



Enforcement Committee Report

**John Jones, Chair
Stan Goldenberg
Bill Powers**

Report of June 23, 2004

FOR ACTION 

RECOMMENDATION 1

That the Board of Pharmacy support a statutory change to Business and Professions Codes section 4115(f) that would allow for another verification process other than a signature on the prescription label as approved by board regulation.

Discussion

When a pharmacy technician assists in the filling of a prescription, Business and Professions Code section 4115(f) requires a pharmacist to initial a prescription to verify that he/she checked the prescription before the medication is provided to the patient. This requirement is also in regulation, CCR, title 16, sec. 1793.7(b)

At the Enforcement Committee meeting, the Rite Aid Corporation requested a waiver of the regulation to accept Rite Aid's biometric fingerprint recognition technology as a means of complying with this requirement. **(Attachment A)**

Rite Aid plans to fully use a biometric fingerprint authentication system in its approximately 3,400 pharmacies nationwide with implementation in California by November 2004. The purpose of the biometric system is to provide pharmacy associates with secure access and authorization necessary to create, edit and delete prescriptions during the dispensing process. The biometric function includes the ability to register one or more of the user's fingers, and to use the biometric scan of the fingerprint(s) for secure authorization. It was explained that signing in with the biometric scan then permits Rite Aid to identify the pharmacy associate responsible for various phases of the dispensing process. This technology allows for a more secure authorization of a pending prescription order, including an order prepared by a pharmacy technician.

The committee discussed that the use of biometric fingerprint technology is a viable alternative to the pharmacist's signature on the prescription label; however, a statutory change would be required. The board's inspectors were supportive of such a statutory change that would allow the use of this technology since it appears to be more reliable and legible than an initial on the label often written in haste.

The Enforcement Committee agreed to recommend to the Board of Pharmacy that it support a statutory change to Business and Professions Code section 4115(f) that would allow another verification process other than a signature as approved by board regulation.

Since there was significant support for this proposal, it was suggested that the amendment be placed in the board's omnibus bill this year if possible.

NO ACTION

Importation of Prescription Drugs from Canada

Background information is being provided on the activities related to importation since the last board meeting. The National Association of Boards of Pharmacy (NABP) held an Importation Enforcement Workshop and Task Force meeting on June 22-23, 2004, to address the issue of importation and the prosecution of entities involved in this activity. Also provided was the NABP's updated report on the most recent action by state boards of pharmacy against storefronts, pharmacies, and other groups and individuals who facilitate or assist in the illegal importation of unapproved prescription medication from Canada. Other documents were: the Interim Findings from the Guiliani Partners LLC report on the examination and assessment of prescription drug importation from foreign sources to the United States and a letter from McKesson Corporation to the Task Force on Importation. **(Attachment B)**

At the last board meeting, it was reported that the Food and Drug Administration (FDA), on behalf of the U.S. Department of Health and Human Services' (HHS) Task Force on Drug Importation, announced that it established a docket to receive information and comments on certain issues related to the importation of prescription drugs. The FDA also announced a public meeting on April 14th so that individuals, organizations and other stakeholders could present information to the Task Force for consideration in the study on importation mandated by the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The Task Force is interested in information related to whether and under what circumstances drug importation could be conducted safely, and what its likely consequences would be for the health, medical costs, and development of new medicines for American patients. The public docket will formally remain open until June 1, 2004, so that interested parties can submit written and electronic comments. This task force has held six listening sessions since March 19th. The board requested a copy of the transcript from the April 14th meeting. **(Attachment C)**

The Enforcement Committee also discussed of the legality of importation and the various legislative proposals that have been introduced at the federal and state level that would allow for the safe importation of prescription drugs from Canada. Although the board did not take a position on the California bills, it is tracking their status, which is in the Legislation and Regulation Committee's report.

One bill, AB 1957 (Frommer) would require the Department of Health Services (DHS) to establish a California Rx program to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices and would require DHS to establish a web site before July 1, 2005 to various drug benefit programs including Canadian pharmacies that meet certain standards. One of the standards is that the Canadian pharmacy meets the requirements of a nonresident pharmacy.

Another bill, SB 1149(Ortiz) would require the Board of Pharmacy to establish an interactive Internet Web site to identify licensed Canadian pharmacies that meet specified standard criteria for the safe acquisition, shipment, handling, and dispensing of prescription drugs to persons in California. One of the standards is that the Canadian pharmacy meets the requirements for licensure by the board.

Just recently, the author of SB 1149, Senator Ortiz invited representatives from the Board of Pharmacy to participate in a fact-finding trip to meet with Canadian officials. The plan is for a delegation of legislators and administration representatives to travel to Canada in July to learn more about the Canadian prescription drug system. They would meet with key government and industry officials involved in the drug manufacturing, distribution and dispensing systems in Canada.

The board had to decline the invitation because such a trip would require an individual trip request approval that takes months to obtain because the request must be reviewed and approved by the Department of Consumer Affairs, Agency, the Department of Finance and the Governor's office. Agency has advised the department that it will not begin this review process until the Governor signs the budget for this year. Moreover, the department has also been informed that only those out-of-state/out-of-country trips that will be considered for approval are those trips that are mandated and/or are program essential functions. Information sharing and fact-finding trips generally do not meet this requirement.

Disclosure of Citation and Fines to the Public

At its last meeting, the Board of Pharmacy revised its disclosure policy. During the discussion, licensees expressed concern regarding the disclosure of administrative citations. Administrative citations are not considered discipline of a license. However, they do represent the resolution of an investigation or complaint that has been substantiated and is disclosed to the public.

To address the concerns of licensees, the following language has been added to the citations to advise the licensee: "If a hearing is not requested to contest the citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure (Bus. & Prof. Code §§ 125.9, 4314; Cal. Code Regs., tit. 16, § 1775)."

For cases where no fine has been issued the following will be provided:

“No fine has been assessed with this citation and no proof of abatement has been ordered. If no hearing is requested to contest the citation, the right to contest the citation has been waived. If the citation is not contested, the citation shall be represented as a satisfactory resolution of the matter in any public disclosure (Bus. & Prof. Code §§ 125.9, 4314; Cal. Code Regs., tit. 16, § 1775).”

For disclosure to the public, the following language will be provided:

The issuance of a letter of admonishment and/or a citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The final administrative action including payment of a fine does not constitute an admission of the violation(s) charged and is considered satisfactory resolution of the matter. (Bus. & Prof. Code §§ 125.9, 4314; Cal. Code Regs., tit. 16, § 1775).”

Evaluation of Implementation of the Quality Assurance Program

The National Association of Boards of Pharmacy (NABP) Foundation funded a study on medication errors in California. The purpose of the study was to chart the profession’s implementation of the Board of Pharmacy’s new regulation on quality assurance. The original intent of the study was to prospectively assess, through a board inspector questionnaire, which components of the quality assurance (QA) program were the most difficult for pharmacy to implement, over time. However after the evaluation was implemented, additional limitations were imposed that caused a re-evaluation of the original objectives. The objectives were changed to the following: identify and compile deficiency data and citation/fine data for the new QA regulation, identify the board inspectors’ subjective interpretation of pharmacy’s compliance with various aspects of the regulation and identify and compile data on types of medication errors through a review of the board’s citation and fine data.

The conclusion of the evaluation found that the Board of Pharmacy and its inspectors have fully embraced the concept of quality assurance in an effort to protect consumers through analysis of medication errors. This was supported subjectively through the interview process and objectively through the number and frequency of correction orders (deficiencies) and citations/fines issued by the board during the review period.

The evaluation also compiled a list of medication errors by type in an effort to further medication error prevention. These error types are similar to those reported by national patient safety programs. It was noted that further analysis will be necessary to determine if the implementation of quality assurance requirements actually impacts medication errors encountered by consumers.

It was suggested to share the information regarding the medication errors from the citation/fine data reports with licensees in the next newsletter. (**Attachment D**)

Retired Status of a Physician License

Medical Board of California advised that starting July 1, 2004, a physician who is in retired status will not longer be eligible to practice medicine. While the physician will be exempt from paying a renewal fee and continuing education requirements, they will no longer be allowed to engage in the practice of medicine. The practice of medicine, of course, includes prescribing. **(Attachment E)**

This information will be provided in the board's next newsletter.

Implementation of SB 151 – Changes to the Prescribing and Dispensing of Controlled Substances

The Enforcement Committee discussed the implementation of SB 151 and the many questions that the board has received. These questions have been compiled and will be placed on the board's Web site upon legal review and approval. **(Attachment F)**

Update on SB 1307 Regarding Wholesalers

The Board of Pharmacy is sponsoring SB 1307 to strengthen the regulation of wholesalers by enacting comprehensive changes in the wholesale distribution system for prescription drugs. The Enforcement Committee recommended to the board that it sponsor this legislation after discussing the issue for at least two years. The language was carefully developed to directly address issues found during its investigations of wholesale violations in California. The bill contains the following major elements:

- Requires the development of a “pedigree” that tracks each drug through the distribution system beginning January 1, 2007, and the board may extend the implementation date for wholesalers to 2008 and pharmacies until 2009.
- Requires all out of state wholesalers shipping drugs into California to become licensed (This provision was placed in AB 2862).
- Increases the board's ability to fine for more serious violations related to wholesaling.
- Requires wholesalers to post a \$100,000 bond to secure administrative fines and penalties.
- Restricts wholesale transactions by pharmacies.
- Requires that drugs be purchased only from licensed entities.
- Authorizes the board to embargo drugs when the board suspects or finds drugs that are adulterated or counterfeit.

While SB 1307 will be discussed as part of the Legislation and Regulation Committee report, a segment from “60 Minutes” that was aired in December 2002 will be played for the board. The board originally viewed this tape in January 2003, and some of the new board members may not have seen it. This segment provides a good overview as to why the board is sponsoring SB 1307. Also, being provided is a recent FDA alert regarding counterfeit Viagra that was distributed by two California pharmacies. **(Attachment G)**

Report on the Citation and Fine Program

The Enforcement Committee reviewed the end of the year statistics on the citation and fine program that has been in place for approximately two years. In 2002, the board expanded its citation and fine authority to include all violations of pharmacy law that were issued by a board committee. This year as recommended by the Joint Legislative Sunset Review Committee and the Department of Consumer Affairs, the board amended its regulations to delegate the issuance of citations to the executive officer. It should also be noted that staff has worked extraordinary hard over the last two months to eliminate a backlog of over 700 citations. **(Attachment H)**

Enforcement Committee Meeting Summary of June 23, 2004 (Attachment I)

Enforcement Team Meeting Summary of June 23, 2004 (Attachment J)

Report on Enforcement Actions (Attachment K)

Report on Committee Strategic Objectives for 2003/2004 (Attachment L)

ATTACHMENT A



Rite Aid Corporation

RECEIVED BY CALIF.
BOARD OF PHARMACY

2004 JUN -7 AM 10: 57

• **MAILING ADDRESS**
P.O. Box 3165
Harrisburg, PA 17105

• **GENERAL OFFICE**
30 Hunter Lane
Camp Hill, PA 17011
(717) 761-2633

Direct Dial 717-975-5888

June 1, 2004

SENT VIA FACSIMILE & CERTIFIED MAIL

Patricia F. Harris
Executive Officer
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

Re: Biometric Fingerprint Recognition Technology

Dear Ms. Harris:

On behalf of the 580 Rite Aid pharmacy locations operating in the State of California, I respectfully request that the Board of Pharmacy accept a biometric fingerprint recognition technology as a substitute for the requirement that a pharmacist manually initial a prescription prepared by a pharmacy technician (CCR, Division 17, Title 16, Article 11, §1793.3 and §1793.7(b)).

Rite Aid Corporation is in the midst of fully deploying DigitalPersona's biometric fingerprint authentication system to its approximately 3,400 stores nationwide. By November 30, 2004, Rite Aid plans to have its new pharmacy dispensing system, NexGen, with fingerprint recognition technology in place in all of its California pharmacy locations. Rite Aid is the first U.S. pharmacy chain to use biometric fingerprint recognition technology to augment existing security and privacy policies.

DigitalPersona is the leading provider of fingerprint recognition systems for enterprise and mainstream computing. Founded in 1996 and headquartered in Redwood City, Calif., DigitalPersona designs, manufactures and sells end-to-end solutions for the enterprise, developer and consumer markets. The company's technology is used by leading organizations such as The U.S. Department of Defense.

