less costly than the generic
4 product. Most likely, very well could be.

5 And now you've put another spur in the
6 whole market system in the United States of saying,
7 "Okay. Where is the generic market going to fly in
8 this thing? How is it going to compete?" And as I
9 said earlier, I think you're going to end up with two
10 inventory systems.

11 You're going to have some third party pay
12 system that says, "I want U.S.-made products only."
13 And you're going to have some systems, let's say the
14 Medicaid program in the State of Illinois, who wants
15 to cut their cost. Okay. Well, we will reimburse the
16 pharmacist at the imported cost.

17 No pharmacist out there is going to
18 dispense -- I can't think of a pharmacist out there
19 that is going to dispense the brand-name product and
20 get reimbursed for the quantity of that product out of
21 the State of Illinois at the imported price. He's
22 going to be losing his shirt every time he does it.

23 So he's going to have to have, or she's
24 going to have to have, the pharmacy is going to have
25 to have an inventory of imported products in order to
26 fit that system's plan. And maybe if another health

1 care plan says, "Hey, you know, I don't trust those
2 imported drugs, I only want U.S. drugs," another drug,
3 so you double this inventory in this store, and
4 different products and different placements of it.

5 And you may have ruined and eroded --
6 definitely may not have ruined it, but you've eroded
7 the generic place in the marketplace. And I think we
8 -- you need to sit down and think about that. Where
9 do the generics play in this role, and how would an
10 imported product erode that market? It very well
11 could erode it devastatingly in no time at all.

12 Thank you.

13 MS. WINCKLER: I think the challenge in a
14 government-regulated commercial importation system is
15 the details and the structure. Is it only FDA-
16 approved products? So you take care of some of the
17 clinical confusion that we've talked about.

18 Are there limits on the port of entry, so
19 that doctors and pharmacists don't have to question
20 when they turn around to the pharmacy shelf if indeed
21 they're getting a quality product or not. If those
22 questions can be answered, you resolve many of the
23 issues. But then you have questions of whether the
24 external supplies can meet the need that may be
25 created by third party payers or government payers and
26 those types of things.

1 So we would have much less concern with a
2 well-constructed, closely-regulated, and well-enforced
3 system for commercial importation than most of the
4 things that have been talked about or debated in
5 Congress.

6 SURGEON GENERAL CARMONA: Other questions?

7
8 Well, one from me. You know, as you can
9 see, we've got a dilemma, and it's a tough one. It's
10 been characterized quite simply as: what do we tell
11 the senior citizen who walks across the border and is
12 not aware of or cares about the complexity of all of
13 the issues that you bring to us, and your peers who
14 have come before you, but just wants to get the
15 medication cheaper because it's competing for food
16 dollars or for housing dollars.

17 So I'll just ask a rather broad question,
18 though, in maybe two parts. Is importation a viable
19 option? And if so, how do you do it?

20 DR. SHEPHERD: I flew a long ways. I may
21 as well get my money's worth, right?

22 (Laughter.)

23 SURGEON GENERAL CARMONA: All right. I
24 appreciate it.

25 (Laughter.)

26 DR. SHEPHERD: And I've got to catch a

1 flight real soon.

2 There are two questions here. Number one,
3 is importation a viable option? I think, as stated
4 earlier, it is a viable option on selected products.
5 You could possibly import on selected products knowing
6 the source and where it comes from. That's a
7 possibility.

8 You'd have to really double check on it
9 and make sure you got it, and I would rule out -- if
10 we want to know what those products is, number one, I
11 would rule out narrow therapeutic index drugs. They
12 are too vulnerable and too costly. I have seen too
13 many patients go across to Mexico and get diabetic
14 medications and get welfare, and then come back and
15 they're back in the hospital. They're just too
16 vulnerable in the dosage forms. I'd rule them out.

17 But you could possibly come up with a list
18 and make sure it's FDA approved from the right
19 sources, if you can determine that.

20 And the second part of the question was?

21 MS. WINCKLER: How.

22 DR. SHEPHERD: How do you do it?

23 MS. WINCKLER: The easy part, Marv.

24 DR. SHEPHERD: The easy part.

25 (Laughter.)