The purpose of the biometrics function of the NexGen dispensing system is to provide pharmacy associates with secure access and authorization necessary to create, edit and delete prescriptions during the dispensing process. This biometric function includes the ability to register a user's finger of choice and to use that biometric scan of the fingerprint for secure authorization. By first registering a pharmacy associate's finger (or thumb) print

using the Biometric Scanning Device, NexGen can compare the fingerprint with any other to prevent unauthorized access to the various functions of the NexGen dispensing process.

Rite Aid pharmacists and pharmacy technicians, with varying levels of security, will use fingerprint recognition technology to sign on to Rite Aid's NexGen dispensing system. The NexGen system will accept the biometric scan of those associates authorized to enter in to the dispensing system and will record this information. Signing in with the biometric scan then permits Rite Aid to identify the associates responsible for various phases of each prescription.

Various Quality Assurance Approvals are required of the pharmacist only, as part of the dispensing process. Pharmacy Technicians are not provided this level of security. This quality assurance function enables the pharmacist to acknowledge the accuracy of a prescription order. Included in the quality assurance segment of the NexGen dispensing system are the review and verification of the following:

- Drug Utilization Review (DUR) messages
- Scanned image of the original prescription
- Image of the tablet or capsule

Only the pharmacist can grant approval of the various steps in the dispensing process. Approval is provided by the pharmacist by placing his or her finger to the Biometric Scanning Device. The Rite Aid NexGen dispensing system then records the identity of the pharmacist approving the various steps of the prescription order. The initials of the approving pharmacist(s) are recorded in a computerized audit trail. This record of the pharmacist(s) involved in the dispensing process is retrievable at store level. Technicians do not have access to this level of security.

Rite Aid's Biometric Fingerprint Recognition Technology allows for a more secure authorization of a pending prescription order, including an order prepared by a pharmacy technician. As discussed above, the Quality Assurance Approval requires the review and biometric scan of a pharmacist only. Additionally, this technology provides for a more efficient means of identifying the dispensing pharmacist as compared to deciphering the hand-written initials on the prescription label. Rite Aid's Biometric Fingerprint Recognition Technology is more secure than the process of the pharmacist manually initialing the prescription label as required in CCR, Division 17, Title 16, Article 11, §1793.3 and §1793.7(b).

Based upon Rite Aid's Biometric Fingerprint Recognition Technology and the process described above, I respectfully request that the California State Board of Pharmacy issue a waiver to Rite Aid pharmacies in the State of California from the requirement that a pharmacist manually initial a prescription prepared by a pharmacy technician (CCR, Division 17, Title 16, Article 11, §1793.3 and §1793.7(b)). I further request that the California State Board of Pharmacy accept Rite Aid's Biometric Fingerprint Recognition Technology as a method of complying with the aforementioned Board of Pharmacy requirements.

Please do not hesitate to contact me with questions or concerns. Thank you for your attention to this matter.

Yours truly,
RITE AID CORPORATION

A handwritten signature in black ink, appearing to read "M. A. Podgurski".

Michael Podgurski, RPh
Vice President, Pharmacy Operations

ATTACHMENT B

Press Release Source: National Association of Boards of Pharmacy
Wednesday June 23, 11:30 am ET

National Association of Boards of Pharmacy Convenes Enforcement Workshop, Acts on Illegal Prescription Drug Importation
As 30 States Take Action Against Importation, Pharmacy Regulators, State Attorneys General, and Canadian Authorities Gather to Discuss Strategies

WASHINGTON, June 23 /PRNewswire/ -- Appearing today at a joint press conference, authorities from the National Association of Boards of Pharmacy (NABP), the United States' leading regulatory agency for pharmacists and the practice of pharmacy, and the US Food and Drug Administration (FDA) discussed the results of an enforcement workshop convened to deal specifically with the dangers of illegal importation and the prosecution of entities involved in the illegal importation of drugs. The two-day enforcement workshop featured high-level discussion between officials from NABP, state board of pharmacy members, NABP's counterpart in Canada -- the National Association of Pharmacy Regulatory Authorities (NAPRA) -- the FDA, US Drug Enforcement Administration (DEA), and representatives of the state attorneys general from across the country.

"The illegal importation of prescription drugs bought via the Internet presents unique challenges to those state and federal agencies responsible for regulating the practice of pharmacy," said Carmen A. Catizone, MS, RPh, DPh, NABP Executive Director/Secretary. "As guardians of the public health, our obligation is to ensure that the medications dispensed helps patients, not harms them. Unfortunately, the well-being of the patient and the safety of our national drug supply are threatened by the illegal and increasing problem of illegal Internet importation. To that end, we are anxious to understand and share the successes that some 30 states have had in the enforcement of regulations that prohibit illegal importation."

Catizone pointed out that numerous states including Alabama, North Carolina, and Oklahoma have either successfully stopped importation of illegal prescription drugs into their states or are currently in the process of shutting down or challenging the operation of drug importation firms in their states. Overall, more than half the nation is acting against illegal drug importation.

The issue of drug importation has received significant attention in this election year as some politicians have championed the issue as a means to lower the cost of prescription drugs despite warnings from experts that the safety of the imported drugs cannot be guaranteed. "The FDA continues to stand firm on our long-held position that importing prescription drugs from Canada and other foreign countries is unsafe," said Thomas J. McGinnis, RPh, Director of Pharmacy Affairs in the Office of Policy at FDA. "FDA takes very seriously the safety risks posed to Americans by the importation of prescription drugs. We support and congratulate those state regulatory authorities that have successfully exercised their rights either individually or by working with FDA to protect the drug supplies of their states." Among the concerns the FDA has expressed about imported drugs is the strength, quality and purity of these medicines, which are not subjected to FDA oversight.

The enforcement workshop also revisited the joint communique issued by NABP and NAPRA in May 2003. The communique details the serious dangers of buying and importing prescription medications via the Internet. "It is not safe to presume that Web sites or businesses that claim to be located in Canada are in fact located in Canada and fall under the same oversight as local Canadian pharmacies," remarked Lois Cantin, NAPRA President. "There are Web sites purporting to be Canadian pharmacies that are actually unlicensed, may not be located in Canada, and/or may be shipping drugs from other countries."

Both associations share the common responsibilities in the regulation of the practice of pharmacists, ensuring public safety, and are committed to working together to advocate the ability and effectiveness of individual member organizations in executing their regulated mandates. Due to the continued need to address the cross-border movement of prescription drugs, both associations re-issued the communique stating in part that "illegal international movement of prescription drugs between Canada and the United States undermines the regulatory systems established in each country to protect consumers ..."

"As the regulatory bodies for the practice of Canadian and American pharmacy, we have attempted to lay out clear guidelines that will help protect consumers and the drug supply in both countries from illegal importation of drugs and unscrupulous Internet pharmacies," said Catizone of NABP.

"We hope that this communique will serve to inform policymakers and Internet businesses of the appropriate codes of conduct that will help ensure the safe distribution of needed medications," added Cantin of NAPRA.

A full version of the communique is available at <http://www.nabp.net>

The National Association of Boards of Pharmacy (NABP) was founded in 1904 and represents all of the pharmacy regulatory and licensing jurisdictions in the United States, the District of Columbia, Puerto Rico, Guam, the Virgin Islands, eight provinces of Canada, two Australian States, New Zealand, and South Africa. Its purpose is to serve as the independent, international, and impartial Association that assists its member boards and jurisdictions in developing, implementing, and enforcing uniform standards for the purpose of protecting the public health.

NAPRA is a voluntary umbrella organization of Canada's pharmacy regulatory authorities. The Association was established in 1995 to facilitate the activities of the provincial and territorial regulatory bodies in their service of public interest. This is accomplished by representing the interests of the member organizations, serving as a national resource centre, and promoting the harmonization of legislation and standards.

Source: National Association of Boards of Pharmacy

[IMAGE]

Florida changes tune on Canadian drug storefronts

Florida state officials said Tuesday they will license as pharmacies storefronts that order less expensive prescription drugs from Canada, after threatening to shut down 12 unlicensed stores about 10 days ago. State officials say the decision will protect consumers because licensed stores can be regulated by the state, but some shop owners believe pharmacy licenses are unnecessary because they order drugs, rather than sell, stock or deliver them. "We're just a service," said one storefront owner. [The Washington Post/Associated Press](#) (free registration) (6/30)[IMAGE][IMAGE]

[IMAGE]

Florida targets unlicensed pharmacies

Health officials order 12 businesses, including 5 in Central Florida, to close down

From Staff and Wire Reports

June 19, 2004

Florida health officials have ordered 12 unlicensed pharmacies -- most of which specialize in offering cut-rate drugs from Canada -- to stop operating.

Five Central Florida businesses were among the pharmacies ordered to close for selling medicine without a state license, said Jackie DiPietre, a spokeswoman for the state Health Department.

The pharmacies' owners could be prosecuted on criminal charges if they refuse to stop doing business, she said.

"We haven't heard from pharmacy owners, but expect them to comply," she added.

Hans Jenau, owner of Canada Rx Shop, said Friday he would not challenge the state order to close his 2-year-old Oviedo business.

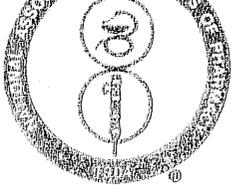
He said he has launched a new firm, Progressive Benefit Masters, that does business with U.S. mail-order pharmacies instead.

"Our intent! on is to assist seniors in saving money on prescription drugs," he said of the new business. "We don't prescribe or handle drugs. We just manage the financial part," he said.

Online and storefront pharmacies such as Jenau's flourished in recent years as spiraling U.S. drug prices made it attractive to import medicines from Canada, where government price controls keep costs well below U.S. levels.

Such businesses operate in a gray area of U.S. law still under debate in Congress and federal courts, acting as intermediaries for customers whose prescriptions are usually filled by a Canadian pharmacy and shipped directly to their homes. But the U.S. Food and Drug Administration and state regulators have taken increasingly hard-line stances in dealing with such operations, citing safety risks for Americans using medications that come from outside the country.

The other pharmacies ordered closed were: Pharmacy Watch in Altamonte Springs, Redwood Drugs of Canada in Ormond Beach, Medoptions Rx in Port Orange, Canadian Discount Rx Inc. in West Melbourne, Discount Drugs of Canada in Lakeland and Springhill, Buy Canadian Discount Drugs of West Palm Beach, Canada Direct Inc. of Sebring, Canadian/Rx Prescription Services Inc. in Bonita Springs, Discount Medicine of Canada in Sun City Center, and Price Pirates in Punta Gorda.



NABP 100 YEARS

1904 BUILDING A REGULATORY 2004
FOUNDATION FOR PATIENT SAFETY

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY
FROM: Mary A. Dickson, Associate Executive Director *MAD*
DATE: May 21, 2004
RE: Actions Against Organizations Facilitating Importation of Canadian Medications

Attached is an updated Excel spreadsheet listing the most recent information that NABP has obtained from the boards of pharmacy and media concerning informal and formal actions that state, federal, and other regulatory agencies have initiated against storefronts, pharmacies, and other groups and individuals who facilitate or otherwise assist in the illegal importation of unapproved prescription medications from Canada.

Please feel free to continue providing us with additional information as it becomes available so that we can add the data to our spreadsheet and periodically provide the boards of pharmacy with updates.

Thank you for your assistance in compiling this table.

cc: NABP Executive Committee
Carmen A. Catizone, Executive Director/Secretary
Jim Weiss, Information Technology and Services Director
Courtney Nashan, Communications and Services Senior Manager
Moirra Gibbons, ELTP/VIPPS Manager
Charisse Johnson, Professional Affairs Manager

National Association of Boards of Pharmacy

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Web Site: www.nabp.net

TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS
Information Obtained 5/03 to Present

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
AK	7/1/03 - No actions have been initiated to date.		
AL	<p>3/20/03 - AL BOP filed a complaint against Discount Drugs of Canada (DDC) and its owner/operators, Timothy Morton & Steve Reese, in the Circuit Court of Jefferson County, seeking a temporary restraining order (TRO) as well as preliminary & permanent injunctive relief, due to allegations that it is, among other things, engaging in the unauthorized practice of pharmacy in AL. The TRO was granted by the court the same day of the filing, and the Board immediately enforced the order, shutting down DDC.</p> <p>3/31/03 - Circuit Court of Jefferson County issued an order extending a previously entered temporary restraining order (TRO) against DDC, until further court order.</p> <p>6/30/03 - Board's request was granted and a circuit court issued a temporary restraining order against Canadian Discount Drugs. A hearing on the Board's request for a preliminary injunction is scheduled for July 8, 2003.</p>	<p>6/03 - FDA issued warning letter to staff of CanadianDiscountDrugs and Ameri-Can Global Pharmaceutical Supply, Inc, in Ozark, AL, which assists US consumers in obtaining prescription drugs from Canada, specifically Total Care Pharmacy in Calgary, Alberta, CAN.</p>	
AR	<p>3/03 - BOP issued a warning letter to Rx Depot (www.therxDepot.com), Lowell, AR, a company that facilitates US consumers obtaining Canadian prescription medications.</p>	<p>3/21/03 - (Rx Depot/www.therxDepot.com) - the FDA issued a warning letter to the company, located in Lowell, AR, notifying the firm that the agency considered the firm's operations to be illegal and a risk to public health, and in clear violation of the drug safety laws that protect Americans from unsafe drugs. FDA is also acting in conjunction with AR BOP action.</p> <p>4/10/03 - the Manitoba Pharmaceutical Association in Winnipeg, Manitoba, CAN, sent a "warning letter," signed by Ronald F. Guse, BScPharm, and addressed to Derek Chan, Pharmacy Mgr of Northgate Clinic Pharmacy, 1410-1399 McPhillips St, Winnipeg, Manitoba, CAN. The warning letter states that Northgate Clinic Pharmacy must immediately cease business agreements with Rx Depot in any state, that Rx Depot is operating in AR in violation of the state law, and that it has been given direction from the State Board of Pharmacy to cease its operation.</p>	

The National Association of Boards of Pharmacy may not be aware of some actions taken by regulators. NABP believes that the information in this table is accurate; any errors are unintentional.

**TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS
Information Obtained 5/03 to Present**

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
AZ	<p>2002-2003 – Seven (7) Canadian pharmacies applied for nonresident pharmacy permits. The Board requested information on how they would comply with FDA regulations on importation. None of the applicants has responded; their applications have been deemed incomplete.</p> <p>5/9/03 - AZ BOP issued a letter to the AZ Better Business Bureau asking it to warn consumers about the risks of purchasing prescription drugs illegally from Canada and other foreign countries. The letter cited the sentencing of Rory Dannenberg, operator of Value Prescriptions located in Phoenix, AZ, for an unrelated felony conviction. Dannenberg is one of several illegal Canadian prescription service operators being investigated by the Board for offering prescription drugs for sale without a pharmacy permit and without a licensed RPh in place.</p>		
CA	<p>7/1/03 - No actions have been initiated to date.</p> <p>10/20/03 - Nothing to report.</p>	<p>8/03 - FDA issued a written opinion in response to a 7/03 letter from the CA Attorney General inquiring about the importation of prescription drugs from Canada into the state of California. FDA notifies the CA AG about the legal and safety issues concerning the importation of prescription drugs.</p>	<p>2/04 - CA S1144 - A bill introduced in the California Senate would authorize the Department of General Services to negotiate contracts with Canadian sources for the purchase of prescription drugs, in addition to existing sources such as prescription drug manufacturers, wholesalers and suppliers.</p> <p>2/04: AB 1957 (Frommer D-Los Angeles) calls for the state to buy Canadian meds, and proposes to have the CA State Board of Pharmacy establish a consumer Web site to help patients buy drugs from certified Canadian drugstores.</p>

The National Association of Boards of Pharmacy may not be aware of some actions taken by regulators. NABP believes that the information in this table is accurate; any errors are unintentional.

Information Obtained 5/03 to Present

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
CO	<p>10/03 - Board is reviewing its laws and considering amendments to strengthen the language.</p>	<p>2003-2003 - AG is reviewing whether to take action against individuals that facilitate foreign business.</p> <p>11/03 (article from www.ajc.com) - The 10th US Circuit Court of Appeals in Denver denied a request from Rx Depot, which asked that its 85 stores be allowed to continue operating until a ruling on its appeal.</p> <p>2/04 - (Rocky Mountain News) - CO regulators urged the FDA and CO attorney general to investigate an Englewood retailer that helps consumers buy prescription drugs from Canada. The Dept of Regulatory Agencies said 2-week-old Canada Drug Service is "flouting federal law" and misleading consumers in its radio ads.</p> <p>5/6/04: Rx Depot filed a petition in federal court requesting that the ban on its operations be lifted. Rx Depot Inc. asked the Denver-based 10th US Federal Circuit Court of Appeals to hear arguments because of the "significant public policy implications" for the elderly and poor.</p>	
CT	7/2/03 - No actions have been initiated to date.		
DC			
DE	<p>1/8/03 - At its January meeting, the Board voiced its concerns and strong opposition to the importation of medications from Canada. The Board formalized its concerns in a letter encouraging NABP to oppose this activity.</p>		
FL	<p>8/02 - Board denied a nonresident pharmacy license to a Canadian pharmacy; statutes require that pharmacy be located in a US state.</p> <p>12/02 - FL Board attorney issues legal opinion stating businesses that assist people in importing prescription medications should be treated like pharmacies because they lead to prescriptions being dispensed.</p> <p>1/04 - NABP staff discovered that the Florida Board issued a non-resident pharmacy license #PH17987 to Canadian pharmacy Adv-Care/Adv-Care.com based in Markham, Ontario, Canada.</p> <p>2/04 - A Board representative indicated that licenses were mistakenly issued to two Canadian pharmacies, and that the Department was going through procedures to revoke/invalidate the licenses. In fact, the Board may be reviewing the Adv-Care license matter at its upcoming meeting.</p>		

The National Association of Boards of Pharmacy may not be aware of some actions taken by regulators. NABP believes that the information in this table is accurate; any errors are unintentional.

TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF DRUGS
Information Obtained 5/03 to Present

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
GA		6/03 - FDA issued a warning letter to president/CEO of CanadianDiscountDrugs in Peachtree, GA, a business that assists US consumers in obtaining prescription drugs from Canada, specifically Total Care Pharmacy in Calgary, Alberta, CAN.	
GU			
HI	6/03 - No actions initiated to date. 10/03 - There are 2 pending cases currently under investigation - no other information is available at this time.	6/03 - Pending.	
IA	6/03 - Board sent a C&D letter to Nuway Drug .		
ID			
IL	Early 2003 - Board inspectors initiated investigations into several storefronts.		
IN	6/03 - Board has filed complaints with the Attorney General of IN. 9/8/03 - IN BOP requested that the AG file an injunction in Marion County Circuit Court against Rx Depot, Inc of 1647 N Shadeland Ave, Indianapolis, IN 46219 for violation of I.C. 25-26-13.		
KS			
KY			
LA	9/02 - Cease and Desist Notification sent to FNC Canadian Discount Medication of Monroe, LA. 3/19/03 - Cease and Desist Notification sent to Prescription Referral Services of Monroe, LA. 9/26/03 - NorthlandMeds Pharmacy , Winnipeg MB, CAN; Total Care Pharmacy , Calgary, AB, CAN; American Drug Club , Winnipeg, MB CAN; American Medical Services LLC , Gretna, LA; Native American Rx , Irving, NY; and Southern Pharmacy Services , Baton Rouge, LA. 10/8/03 - NorthcareDrugs.com (aka Northcare), Winnipeg MB, CAN. 10/13/03 - Canada Discount Rx , Winnipeg MB, CAN. 11/8/03 - NorthCareDrugs.com refuses to obey a C&D order from the Board. 11/17/03 - C&D notice issued to Access Canada Rx . Since the issuance of the C&D order, the company has ceased operations in the state of LA.		

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TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS
Information Obtained 5/03 to Present

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
LA	<p>3/22/04 - C&D notice issued to Glenway Pharmacy, 2213 Henderson Hwy, East St. Paul, Manitoba Canada R2E OB8</p> <p>3/22/04 - C&D notice issued to Rx Metro, 1308 W Thomas St, Hammond, IN 70401</p>		
MA	<p>7/03 - Board has been closely monitoring the issue and has been providing info to the Office of the Attorney General.</p>		<p>3/04 - Under a proposed bill, the state would be required to seek federal permission to help citizens buy drugs from Canada. If granted, Massachusetts would then set up a Web site listing Canadian Internet Pharmacies.</p>
MD	<p>10/27/03 - BOP intends to send out about a half-dozen warning letters to storefront operations in its state in the coming weeks.</p>		
ME			
MI			
MN	<p>7/2/03 - No actions initiated to date.</p>		
MO	<p>7/2/03 - No actions initiated to date.</p>		
MS	<p>7/2/03 - No actions initiated to date.</p>		
MT	<p>3/03 – Board issued an official complaint against RealFast Drug Store, known as RF Drugstore (www.realfastdrugstore.com), located in Manitoba, CAN. RF Drugstore has entered into an arrangement with Club Medz, a storefront located in Great Falls, MT. Board also intends to take Club Medz to court within a month if it does not comply with the Board's order to cease and desist, and have been working with the FDA in hopes of obtaining the involvement as well.</p> <p>4/03 – Board investigated Club Medz, issued a subpoena, and Club Medz ceased operations at the end of the business day on 4/11/03. Board had charged that the lay people manning the storefront were engaged in the unlicensed practice of pharmacy and that they were aiding and abetting an illegal act.</p> <p>4/03 - Board filed a complaint with the Manitoba Pharmaceutical Association against RealFast Drugstore (aka RF Drugstore). The matter is still under MPA's consideration.</p>	<p>12/03 - Judge lifts injunction against Billings' Rx Depot Store. Judge Jeffrey Sherlock in Helena dissolved the temporary court Order against Rx Depot in August by the MT Board of Pharmacy, saying proper notice of a hearing on the injunction was not given.</p>	

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TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS
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STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
MT	<p>Spring '03 - Several C&D letters have been sent to Canadian mail order pharmacies.</p> <p>5/03 - Denied an out-of-state mail service pharmacy license to Canadian pharmacy on grounds that the Board is unable to license an entity to perform an illegal act.</p> <p>5/03 - Contacted both a RPh and a layperson seeking to open storefront operations, counseling the RPh not to aid and abet illegal activity or face disciplinary action. The layperson was told that the Board would consider her to be engaged in the unlicensed practice of pharmacy and aiding and abetting an illegal act. So far, neither operation has begun.</p> <p>6/03 - Began action against a new Rx Depot in Billings, MT, and will follow the same rationale as previously used in the Club Medz case. Informed the FDA of the situation via phone.</p>		
MT	<p>7/30/03 - Board filed a petition for injunctive relief against Sandra S. Kennedy d/b/a Rx Depot based upon allegations of aiding and abetting the unlawful practice of pharmacy in violation of Montana law.</p> <p>8/5/03 - MT Pharmacy Board's petition for a preliminary injunction was granted. Sandra S. Kennedy d/b/a Rx Depot was ordered to cease engaging in any type of prescription service involving advertising for, solicitation of, and transfer of prescription drug orders from consumers/patients, until further order of court. A hearing is scheduled for 11/20/03.</p> <p>10/03 - The board is preparing to file a complaint with the Manitoba College of Pharmacists against CanadaDrugMart.com, Manitoba license #32386. From now on, MT BOP will file a board complaint with Canadian authorities against any Canadian pharmacy advertising its services within the state.</p>	<p>7/03 - FDA sent a letter in support of Montana's actions case Rx Depot.</p> <p>9/03 - Montana Pharmacy Association offered to file an amicus brief on behalf of the Montana Board of Pharmacy, in the Board's case against Rx Depot.</p>	