26 How do you do it? If you choose Canada --

1 and I just did -- in fact, I just told Tom a little
2 while ago I just did a report for the House Energy and
3 Commerce Committee on the Canadian market. Canadians
4 right now are importing more drugs than they're
5 making, and U.S. share of the importation is
6 decreasing. It's decreasing. It's not -- it's
7 increasing as a dollar amount. As a matter of fact,
8 it has gone up a billion dollars since 1999, to Canada
9 from the United States.

10 However, as a proportion of the total
11 amount of imports that Canada gets, it's been
12 dropping. It's down to 43 percent right now. And the
13 other drugs they are bringing in, other countries are
14 bringing in, is -- it's over 100. They're coming from
15 everywhere into that system.

16 So how would I do it, if I was going to
17 send one of my graduate students and do it? I would
18 come up with a list of the high-cost drugs that our
19 elderly need, and that's my target market -- the
20 elderly or the people who have low costs. I'd come up
21 with a list of utilization of the highest cost drugs
22 possibly out there that are really causing the
23 problems. And it could be, you know, 10, 15. It
24 could be 30.

25 Now, let's look at sources of possible
26 structuring importation, get good quality product in

1 from those other sources. And maybe we could do it
2 that way. And then you've got to structure it so the
3 point of who is going to get them and what people are
4 going to get them, because everybody in that pharmacy
5 is going to come in and want that drug. You may have
6 to designate who is going to get them, because I don't
7 think you're going to get it.

8 Whenever you have a supply and demand,
9 you're going to have a lower supply here, and you're
10 going to have a heck of a lot of demand -- that raises
11 your price. It's straight Economics 101. It's going
12 to happen in Canada, and you're seeing it in Canada.
13 The prices will gradually go up as we get more and
14 more demand in the system, and so the differential now
15 is shaping down as much as it can.

16 SURGEON GENERAL CARMONA: All right. If
17 you're entertaining this, then, a follow-on. The
18 hypothesis you present -- and, please, the rest of you
19 also, if you have some input -- add in the
20 consideration of a short-term versus a long-term
21 remedy as it relates to economics to marketplace, and
22 just our strategic plan.

23 DR. SHEPHERD: It would be a short-term
24 solution, because I do think the prices would adjust
25 over time. You may not get the savings five years
26 from the time you started it. However, you may lower

1 U.S. prices. You just may, and I -- I really believe
2 that's where you should start right there is
3 negotiating with those people and getting a task force
4 on pricing in the United States pharmaceuticals.

5 But I think that the possibility is you
6 may lower them, and you could increase the amount of
7 generics out there and make better availability, as
8 the former FDA Chairman made very good progress to
9 developing generics that are on the market, faster
10 approval.

11 But it's possible to do, but you'd have to
12 be very careful with it. And I'm not too sure -- even
13 the top 50 drugs, it's a small percentage of the total
14 arsenal of drugs we have. So it may not have a big
15 impact.

16 SURGEON GENERAL CARMONA: Exactly.

17 DR. SHEPHERD: So you have to look at
18 that.

19 SURGEON GENERAL CARMONA: Others? Yes,
20 please.

21 MR. CATIZONE: In response to your first
22 and second question, is it a viable option? It's an
23 option for access to affordable medications or more
24 affordable medications. Is it viable? Only if those
25 safety issues are addressed.

26 How can you do it? I think very simply.

1 You would have to make sure that the product met the
2 same standards and went through the same approval
3 process currently in place for the U.S. and through
4 the FDA. And once that was assured, the second part
5 of that would be to make sure every chain of that
6 distribution system was licensed or registered in the
7 states as the current system is. So wholesalers,
8 pharmacies, pharmacists, there would have to be that
9 accountability in licensure or registration in the
10 United States.

11 Is it a short-term or long-term solution?

12 If your long-term solution or strategy is
13 globalization and harmonization, then rather than pick
14 a select number of drugs I would go country by country
15 and approve those countries or -- or devise those
16 regulatory frameworks with those countries, because
17 once you put standards in place they should be able to
18 meet those standards for any product.

19 And if they can't meet them for certain
20 products, then that country shouldn't be involved in
21 exporting drugs to the U.S. So the solution, both
22 long term and short term, is exporting the U.S.
23 regulatory system to other countries that can meet the
24 standards that we require for U.S. patients.