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TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS
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STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
NC	<p>6/11/03 - the NC BOP announced the issuance of Cease & Desist Orders for five businesses that are forwarding prescriptions to Canada to be filled and returned to the US. Orders were sent to: Discount Drugs of Canada, Gastonia, NC; Canada Drug Outlet Inc, Concord, NC; Rx Price is Right, Inc, Winston-Salem, NC; Canada Drugs, Asheboro, NC; and Prescription Care of NC, Banner Elk, NC.</p> <p>7/14/03 - Per Carlson Carmichael, lawyer for the NC BOP, as of mid-June 2003, they have sent C&Ds to 6 locations in NC that are storefront-type operations.</p> <p>10/15/03 - Board filed suit against five (5) storefronts in NC and is seeking preliminary injunctions. The hearings are to be held on 11/20/03.</p> <p>11/03 - NC judge ordered Canada Outlet to show that it complies with state law. After 10 days, the judge will determine whether or not to grant a preliminary injunction.</p> <p>11/03 - Prescription Care of North Carolina signed a consent Order.</p> <p>11/03 - Discount Drugs of Canada is no longer operating.</p>	<p>7/1/03 - FDA issued a letter supporting the Board's efforts to stop businesses that forward prescriptions to Canada to be filled by Canadian pharmacies for US consumers, and the FDA offered its assistance in the Board's efforts to stop such businesses.</p> <p>4/04 - North Carolina's Caldwell County links employees with Canadian pharmacies. The FDA and NC BOP have sent the county letters of objection.</p>	
NC	<p>1/9/04 - David Work of the NC BOP called NABP and stated the Board had just won an injunction against a Canadian storefront, located in Concord.</p> <p>2/04 - The NC Board of Pharmacy is trying to shutter the last storefront Canadian prescription service in the Charlotte area. The board ordered "Canada Connection" to stop doing business in NC and helping people place orders with Canadian pharmacies.</p> <p>4/04 - The NC Board of Pharmacy wrote to the Manitoba Pharmaceutical Association about Redwood Drugs of Winnipeg. The letter states that Redwood Drugs, www.redwooddrugs.ca, is soliciting residents of North Carolina, but Redwood Pharmacy does not have an out-of-state pharmacy permit, which is required according to North Carolina law.</p>		

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TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF DRUGS FROM CANADA
Information Obtained 5/03 to Present

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
ND	<p>Fall 2002 – BOP has sent numerous cease and desist orders to Canadian and other international pharmacies that ship into ND.</p> <p>9/5/03 - ND BOP sent a C&D letter to: Arnel A. Inocando, Redwood Drugs, Winnipeg, Manitoba, CAN for: 1) offering to ship prescription medications to ND; 2) offering to pay physicians for referral of prescription business.</p> <p>9/9/03 - C&D letter sent to David King of Canada Direct Pharmacy in Calgary, Alberta, CAN, for offering a financial and business referral arrangement between one health care provider and another.</p> <p>10/17/03 - A C&D letter was sent to Canada Direct Pharmacy, Milind Pendharkar, VP, Corporate Development, Kelowna, British Columbia, CAN.</p> <p>Letter undated - Milind Pendharkar, VP, Canada Direct Pharmacy, responded to the Board's C&D letter.</p> <p>Letter undated - signed by Anton Gjerek, Redwood Drugs, responded to the Board's C&D letter.</p>		
NE			
NH	<p>7/2/03 - No actions have been initiated to date.</p>		<p>2/04 - Gov. Craig Benson recently outlined a plan to purchase prescription drugs from Canada for inmates in state correctional facilities and Medicaid recipients taking drugs for mental illness. NH S 434 - The bill establishes a commission to examine the purchase of prescription drugs in Canada.</p> <p>5/04 - Concord, NH, American Drug Club to assist US consumers in obtaining prescription drugs from Great Britain.</p>

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**TABLE OF ACTIONS AGAINST SITES PROMOTING IMPORTATION OF CANADIAN DRUGS
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STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
NJ	10/27/03 - No further actions have been taken as of this date.		5/12/03 - New Jersey Legislature bill No. 570 Section 34 (b) addressing pharmacists was amended to prohibit the shipping of Canadian and unapproved meds to NJ. 5/22/03 - amendment prohibiting the shipment of Canadian/unapproved meds is dropped.
NM			
NV			
NY	7/03/03 - Investigations have been initiated. 10/27/03 - NY has closed Canadian drug storefronts either by issuing letters of warning or obtaining orders to shut them down.		
OH	11/00 - Cease and desist order issued against Provincial Pharmacy, Inc , in Windsor, Ontario, CAN. Basis: unlicensed shipping of prescriptions to OH residents. 7/03 - No recent actions initiated to date.		
OK	3/27/03 - The state authorities filed a petition in OK state court alleging that Rx Depot is illegally operating an unlicensed pharmacy. 6/3/03 - State court granted a temporary restraining order against Rx Depot , which becomes effective on approximately 8/31/03 so that Rx Depot may appeal. Judge's order stated Rx Depot violated state statutes.	3/27/03 - FDA issued a statement strongly supporting the filing by the OK SBOP and the OK AGO of a petition for injunction seeking to stop the Rx Depot storefront pharmacy from violating state law. 4/10/03 - the Manitoba Pharmaceutical Association (MPA) in Winnipeg, Manitoba, CAN, sent a "warning letter," signed by Ronald F. Guse, BScPharm, and addressed to Derek Chan, Pharmacy Mgr of Northgate Clinic Pharmacy , 1410-1399 McPhillips St, Winnipeg, Manitoba, CAN. The MPA received a copy of the court document filed in the District Court of OK (case # CJ-2003-2643) describing the conduct of Rx Depot in the state of OK being in violation of state law. The warning letter states that Northgate Clinic Pharmacy must immediately cease business agreements with Rx Depot in any state and the shipment of medication into the state of OK. 10/27/03 - Federal prosecutors sued storefront operator, Rx Depot, Inc. of Tulsa, OK. The case is in US Dist. Court, in Tulsa, OK. Prosecutors claim the company illegally helps import drugs from Canada.	

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STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
OK		11/6/03 - Federal District Court in OK granted the FDA a preliminary injunction against Rx Depot, Inc , and Rx of Canada which, the Judge declared, violated the law.	
OR	<p>7/2/03 - No actions have been initiated to date; however, the Board has ongoing investigations.</p> <p>10/27/03 - Board sent warnings to eight storefronts recently.</p> <p>10/30/03 - City of Roseburg refused to issue a business registration to a storefront and the BOP sent a warning letter to the same storefront: Canada Drug Supply.</p>		
PA	10/15/03 - No action to report by PA Board.		
PR			
RI	<p>2002- Cease and desist order sent to two Manitoba pharmacies. Complaint sent to MB pharmacy regulators regarding MB pharmacies shipping to RI.</p> <p>11/25/03 - RI Board of Pharmacy sent a C&D letter to Prescription Discounters, Inc. and MediMart Pharmacy. Board accused the storefront of helping customers order prescription meds from Canada. MediMart Pharmacy in Winnipeg, Manitoba fills the order and ships the medication directly to the customer's home.</p>		<p>2/03 – Legislation introduced to allow Canadian pharmacies to ship prescription meds to RI. Legislation, backed by RI Medical Society, would allow BOP to license CAN pharmacies. BOP ED Cordy said Board would oppose the bill.</p> <p>2/04 - RI H 7320 - This bill, which is being considered by the House Committee on Health, Education and Welfare, would allow pharmacies licensed in Canada to obtain licensure from the state health department.</p>
SC	2003- Warning letters sent to several storefronts.		
SD	<p>2002-2003 - Board sent cease and desist letters and has phoned Canadian pharmacies to inform them of their illegal shipping of meds into SD. Board has also warned Nuway, an insurance agent that was providing seminars and assisting seniors in purchasing meds from Canada.</p> <p>2002-2003 - Complaint sent to MB pharmacy regulator concerning MB pharmacies shipping to SD residents.</p>		

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STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
TN	<p>10/02 – State sent cease and desist order to CanadaDiscountRx.</p> <p>1/03 - C&D letter sent to Canadian Rx Consultants Group, Maitland, FL.</p> <p>3/03 - C&D letter sent to Canadian Drugs2U, Nashville, TN. No response yet; Board is considering next action.</p> <p>4/03 - C&D letter sent to Global Pharmacy Rx, Cookeville, TN. Owner advises that they are no longer in business.</p> <p>5/03 - Board stated that facilitating the importation of Rx's for Canadian pharmacies is the practice of pharmacy and storefronts should be licensed.</p> <p>5/03 - C&D letter sent to Medi Save, Knoxville, TN. Attorney for the owners of Medi Save advises that they are no longer in business.</p> <p>5/03 - C&D letter sent to RealFast of Winnipeg, Manitoba, CAN.</p> <p>6/03 - C&D letter sent to Canada Direct Pharmacy, LTD, in Calgary, Alberta, CAN. No response.</p>		<p>1/04 - Legislation introduced, House Bill 2173, which requires governor and state insurance committee to request federal approval for importation of prescription drugs from Canada by pharmacy benefits managers; proposal to contain protections to ensure only quality prescription drugs are imported.</p>
TN	<p>7/9/03 - C&D letter sent to two Pak Mail storefront locations representing CanadaValueRx.com in Manitoba. Advised by the owner of Pak Mail that he had discontinued the practice. No response from CanadaValueRx.</p> <p>7/7/03 - C&D letter sent to ThriftyMedsNow.com, Manitou, Manitoba, CAN. Phone calls to the office indicate that they have complied with the order. Consumers (approx. 20) stated that they have been informed by reps of ThriftyMedsNow that TN is the only state that has taken an action and the company advised customers to have their meds mailed to another state where it is "legal."</p> <p>9/11/03 - C&D letter sent to Canadian Rx Depot, Winnipeg, Manitoba, CAN. No response.</p> <p>9/11/03 - mailed a second C&D letter to CanadaDiscountRx.com, aka McKnight's Pharmacy, Winnipeg, Manitoba, CAN. No response.</p>		

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TN	<p>9/17/03 - Closed complaints on Century Advantage, a storefront representing Canadian Discount Pharmacy, and MediSave, a storefront representing an unidentified Canadian pharmacy. The board was advised that these locations had complied with a previous C&D letter.</p> <p>9/30/03 - C&D letter sent to AccessCanadianPharmacy.com, aka Total Care Pharmacy, West Hillhurst 100, Calgary, Alberta, CAN. No response.</p> <p>1/30/04 - As of this date, the board has not received a response to a number of C&D letters.</p>		
TX	<p>7/03 - The Board will send C&D letters to any facilitators who receive or process prescriptions, and any person or business that uses the word "pharmacy," or graphical representations of the same.</p> <p>7/3/03 - TX SBOP mailed nine (9) C&D letters. A 10th C&D letter will be mailed soon.</p> <p>8/5/03 - as of this date, Board has mailed twelve (12) C&D letters.</p>		
TX	<p>As of 10/22/03, the TX BOP has mailed twenty C&D letters, mailed between 6/30/03 and 10/21/03. The six (6) most recent C&D letters were mailed to the following storefronts: 9/24/03 - Rx Source, Dallas TX; 9/26/03 - Canada Drug Service of West TX, Amarillo, TX; 9/30/03 - North America Drug Co, San Antonio, TX; 10/8/03 - Canadian Rx Depot, Inc, Denton TX, Canadian Prescriptions Direct, Houston, TX; and 10/21/03 - Rx Depot, Waco, TX.</p> <p>1/22/04 - Expedite-Rx was directed by the Texas State Board of Pharmacy last July to "immediately discontinue receiving/processing prescription drug orders."</p>		

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STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
UT	<p>7/02 - C&D Order issued to Rx North America.</p> <p>4/03 - C&D Order issued to Discount Prescription Service, a facilitator.</p> <p>4/03 - Complaint filed with the College of Pharmacists of British Columbia against a B.C. pharmacy that appeared to be shipping prescriptions into UT.</p> <p>4/03 - Complaint filed with the College of Physicians and Surgeons of British Columbia against a doctor allegedly prescribing medications for export to UT.</p>		
VA			<p>1/04 - John O'Bannon (R) of Virginia proposed legislation (HR 632) that provides criminal penalties for those businesses that assist individuals in obtaining prescription drugs from businesses that are not licensed in the US.</p> <p>2/04 - VA H 190, in consultation with the Office of the Attorney General and the Executive Director of the Board – D59the bill calls for evaluation and implementation, if feasible and cost effective and consistent with federal law and regulation, a process for purchasing reduced-cost prescription drugs from Canada for some state employees.</p>
VI			

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Information Obtained 5/03 to Present

STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
VT	<p>6/03 - "Position Paper on the Reimportation of Foreign Prescription Drugs" is published in the Vermont Board of Pharmacy Newsletter.</p> <p>7/03 - The Board currently has two (2) Investigations open regarding Canadian Internet pharmacies. The allegations are: one is a storefront, the only one believed to be in VT; and the second involves a firm that has come to VT, advertised a "Canadian Drug" seminar, and had a pharmacist representing the company at the conference. Both investigations are still open.</p>		<p>8/1/03 - VT has new rules in the legislative process, slated to go into effect. In the new rules, any pharmacy that ships meds into VT must be licensed by the state.</p> <p>2/04 - VT SJR 40, a resolution that passed the House on Jan. 21, 2004, urges Gov. James Douglas to establish a drug importation program for the state. VT H 502 proposes to require the state of Vermont, municipalities, and school boards to purchase drugs covered by a health benefit plan from Canadian sources.</p>
VT			<p>VT S 276, the Senate health and welfare committee will consider legislation that would allow the state department of prevention, assistance, transition and health access to establish a program, Web site and written information to publicize how Vermont residents are able to order drugs through the mail as well as purchasing prescription drugs from Canada.</p>
WA	<p>Several letters have been sent advising Canadian pharmacies not to ship to residents of WA.</p>		<p>2/04 - WA H 2469 would authorize certain state agencies to purchase prescription drugs, approved by the Food and Drug Administration, from Canadian wholesalers and pharmacies. The health care authority would also develop a Web site to facilitate the purchase of prescription drugs from Canada by Washington residents.</p>

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WI	<p>7/7/03 - There is one case pending which is against Philip D. Kuehnl and Premium Discount Pharmaceutical Services.</p> <p>10/03: Philip Kuehnl and Premium Discount Pharmaceutical Services were enjoined from using or displaying a symbol or insignia having the same or similar meaning as "pharmacy", "drugstore", "apothecary" or any other title without having obtained a pharmacy license.</p>		
WV	<p>5/13/03 - Cease and desist letter sent to Discount Prescription Center of WV, a storefront. Discount Prescription Center filed an action in court to bar authorities from closing it, claiming it is not a pharmacy.</p> <p>11/03 - Judge ruled in favor of Discount Prescription Center, enjoining the board from closing the business because, the judge declared, its operations are not in violation of WV law. However, business must change its name. DPC uses CanAmerica Pharmacy in Manitoba to dispense medications. Board of Pharmacy is seeking to revise its laws and the definition of pharmacy/practice of pharmacy.</p>	<p>2/18/04 - the FDA sent a warning letter to Ms. Carole Becker, President, Discount Prescriptions from Canada, Inc, 709 Benoni Ave, Fairmont, WV 26554. Discount Prescriptions from Canada uses CanAmerica, located in Manitoba, Canada, to fill prescriptions and sends the drugs directly to the US consumer.</p> <p>3/04 - Discount Prescriptions from Canada, Inc, in Fairmont, WV, stopped its service of helping consumers buy prescription meds from Canada.</p>	
WY	<p>6/3/03 - Board sent cease and desist letter to Canada Direct Pharmacy in Calgary, Alberta, CAN, which sent advertising to St Anthony Manor in Casper, WY. Any pharmacy desiring to do business in WY must be licensed by the Board.</p> <p>7/03 - Board sent a cease and desist letter to ThriftMedsNow Pharmacy in Manitoba, CAN, due to its being an unlicensed pharmacy that is advertising in a Wyoming paper.</p> <p>8/27/03 - Board sent a C&D letter to AccessCanadianPharmacy.com, Calgary, Alberta, CAN, re advertising or dispensing prescription drugs in WY.</p>		

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STATE	Actions Taken by SBOP	Other Regulatory Agencies' Actions	Current Legislation
FEDERAL ACTIONS			
FDA - Cyber Warning Letters to Canadian Pharmacies			
	10/31/01 - www.RxNorth.com ; www.OnlineCanadianDrugstore.com (MediPlan)		
	10/31/01 - www.Canadameds.com (Point Douglas Pharmacy)		
	11/15/01 - www.Canadarx.net (Target Zone)		
	9/9/03 - The FDA has asked the DOJ to file a complaint for injunction against Rx Depot, Inc. , and Rx of Canada, LLC (Rx Canada), to stop them from importing drugs that pose a serious threat to the public health.		
	<p>11/6/03 - FDA sent a letter warning CanaRx, a company supplying prescription drugs to Springfield, MA, that its operations are illegal under federal law.</p> <p>11/6/03 - FDA sent a detailed letter informing the state of Illinois that its report, which reviews the feasibility of and recommends importing prescription medications from Canada, is potentially in violation of federal and state law, is flawed, and that unregulated importation endangers people's lives.</p> <p>1/9/04 - The FDA is not ruling out legal action if cities of states defy its ban on importing cheaper drugs from Canada, per Commissioner McClellan.</p>		
	1/22/04 - The FDA issued a warning letter to Expedite-Rx , a PBM; SPC Global Technologies, Ltd , an insurance claims processor; and Employer Health Options, Inc , an insurance company, all of Temple, TX, notifying them that it considers their drug import program to be illegal and a risk to the public health. The letter accuses the firms of facilitating illegal imports of prescription drugs from Canada. Expedite-Rx, SPC Global Technologies, and Employer Health Options have 15 working days to inform FDA about the specific steps they will take to bring their operations in full compliance with US law. In case of non-compliance, FDA may take legal actions, including seizure and/or injunction, without further notice.		
ACTIONS TAKEN BY CANADIAN REGULATORY AGENCIES			
	<p>May 2002 - The Ontario College of Pharmacists, the regulatory body for enforcing pharmacy practice standards, charged The Canadian Drugstore, Inc, with 15 different violations, including operating an unlicensed Internet pharmacy without registered pharmacists from November 2001 to February 2002.</p>		
	<p>March 2003 – Cross-Border Statement was issued by Nova Scotia College of Pharmacists stating, among other things, that Nova Scotia pharmacists and pharmacies should not participate in any scheme or service to accommodate importation of Canadian medications by US citizens. Pharmacists/pharmacies that accommodate such services may be found to be practicing unethically and may be found guilty of professional misconduct.</p>		
	<p>April 2003 – Canadian Broadcasting Corporation (CBC), Fredericton – The New Brunswick College of Physicians has suspended the license of Dr Andre Loiselle, a physician accused of helping to sell prescription drugs over the Internet. Dr Loiselle wrote prescriptions for a Web site that markets drugs to senior citizens in the US, even though he had never met the patients.</p>		

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	<p>April 2003 - The Manitoba Pharmaceutical Association (MPA) in Winnipeg, Manitoba, CAN sent a "warning letter" to Derek Chan, Pharmacy Mgr of Northgate Clinic Pharmacy. The warning letter states that Northgate Clinic Pharmacy must immediately cease business agreement with Rx Depot in any state and the shipment of medication into the state of OK.</p> <p>July 2003 - The Ontario College of Pharmacists (OCP) resolved its prosecution against The Canadian Drugstore Inc; Rep-Pharm, Inc; Stephen Bederman, RPh; and Dr Stanley Gore and his company Canadian Custom Prescriptives, Inc. Summary of charges involved: unlawful dispensing or selling of a drug to a patient; operating an unlicensed pharmacy; and dispensing a prescription without written authorization of a Canadian doctor. The specific judgment follows in paragraphs 1-3, below:</p>		
	<ol style="list-style-type: none"> 1. The Canadian Drugstore, Inc, pled guilty on 6/23/03 to one offense contrary to the Regulated Health Profession Act, 1991 (RHPA), and four charges contrary to the Drug & Pharmacies Regulation Act (DPRA). The Ontario Court of Justice fined the company (Canadian Drugstore, Inc) \$20,000. This fine amount was part of an overall disposition that included a \$125,000 payment by the Canadian Drugstore, Inc, to the Leslie Dan Faculty of Pharmacy, University of Toronto, to establish the Ontario College of Pharmacists' Professorship in Pharmacy Practice. 2. Rep-Pharm was fined \$5,000. 3. Charges against the RPh Bederman, Dr Gore, and affiliated companies were dropped; however, the pharmacist faces a disciplinary hearing on December 2003, and the doctor was referred to the College of Physicians and Surgeons of Ontario for a hearing and determination. 		
	<p>10/31/03 - Four Manitoba doctors have been reprimanded by their professional organization for countersigning prescriptions for U.S. patients seeking Canadian drugs through Internet pharmacies. Registrar of the College of Physicians and Surgeons of Manitoba stated the disciplined doctors were Raj Vijay, Michael O'Sullivan, Alexander Wilson, and Henry Dirks. The four doctors were censured 9/15/03 after the college investigated. The doctors have allegedly stopped cosigning prescriptions; however, should they do so again, they could face more severe penalties.</p> <p>11/03 - NAPRA issued a statement requesting that the Canadian federal government ban the exportation of prescription medications to the United States.</p>		
	<p>5/4/04 - Manitoba Pharmaceutical Association recently upheld a discipline committee's earlier finding that pharmacist Andrew Strempler of Mediplan Health violated the Pharmaceutical Act by filling more than 10,000 prescriptions for American patients that were written by doctors who were not licensed to practice in Canada. Strempler has asked the court to stay the Association's decision pending the outcome of the current appeal and then to overturn the ruling under provisions of the Act.</p>		

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Giuliani Partners LLC
Examination and Assessment of
Prescription Drug Importation From Foreign Sources
To the United States

Interim Findings
May 11, 2004

INTRODUCTION

The availability of safe, effective and reasonably priced medications for all Americans is at the center of an important, ongoing debate regarding our health care system. As the costs of medicines have increased, so has the focus of pricing on this debate. Individuals and even local and State governments have sought alternative means to obtain necessary medicines at lower costs, and these initiatives have further narrowed the debate to the value of importing Canadian or foreign medicines into the United States.

However, the safety and efficacy of these same imported medicines has received less attention and focus and is often overshadowed or even ignored by the pricing issue. From the outset, there is little dispute that the high price of many prescription medicines becomes an impediment to access. And while the price of today's medicines exist in part to provide for the development of tomorrow's cure, patient access should be expanded by exploring methods for lowering costs for those in need.

Giuliani Partners LLC has been retained by the Pharmaceutical Research and Manufacturers of America (PhRMA) to evaluate the risks, if any, associated with the importation of Canadian and foreign medicines.

In recognition of the public health implications associated with importation, and at the request of Congress, the United States Department of Health & Human Services has convened a Task Force on Drug Importation to examine these very concerns. Acknowledging the importance of this issue to the public, the Task Force is working with great alacrity to provide its recommendations to HHS. Giuliani Partners LLC will be providing the Task Force with a more detailed report encompassing our preliminary findings and conclusions as part of our effort to inform this critical debate and to assist the Task Force in its work. For now, we have made a series of interim findings that are worth discussing today to widen the lens through which the issue of the importation of drugs is viewed, and consequently address the equally important issues of safety and risk in the Task Force's assessment.

It is important to note from the outset that there appears to be a fundamental misunderstanding about the source of the less expensive drugs at the center of this discussion. Initially, this debate was framed around "re-importation" – in other words, the importation (from Canada) of medicines manufactured under U.S. Food and Drug Administration (FDA) oversight and now available at a lower cost via Canada. Under such a system, a patient could reasonably assume that the medicine

was safely and properly manufactured under FDA oversight without corruption in the supply chain. However, that is not necessarily what is occurring. Instead, U.S. patients are receiving medicines from foreign countries (albeit ordered through Canada or sources purporting to be Canadian based) that were manufactured or re-packaged without any oversight by the FDA or Health Canada (the Canadian FDA counterpart).

Indeed, several U.S. States that provide links to websites for their citizens to order “Canadian” drugs have graphic disclaimers disavowing any warranty about the product and relinquishing the state government from any legal liability with regard to the product or care from the on-line pharmacy. In some instances, the Canadian pharmacy website requires the patient to sign a waiver that denies the patient any legal recourse in the U.S. for harm caused by these imported drugs. The current U.S. regulatory process, while not perfect, protects patients seeking medicines from U.S. pharmacies. This raises an important question that must be reviewed when assessing the relative risks associated with obtaining imported medicines against the potential rewards of lower prices.

Product Quality: What Is In Our Medicine?

When a patient seeks to fill a particular prescription for a particular medicine, there is an assumption that the medicine is in the exact form, quality, potency and dosage as directed by the patient’s physician. Anything less constitutes a risk to that patient’s health and well-being.