25 SURGEON GENERAL CARMONA: Just one second.

26 In effect, I think as Ms. Winckler pointed out

1 earlier, then we -- it's quite complex. We're
2 importing price controls I guess is one way to look at
3 it, and we're exporting something else.

4 Let me defer, then, to Mr. Sachdev for
5 now, and then I'll come back with another.

6 MR. SACHDEV: To follow up on that
7 comment, which is a good one, so then would you be
8 suggesting -- are there certain categories of products
9 that you would think would not be appropriate for
10 importation in that context? Or would it just be once
11 a country has established a standard that anything
12 from that country could be allowed in?

13 MR. CATIZONE: I think once the country
14 was approved and the standards put in place, and the
15 regulatory framework, then it would be country rather
16 than products.

17 MR. SACHDEV: Including controlled
18 substances, injectibles, biologics?

19 MR. CATIZONE: Yes. Because there would
20 be a partnership between those regulatory authorities
21 in that country to monitor those products as well as
22 adherence to an FDA similar equivalent system for drug
23 approval.

24 MR. SACHDEV: Now, that's actually
25 something I need to ask you about, because you
26 originally said basically the same as FDA. Now you're

1 saying similar or equivalent. Is there a distinction
2 you're trying to draw?

3 MR. CATIZONE: No distinction.

4 SURGEON GENERAL CARMONA: Ms. Winckler,
5 please.

6 MS. WINCKLER: I guess I would add a step
7 into what Dr. Shepherd said when he said, "Let's look
8 at the drugs where we would need to do this." If
9 indeed the idea is that we want to provide cost to
10 lower -- I'm sorry -- want to provide access to lower
11 cost pharmaceuticals, I guess I'd put in a second step
12 there.

13 When you have that list, then look at what
14 alternatives are available in the U.S. that you don't
15 need to go to importation. And you may end your
16 inquiry there. Let's remember viable option doesn't
17 mean only option.

18 If, though, we need to go to the system, I
19 think narrowing as best we can is the best approach,
20 if we can -- I guess I'd say narrow the products,
21 certainly narrow the countries, and we have to keep
22 the U.S. system intact. In my written statement, I
23 had about -- I think it's only nine things that you'd
24 want to check, including the coordination with the
25 U.S. health care system, the liability concerns, the
26 pharmacist-patient-physician relationship -- all of

1 those things.

2 If we can do that in a narrow subset, I
3 think we're better off. But that's the only viable
4 option.

5 MR. CATIZONE: From a public policy issue,
6 I think we have to look at what our patients are
7 doing. Despite warnings from the FDA, despite
8 warnings from the state boards of pharmacy that this
9 is illegal and dangerous, they are still ordering
10 medications.

11 If we close Canada, if we close other
12 countries, they will find ways to order those
13 medications. So all we can do at this point is be
14 responsible and say, "Here is a safe country or here
15 are safe pharmacies for you to use," and hope that
16 those citizens will use those pharmacies and then take
17 action against those entities that promote illegal
18 importation outside of that safety net which we have
19 created.

20 Now that the internet has been opened,
21 we're never going to stop that flow of illegal drugs
22 to patients. They have already decided the issue in
23 many regards.

24 MR. SACHDEV: One follow up to that?

25 SURGEON GENERAL CARMONA: Please. Go
26 ahead, sir.

1 MR. SACHDEV: On this point -- and this
2 was a very interesting line of discussion -- we
3 haven't had this one at the task force before. If
4 you're doing a list -- if you're deciding whether to
5 have an importation scheme where you limit the
6 products coming in to some set amount of products
7 versus a system where you would allow, for instance,
8 maybe country delineations -- it raises the question
9 that I want you all to speak clearly about if you can,
10 about how you think it would work in terms of the
11 mechanism by which the U.S. regulatory authority -- in
12 this case the FDA -- would do its job.

13 Would we be at the border essentially
14 trying to make determinations about products that are
15 coming in? Or, in fact, what you're speaking about is
16 an approval process that's broader than just the
17 inspector, because I think one of the issues that has
18 been raised that's a really difficult question is, how
19 you would have -- how you take a law that's designed
20 to go from pre-market approval and include inspections
21 and turn it on its head at the border and have an
22 individual inspector try to apply all of those
23 requirements by looking at a product when it comes in.

24 And so I need to understand in your
25 proposals what you mean. Are we talking about border
26 inspectors trying to assess equivalency, or something