Based upon our review to date, we have found that some patients who believe they are purchasing re-imported Canadian medicines are in fact receiving non-FDA approved drugs from foreign countries that are not at all what they claim to be. There is significant evidence that patients have received drugs through the internet that are past their expiration date, are sub-potent (or, in some cases, more potent than indicated), contain the wrong dose, are contaminated or clearly counterfeited, are not properly stored or shipped (i.e. medicines that require constant refrigeration or others that must be protected from freezing) among other problems. We have found that medicines ordered over the internet that purport to be manufactured under FDA oversight or delivered through Canadian pharmacies are in fact manufactured in countries such as Pakistan, China, Iran, Singapore and many others. The fundamental question of product quality and integrity must be at the center of this important discussion.

Set forth below is an outline of the review we have undertaken. Significant questions are raised regarding the level of safety for patients and indeed for our nation from the relaxation of importation controls. It is vital that the Task Force and others carefully and thoughtfully consider all of these legitimate concerns so that our health care system can be as safe, effective and accessible as possible.

SYSTEMIC ISSUES

The American system for manufacturing, distributing and selling prescription medicines is significantly regulated and often referred to as the “gold standard.”

Notwithstanding this fact, however, there are identifiable weaknesses in this process that can compromise the quality and integrity of our medicine supply.

The Distribution Chain

On its face it appears that the distribution chain for prescription medicines in the United States is fairly straightforward – manufacturers sell their products to wholesalers, who in turn sell the products to retail pharmacies or stores, who in turn dispense medicines to patients with prescriptions. It is not until the system is studied in greater detail that one begins to appreciate both the complexities and the vulnerability of the distribution chain and the potential for exploitation or abuse.

Some contributing factors are as follows:

- Wholesalers or distributors are primarily regulated by the states with no uniform standards across state borders. States have a comparatively small number of investigators to monitor the licensed wholesalers; thus, given the sheer number of wholesalers, oversight is minimal.
- There are thousands of “secondary” pharmaceutical wholesalers in addition to McKesson, AmerisourceBergen and Cardinal Health (the “big three”) involved in the distribution of prescription medicines. As reported in The Washington Post, there are more than 6,500 small wholesalers nationwide.
- There is no uniform mechanism, i.e., a chain of custody or “pedigree,” to track the medicine from point of manufacture to point of sale; the FDA has not implemented the pedigree requirement that was mandated by law in 1988.
- Repackaging is a vulnerable point in the process and can provide an opportunity for counterfeit or non-FDA approved products to compromise the system.

Report of the Florida Grand Jury

Two years ago the State of Florida convened a statewide Grand Jury to examine the safety of prescription drugs in Florida and to analyze the sale and resale of prescription drugs in the wholesale market. The report, released in February 2003, found an overwhelming need for tighter regulation and oversight of the pharmaceutical distribution industry. Many of those interviewed by Giuliani Partners indicated that the problems identified in the Florida Grand Jury Report are pervasive throughout the United States. A summary of the Grand Jury’s findings follows.

- Oversight of the system is lax.
 - Minimal background checks are required for licensing wholesalers and warehouse operators were found to be uneducated amateurs, some with criminal records.
 - Corrupt wholesalers are neither investigated nor prosecuted.
 - Despite existing requirements, drugs are being distributed with either incomplete or, in many cases, non-existent pedigree papers to document the products’ supply chain history.

- Inspection of wholesaler operations by the appropriate authorities and oversight by responsible agencies is spotty at best.
- Funding for oversight agencies is inadequate.
 - The Florida Bureau of Statewide Pharmacy Services employs only nine field inspectors to inspect 422 wholesalers statewide.
- Product quality is compromised.
 - Widespread problems with the quality and integrity of the secondary wholesale drug supply were found to include:
 - expired drugs re-labeled with falsely extended dates
 - previously dispensed medicines
 - illegally imported drugs
 - sub-potent drugs
 - drugs that contained an entirely different substance from the one listed on the container's label
- Health risks are significant.
 - The mainstream market is compromised by corrupt, secondary wholesalers. Diverted drugs are often combined with counterfeit medicines or re-labeled or repackaged. Then, these compromised drugs enter the mainstream market through corrupt secondary wholesalers and are dispensed by legitimate pharmacies, hospitals or clinics. By way of example, a father in Michigan who thought he was injecting his son with a growth hormone later found that the vials actually contained insulin. These drugs were traced to a legitimate pharmacy in Orlando, Florida.
- Incentives for counterfeiting and diversion are considerable.
 - The huge profits derived from these activities rival those of illicit narcotics traffickers, while the penalties are minor by comparison.

Challenges to Oversight and Enforcement

There are challenges associated with the oversight and enforcement of our current laws with regard to ensuring that medicines being purchased or sold in this country are FDA-approved, safe and effective.

- The current volume of parcels of drugs coming into this country through the mail (it is estimated to be more than 10 million packages annually) and the increasing volume of internet purchases make meaningful inspection by the FDA almost impossible.
- The FDA has less than 100 investigators to deal with drug importation issues nationwide, and its investigative authority is limited relative to its ever-increasing law enforcement responsibilities. For example, the FDA has no administrative subpoena authority in order to facilitate the conduct of its investigations; thus it must either partner with another investigative agency or request subpoenas from the local United States Attorney's office.

- Investigating and prosecuting counterfeit drug cases or illegal internet sales cases are not, with few exceptions, a priority for the federal or state law enforcement agencies.
- The penalties are comparatively low for engaging in this kind of activity – the current penalties for FDA violations are approximately 3 years.
- The technologies being advanced as mechanisms to ensure an imported drug shipment is safe and effective are not foolproof, and, in some instances, not yet available.
 - Electronic Track and Trace – most agree that these technologies, e.g., using bar coding or radio frequency identification (RFID) chips that could track drug products in real time throughout the system and then provide an electronic pedigree, are still very costly when available.
 - Counterfeit resistant technologies that include covert and overt packaging and labeling techniques, such as holograms, watermarks, color shifting inks or fluorescent inks, as well as chemical agents, are widely used by the industry already. However, they can be easily duplicated and, therefore, must be changed on a periodic basis.
 - “Unit of Use” packaging, which is a container closure system designed to hold a specific quantity of drug product for a specific use and dispensed to a patient without any modification except for appropriate labeling, does eliminate the need for some repackaging; however, there are packaging and cost issues for the manufacturers, and some drugs do not lend themselves to such packaging.
 - Authentication testing, while not a technology *per se*, is also an option when determining the integrity of a pharmaceutical product. It is a complicated, time consuming and costly process, however, and can be performed only by the original manufacturer. There are no available tests that can be conducted “in the field” to ascertain whether a product is real or fake.

These factors, among others, make it a high profit, low risk business for the counterfeiters or those involved in circumventing the laws in supplying medicines outside the traditional distribution chain, and, therefore, it may be appealing to organized crime and terrorist organizations.

PRODUCT QUALITY

Weaknesses in the existing system already threaten the quality and integrity of the nation’s drug supply. Despite best efforts, the evidence we have seen thus far supports the notion that the drug supply is indeed vulnerable. Some examples are as follows:

Random Examinations Conducted by the FDA and U.S. Customs and Border Protection

The FDA and U.S Customs and Border Protection conducted a number of random inspections or “blitzes” at several mail ports in the fall and early winter of 2003.

- In the first inspection, 1,153 drug products were examined and 1,019 or 88% were not approved by the FDA; the drugs came from countries such as India, Thailand, and the Philippines.
- In the second exam, 1,982 parcels were examined and 1,728 or 87% were not approved; 16% of those shipments were from Mexico.
- Many of the drugs examined during these visits were non-FDA approved for many reasons, including:
 - improper labeling, e.g., there were no instructions for proper use;
 - the presence of controlled substances;
 - potentially recalled drugs, e.g., drugs that had been withdrawn from the market for safety reasons;
 - animal drugs not approved for human use;
 - drugs requiring risk management and/or restricted distribution (e.g., initial screening or periodic monitoring); drugs with clinically significant drug interactions; or drugs requiring careful dosing; and
 - required special storage conditions for certain drugs were violated.

Portal Visits

In order to gain an appreciation for the scope of the problem, United States mail facilities were visited to observe the volume and nature of the packages allegedly containing prescription drugs entering the United States. A number of the observations follow.

John F. Kennedy Airport Mail Facility

At the invitation of United States Senator Norm Coleman, former New York City Mayor Rudolph W. Giuliani and former New York City Police Commissioner, Bernard B. Kerik, accompanied the Senator on a visit in March, 2004 to the US Mail facility located at JFK Airport. Customs officials advised that approximately 40,000 packages of suspected drug shipments are received each day from the postal service for review and inspection. Based upon information, the FDA focuses on "countries of interest" and visually inspects 500 to 700 parcels per day. Thus, the majority of packages are sent on to the addressee uninspected. The following was learned:

- Drugs purported to be Xanax, Valium (Diazepam), Lorazepam, Vicodin (all controlled substances) and Lupron were observed; there were numerous packages from the Netherlands, Brazil, Pakistan, as well as other countries.
- Many of the drugs contained in the parcels were non-FDA approved because they were inappropriately packaged, expired, mislabeled or otherwise noncompliant.
- The sheer volume of shipments overwhelms Customs and FDA; FDA has only 6 staff members assigned to JFK.
- Although much of what is inspected is non-FDA approved, few parcels are actually detained. The processing requirements to detain a shipment are

cumbersome and time consuming. The rules require the FDA to send a notice to the addressee of the package. If the person does not respond or the response is insufficient, the package must then be returned to the sender (manufacturer). This process varies significantly from the way controlled substances or narcotics are handled. Such drugs can be destroyed without further processing.

Miami International Mail Branch Facility Visit in March 2003

Giuliani Partners was provided with a Congressional staff report regarding a similar review of the Miami facility in March 2003. The findings of the bipartisan Congressional report were consistent with the findings of this review:

- Congressional staff witnessed “thousands of shipments of foreign drugs” being processed; the packages were from countries such as Honduras, Costa Rica as well as Great Britain; and the packages purportedly contained “valium” (diazepam), Reteina (Ritalin), Zolipidem, and Ciprofloxacin.
- The volume of drugs coming through the mail facilities is too great to allow for any meaningful inspection.
- Parcels are only visually inspected; there is no testing as to the quality or integrity of the product.
- FDA and Customs detain very limited numbers of questionable drugs coming into the facility because of the cumbersome nature of the detention process.

The Increase in Counterfeit Drugs

- Most of those interviewed by Giuliani Partners agreed that:
 - The number of incidents involving counterfeit medicines is increasing;
 - The increased use of internet sale and purchase is exacerbating the problem;
 - The counterfeiting techniques are becoming more sophisticated and harder to detect;
 - There are vulnerabilities in the current distribution system that contribute to the problem; and
 - Opening the borders for wholesale importation will worsen the problem.
- The former Commissioner of the FDA, Dr. Mark McClellan, testified before the U.S. Senate Committee on Commerce, Science and Transportation on March 11, 2004 that the FDA has seen its number of counterfeit drug investigations increase four-fold since the late 1990’s. “Although counterfeiting was once a rare event, we are increasingly seeing large supplies of counterfeit versions of finished drugs being manufactured and distributed by well funded and elaborately organized networks.”
- On its website, the World Health Organization (WHO) states that while the true extent of the problem of counterfeit drugs is difficult to know or measure,

they have estimated that at least 8% – 10% of the world's total drug supply is counterfeit.

- An August 30, 2002 Washington Post story cites the Shenzhen Evening News in reporting that an estimated 192,000 people died in China in 2001 because of counterfeit drugs. Another news story reported that as much as 50% of China's drug supply is counterfeit (Investor's Business Daily dated October 20, 2003).

Reported Incidents of Adverse Effects

Without question, the most frequently asked question by proponents of importation is "who is really being harmed by the purchase of medicines from outside of the United States?" There appears to be no easy answer to the question. Because receipt of imported medicines is unregulated, there are no systems in place to effectively monitor whether injuries result from the taking of compromised medicines. When complications arise from taking imported medicines and a patient does consult with his or her doctor or reports to an emergency room, no one is asking the question "where do you purchase your prescription medicines?" Patients are also reluctant to report adverse reactions that may be attributable to medicines illegally purchased from outside the country.

Given these circumstances, coupled with the systemic challenges discussed earlier, it is difficult to ascertain the actual source of an imported drug. The following are some examples of actual incidents where people taking medicines with undocumented origins were adversely affected as a direct result of taking the prescription drugs. These cases represent the dangers of obtaining drugs from sources outside of the United States' closed system.

- In La Mesa, California, Ryan T. Haight, 18, died in his bedroom of an overdose after taking narcotics obtained on the internet. After his death, his parents found a bottle of the painkiller Vicodin in his room with a label from an out-of-state pharmacy. An investigation by federal drug agents showed that the teenager had been ordering addictive drugs online and paying with a debit card his parents gave him to buy baseball cards on eBay. (Washington Post, October 19, 2003)
- In Sacramento, California, James Lewis, 47, a former triathlete, shopped the world for painkillers that flowed unimpeded from pharmacies in South Africa, Thailand and Spain. His wife discovered him dead of an overdose on the living room couch. (Washington Post, October 19, 2003)
- A 15-year-old paraplegic boy went into convulsions and died after taking a non-FDA approved drug called Lincocin which had been smuggled in from Mexico. (Los Angeles Times, March 10, 2001)
- Juris Abolins, 43, used painkillers off and on for years to treat pain from kidney stones. His roommate found him slumped on his bedroom floor dead. An autopsy revealed the presence of controlled substances in his blood stream.

Relatives found a Federal Express slip for drugs purchased from a website in Tijuana, Mexico. (Washington Post, October 19, 2003)

THE INTERNET

Over the past several years, hundreds of websites have appeared on the internet selling prescription medicines. While some sites provide legitimate prescription services, many sites are illegitimate and pose significant risks to all patients who use them.

Private Investigation Regarding Internet Purchases

A security and investigative firm based out of New York City, Beau Dietl & Associates, conducted an investigation regarding the importation of foreign medicines and reported its findings in December 2003. The results were disturbing:

- More than 1400 websites were identified as selling prescription drugs.
- 352 of those sites did not require a prescription when ordering.
- 142 of 170 orders were placed without a prescription and at the time of the report, 79 orders were filled without a prescription.
- Many of the medicines received were not only shipped in improper packaging but came from foreign countries such as Pakistan.
- An order for Ciprofloxacin was placed, received and tested. It was determined to be only 65% potent.
- The investigation found that website operators were often difficult to identify and trace; and some of those identified were found to have questionable backgrounds:
 - One website owner/operator was a convicted felon;
 - Other website owners could not be traced because the registration information was false;
 - Many sites failed to comply with legal requirements – doctors wrote prescriptions without ever meeting the patient; and one internet doctor was a convicted sex offender.
- Websites were easily established with no minimum qualifications, standards, or oversight.
- Once the websites were established, emails were received from various suppliers offering to provide medications from “several countries,” or “bulk meds from Pakistan” for resale in the U.S. market.

The results of this investigation offer a troubling snapshot of the nature of the internet pharmaceutical business.

The CASA White Paper

The National Center on Addiction and Substance Abuse at Columbia University, under the direction of Joseph Califano, former Secretary of the Department of Health, Education and Welfare, the predecessor of the U.S. Department of Health and Human Services, released a study in February 2004 regarding the sale of controlled, dangerous and addictive prescription drugs in America. It looked particularly at internet sales and teamed with the same New York City investigative firm to conduct the review. CASA characterized its findings as “alarming.”

During a one-week period of observation, the firm identified a total of 495 web sites offering Schedules II through V controlled substance prescription drugs. Examples of the controlled substances available online included painkillers, stimulants, and nervous system depressants.

- Of the 157 sites selling controlled substance prescription drugs on the internet
 - 90% (141) did not require a prescription
 - 4% (7) required that a faxed prescription
 - 2% (3) required that a mailed prescription
 - 4% (6) made no mention of prescriptions
- Of the sites, 47% disclosed that the drugs would be coming from outside the United States; 28% stated the drugs would be shipped from a US pharmacy; and 25% gave no indication where the drugs would be coming from.
- The analysis determined that there were no mechanisms in place to block children from purchasing these drugs.

Canada – The Implications of Importation

It is generally agreed that prescription medicines purchased by Canadians in a Canadian drug store are safe and effective. Like the United States, Canada has a system of regulatory controls over its medicine supply. However, the same cannot be said for the drugs that are being imported to Canada and then exported. In fact, the Canadian government is not inspecting those medicines that are being imported to Canada and then exported to the United States. The Canadian government has clearly stated that it would not be responsible for the safety and quality of prescription drugs exported from Canada into the United States or any other country. Furthermore, the Canadian Food and Drug Act does not apply to any packaged food, drug, cosmetic or device not manufactured for consumption in Canada and not sold for consumption in Canada.

With respect to the question of drug supply capacity, it is undisputed that Canada does not have supply sufficient to provide for its residents and Americans as well. (In 2002, 3.1 billion prescriptions were filled in the U.S. compared to 335 million prescriptions filled in Canada.)

According to information provided by Industry Canada, a department of the Canadian Federal Government, from September 2002 to September 2003, there was a significant increase in drugs imported into Canada from the following countries:

- Singapore up 30%
- Ecuador up 198%
- China up 43%
- Iran up 2,753%
- Argentina up 221%
- South Africa up 84%
- Thailand up 52%

Prudential Financial, Inc. released similar findings, stating that Canadian internet pharmacies were increasingly obtaining their product from other countries such as Bulgaria (exports to Canada up 300%), Singapore (up 101%), Argentina (up 171%), South Africa (up 114%), Pakistan (up 196%), as well as others. Further, some Canadian pharmacies, such as Canadameds.com, have publicly indicated that because of the increasing demand from the United States, they are turning to Great Britain for prescription drugs.

THE POTENTIAL FOR EXPLOITATION BY NARCOTICS TRAFFICKERS, ORGANIZED CRIMINALS AND TERRORISTS

The terrorist attacks of September 11, 2001 demonstrated how vulnerable this country is to those who have total disregard for human life or who mean us harm. Since that time, the United States has invested billions of dollars to protect our borders. Despite all that has been done, we have not focused on the vulnerability of the nation's medicine supply as a potential target. The present controlled system of importation and inspection is open to exploitation and abuse. Any further removal of controls, much less the total opening of the borders to foreign drugs, would create a situation that terrorists, drug dealers and organized criminals might well use to their advantage. It seems counter-intuitive to contemplate opening our borders with regard to our medicine supply when in all other aspects of border security and protection, we as a country are looking for ways to tighten security.

A July 22, 1998 story in Insurance Day, while reporting on pill piracy and the World Health Organization's efforts to confront pharmaceutical fraud, stated that "Interpol believes that this aspect of the drug trade is closely connected with the narcotics cartels and that the profits generated by it are in part used to finance international terrorism." The article further stated that Interpol had been following the global counterfeit drug racket for some time and based its belief on evidence uncovered by police in North America and Western Europe.

Further, in her book, Funding Evil, How Terrorism is Financed – and How to Stop It, Rachel Ehrenfeld makes numerous references to the fact that terrorists use counterfeiting activities as a means to fund their terrorist acts. While counterfeit prescription drugs are not specifically referenced, the use of illegal drugs to fund such activities is well documented.

GlobalOptions Inc. identified the potential terrorist threats to America's medical supply in its work, An Analysis of Terrorist Threats to America's Medicine Supply. In sum, it identified three potential threats. First, the "mere infiltration of terrorists in the counterfeit drug market poses a threat to the public." Terrorists could easily produce and sell harmful prescription drugs. Second, terrorist groups could use the profits raised through the sale of counterfeit or diverted drugs to fund their activities. And third, terrorists could use poisoned drugs as a method of attack or, worse, as a weapon of mass destruction.

This study cited numerous examples of links between counterfeiting activities of various types and terrorist groups, where such groups were using the proceeds from these sales to fund their terrorist activities. In particular, the authors pointed to the following:

- The activities of the Irish Republican Army in the early 1990's in Florida that included the manufacture of a counterfeit drug product used to treat livestock. Proceeds from this operation were used to purchase guns;
- An international drug ring raised millions of dollars for Hezbollah. The report states that the terrorist group's operatives legitimately purchased large quantities of pseudoephedrine in Canada, smuggled it into the United States, and produced "speed."

THE CONCLUSION

After conducting a preliminary, independent review of the issues associated with the wholesale importation of prescription medicines, it is evident that the existing pharmaceutical system is open to significant exploitation of counterfeit, diluted or adulterated drugs coming into the United States. The limitations of our system should be addressed before it is opened to wholesale importation.

The Health and Human Services Task Force on Drug Importation is currently considering all of these issues. The Task Force should be allowed to complete its mission as Congress directed before any major statutory changes are contemplated. Given the seriousness of this issue and its implications for the health and safety of Americans, a thorough and well-informed analysis is necessary.

Our interim findings can be summarized as follows:

- Although the current pharmaceutical manufacturing and distribution system is comprehensive and regulated, counterfeit or otherwise adulterated products still penetrate the market.
- There are serious questions as to the quality and safety of the medicine products coming into the United States from foreign sources.
- There are no minimum standards and little or no regulation regarding the operations of internet pharmacies.

- There are identifiable weaknesses in the current pharmaceutical distribution chain (e.g., the “secondary” wholesale distribution market and the lack of a drug pedigree)
- The agencies responsible for enforcing the existing laws and regulations are already overwhelmed with the current volume of non-FDA approved prescription medicines coming into the United States.
- The potential exists for the use of the nation’s medicine supply as a vehicle for terrorist activity.
- There are serious implications for Canadians with the current demand on their drug supply.

As noted previously, this review and these findings are preliminary. However, the issues discussed herein strongly suggest that no action be forced on the FDA or other government oversight agencies until the HHS Task Force has completed its analysis. In the meantime, the public should be made aware of the risks associated with importing medicines from outside the United States. As the importation debate continues, it is vital that all aspects of this important public health issue be carefully assessed. We should not minimize the potential risks surrounding importation.

Merrill R. Jacobs
Deputy Vice President
State Government Affairs

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BOARD OF PHARMACY



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April 15, 2004

California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, California 95814

RE: Importation of Illegal Drugs

Dear Members:

The Pharmaceutical Research and Manufacturers of America (PhRMA) respectfully urges you to oppose facilitating the purchase by California residents of prescription drugs from Canadian pharmacies.

As confirmed by the U.S. Food and Drug Administration (FDA), importing drugs from abroad is unsafe and violates federal law that exists to protect patients from illegal, contaminated and counterfeit products. Virtually all drugs imported into the United States, other than those imported by the original manufacturer, pose serious safety concerns. To illustrate, a recent U.S. Customs and FDA investigation found that 88% (1,019 of 1,153) of imported drugs contained unapproved drugs, such as mislabeled, misbranded, expired, and mishandled drugs that might cause patient health problems.

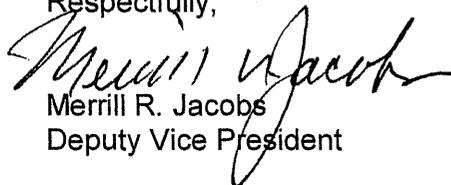
The drug importation programs by proposed legislation or regulation would likely cause the state to suffer potential liability if recipients of foreign drugs were injured by these imports.

As a general matter, it is unlawful under the Federal Food, Drug, and Cosmetic Act for the state or anyone to import a drug into the United States that is not approved first by the FDA. Violating federal law invites FDA enforcement actions. Not only is it illegal for a state to import an illegal drug into the United States, it is also illegal for a state to even *cause* the importation. Even if a state structures a program so that patients themselves are importing drugs for their personal use, it is still illegal. To this end, I attach a letter dated August 25, 2003 from the FDA to the Deputy Attorney General in California concerning FDA's position on the legality of acquiring drugs from a foreign source for importation into a state.

I am also attaching a legal opinion raising issues of state liability for importation of such drugs.

Thank you for your consideration.

Respectfully,



Merrill R. Jacobs
Deputy Vice President

Pharmaceutical Research and Manufacturers of America

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October 3, 2003

LIABILITY OF STATES IMPORTING PRESCRIPTION DRUGS FROM CANADA

This memorandum evaluates the potential liability that could be incurred under recently announced proposals by certain state governments to import prescription drugs from Canada. This memorandum also addresses the legality under the Federal Food, Drug, and Cosmetic Act (FDCA) and other laws of such proposals. For the reasons discussed below, states could potentially face substantial liability under various tort theories if recipients of Canadian drugs were injured by these imports. Further, these proposals implicate core provisions of the FDCA and are illegal, as FDA has itself made clear. Serious questions also exist as to whether drugs imported from abroad may be reimbursed under Medicaid or Medicare. In addition to these legal issues, strong public policy and public health grounds exist to support enforcement action against such programs.

Drugs Imported from Canada May Pose Serious Dangers to Patients

FDA recently announced that a series of spot examinations of mail shipments of foreign drugs to U.S. consumers revealed that these shipments often contain dangerous unapproved or counterfeit drugs that pose potentially serious safety problems. FDA's press release describing the results of these examinations is available at <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00948.html>. Of 1,153 imported drug products examined, 88% constituted unapproved drugs, many of which could pose clear safety problems. Over fifteen percent of the drugs examined entered the U.S. from Canada.

While it is commonly perceived that drugs imported from Canada can be safely substituted for their American counterparts, FDA's examinations revealed serious safety concerns about a number of Canadian imports. For example, the agency found that taro-warfarin, an apparently unapproved version of Warfarin[®], is being imported from Canada. Warfarin is used to prevent blood clotting and its potency may vary depending on how it is manufactured. Because it can cause serious, life-threatening bleeding if not administered appropriately, it requires careful monitoring by a health care provider of a patient's blood count during treatment. Use of imported taro-warfarin that differs in potency from Warfarin could substantially interfere with a patient's treatment. FDA expressed similar concerns with unapproved Canadian versions of Synthroid[®] and Glucophage[®], which also require individual titration and very careful dosing to avoid serious life-threatening side effects. FDA also noted that unapproved versions of Zocor[®] from Canada are being imported and have the potential to cause clinically significant interactions with other drugs which consumers may be taking.

FDA's examinations of these products reveal that Canadian drug imports may pose real and serious health risks to patients taking them.

State Tort Liability for Injuries Suffered by Patients Using Canadian Drugs

The potential tort liability that a state could face for providing or facilitating the provision of Canadian drugs to patients who are subsequently harmed by the drugs is illustrated by examining the law in two particular states -- Massachusetts and Illinois. States, of course, have not previously engaged in these types of activities, and thus there is not case law that addresses the precise circumstances that would be presented by a state drug import plan. Nonetheless, as discussed in the following sections, clear potential causes of action could lie where patients are harmed from a foreign-sourced drug. Such harm could occur, for example,

where the potency of the imported drug is not the same as that of the FDA-approved drug for which it is intended to substitute, resulting in an over- or under-dose, or where the import causes side effects or dangerous interactions that would not be expected with the FDA-approved version.

States that provide Canadian drugs directly to patients or that facilitate the provision of these drugs, through a state-sponsored pharmacy benefit plan or by other means, thus face real risks of liability, including under the tort theories of negligence, strict liability/breach of implied warranty of merchantability, failure to warn, and fraud or misrepresentation. Using our illustrative examples of Illinois and Massachusetts, the states would not be immune to such liability. The Illinois Court of Claims Act (705 ILCS 505/9) and Chapter 258 of Massachusetts General Laws expressly allow for causes of action against the state for damages in cases sounding in tort (Illinois) and for state liability for personal injury or loss of property (Massachusetts). Those statutes do, however, impose conditions and procedures for tort actions brought against the states.

A. Negligence

Negligence is the failure of a responsible person to exercise the degree of care required to discharge the duty resting on him. *Nelson v. Massachusetts Port Authority*, 771 N.E.2d 209, 211 (Mass. App. 2002). The elements of a negligence action are a legal duty of reasonable care owed by defendant to plaintiff, a breach of that duty, and injury proximately caused by that breach. *See Id.*; *Swett v. Village of Algonquin*, 523 N.E.2d 594, 597 (Ill. App. 1988). A state that provides or aids the distribution of Canadian drugs to patients ultimately harmed by them could face serious liability for negligence.

The state would likely be deemed to owe a duty to the patient to ensure that drugs provided or procured are safe for their intended use. Whether a legal duty exists involves consideration of legal and social policies, including foreseeability and likelihood of injury, magnitude of burden of guarding against injury, and consequence of placing that burden on the defendant. *Swett*, 523 N.E.2d at 597; *Cottam v. CVS Pharmacy*, 764 N.E.2d 814, 819 (Mass. 2002). It is likely that the states' police power to regulate the public health and welfare would be considered to give rise to a duty to refrain from affirmatively providing potentially unsafe drugs to state citizens.

The duty owed by a state to its employees is even more plain as a matter of social policy, and in Illinois is statutory. The Illinois Health and Safety Act, which expressly applies to the State of Illinois and all political subdivisions as employers (820 ILCS 225/2), provides that "[i]t shall be the duty of every employer under this Act to provide reasonable protection to the lives, health and safety and to furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to its employees." 820 ILCS 225/3(a) (2003). While this provision may have been intended to apply to workplace safety, its wording is broad enough to potentially cover the provision of drugs, directly or through a pharmacy benefit plan, to employees.

The injury to patients could be considered both foreseeable and likely, given FDA's longstanding insistence that such drugs are unsafe, including the agency's most recent report of its examination of imported drugs. A state's provision of drugs it knows to be potentially harmful would likely constitute a breach of its duties to its employees and other citizens, particularly if it provides the drugs to patients directly. *See Shuras v. Integrated Project*

Services, Inc., 190 F. Supp. 2d 194, 200 (D. Mass. 2002) (seller is liable for negligence if it knew or had reason to know of the dangerous condition that caused plaintiff's injury).

Harm resulting from that breach could be shown by evidence demonstrating that the patient's injury was caused by the Canadian drug. The harm could be attributable to the state as either the direct provider of the drug or as the facilitator of the provision of the drug to captive state employees. Attribution of harm to the state may be particularly appropriate because the Canadian drug would not have been legally accessible to the plaintiff through other channels.

Based upon the foregoing considerations, a state that provides Canadian drugs to patients who are then harmed by them could likely be found liable for negligence, because its actions could be deemed a failure to exercise the degree of care required of an entity in the state's position with respect to the patient. It is even possible that the state could be found liable for gross negligence given FDA's repeated pronouncements about the dangers of Canadian drugs.

B. Strict Liability/Breach of Implied Warranty of Merchantability

The contract theory of breach of implied warranty of merchantability is nearly identical to the tort theory of strict liability. *Garcia v. Edgewater Hospital*, 613 N.E.2d 1243, 1249 (Ill. App. 1993). While Illinois continues to recognize both causes of action, Massachusetts has substituted breach of implied warranty under its Uniform Commercial Code (UCC) for the tort principle of strict liability. Strict liability and breach of implied warranty of merchantability may be premised upon an inherent defect in the product itself or upon the defendant's failure to warn. This section addresses liability for product defect; failure to warn is discussed below.

A plaintiff may recover in a strict liability action in Illinois if he or she proves that an injury resulted from an unreasonably dangerous condition of the product, which condition

existed at the time the product left the control of the manufacturer. *Johnson v. Danville Cash & Carry Lumber Co.*, 558 N.E.2d 626, 629-30 (Ill. App. 1990). The rule of strict liability “encompasses the commerce chain in its entirety, including manufacturers, distributors, retailers, and lessors.” *Id.* at 629 (citation omitted). Accordingly, the rule could apply to the state providing or facilitating the distribution of drugs from Canada.

Illinois and Massachusetts could also be found liable for breach of implied warranty of merchantability to the extent the states would be deemed to be “merchants” selling goods. Although this is a contract theory, a plaintiff may recover noneconomic damages for personal injury. *Federal Insurance Company v. Village of Westmont*, 649 N.E.2d 986, 989 (Ill. App. 1995). To recover under this theory, a plaintiff must establish a sale of goods, that the seller of the goods is a merchant with respect to goods of that kind, and that the goods were not of merchantable quality. *Garcia, supra*, 613 N.E.2d at 1249; 810 ILCS 5/2-314; *Chapman v. Bernard's Inc.*, 167 F. Supp. 2d 406, 414 (D. Mass. 2001); M.G.L. c. 106, § 2-314. Thus, states that provide Canadian drugs, through a state-run pharmacy for example, could readily be subject to liability for breach of implied warranty of merchantability, for the drugs could be considered “not of merchantable quality” for the same reasons that they could be deemed “unreasonably dangerous” under a strict liability theory.

States could even potentially face liability as “merchants” even if they do not sell the drugs to patients for a charge; whether a defendant is a merchant is a question of fact to be resolved by the factfinder. *Federal Insurance Company, supra*, 649 N.E.2d at 990. Both the Illinois and Massachusetts UCC define a “merchant” as “a person who deals in goods of the kind or otherwise by his occupation holds himself out as having knowledge or skill peculiar to the practices or goods involved in the transaction.” 810 ILCS 5/2-104; M.G.L. c. 106, § 2-104. In

Garcia, supra, the court found that a hospital's provision of mitral valves was a "sale," independent of the service of performance of mitral valve replacement surgery, that rendered the hospital subject to liability for breach of implied warranty of merchantability. Thus, if the state's provision of Canadian drugs could be comparably characterized, as, for example, in the dispensing of Canadian drugs at state-sponsored clinics, the state could be held liable for breach of implied warranty.

C. Failure to Warn

A failure to warn of a product's dangerous propensities can give rise to a claim of strict liability, breach of implied warranty of merchantability, or negligence. Under a strict liability theory, the failure to warn of the danger posed by the product renders it unreasonably dangerous. *Schultz v. Hennessy Industries, Inc.*, 584 N.E.2d 235, 242 (Ill. App. 1991). The implied warranty of merchantability includes an assurance that the product is reasonably safe for its ordinary purposes. Consequently, the manufacturer or seller of a product known to be unreasonably dangerous may be obligated to warn those who foreseeably will come in contact with the product. *Cocco v. Deluxe Systems, Inc.*, 516 N.E.2d 1171, 1175 (Mass. App. 1987). Under these two theories, the focus is on the adequacy of the warning, whereas under a negligence theory, the focus is on the particular defendant's knowledge and conduct. *Werckenthein v. Bucher Petrochemical Company*, 618 N.E.2d 902, 908 (Ill. App. 1993). Sellers and distributors, as well as manufacturers, may be subject to a claim for failure to warn. *Cocco, supra*, 516 N.E.2d at 1175; *Schultz, supra*, 584 N.E.2d at 242.

A state that sells, distributes, or otherwise supplies patients with Canadian drugs could potentially be held liable for failure to warn under either a strict liability, breach of implied warranty, or negligence theory. A plaintiff predicated a products liability action upon a failure

to warn must demonstrate that the seller or distributor of the product knew or should have known of the danger that caused his injury. *Schultz, supra*, 584 N.E.2d at 242; see also *Cocco, supra*, 516 N.E.2d at 1175. The purpose of a warning is to apprise people coming into contact with a product of dangers of which they are unaware so that they may take appropriate precautions to protect themselves. *Vallejo v. Mercado*, 580 N.E.2d 655, 662 (Ill. App. 1991).

With respect to Canadian drugs that FDA has specifically identified as potentially problematic, an injured patient could likely show that the state was aware of the danger posed by the drug, and that an appropriate warning would have enabled the patient to take precautions such as seeking monitoring by a health care provider if potency may be an issue, or being alert to possible side effects. An argument for failure to warn would be less strong with respect to other Canadian drugs not singled out by FDA, unless perhaps the plaintiff could argue that the state should have communicated that the Canadian drug might not meet the precise specifications of the FDA-approved drug for which it is intended to substitute and that he would have acted differently had he known.

At least with respect to Canadian drugs FDA has specifically identified as potentially dangerous, a compelling argument for failure to warn could be made with regard to state-run pharmacies. In general, the "learned intermediary" doctrine relieves pharmacists of the duty to warn about possible dangers of prescription drugs, for the patient's physician is deemed to be in the best position to provide any applicable warnings to the patient about the drug. However, courts in Illinois and Massachusetts, as well as in a number of other states, have refused to extend the protections of the learned intermediary doctrine to pharmacists who had specific knowledge of a particular danger to the patient. In *Happel v. Wal-Mart Stores, Inc.*, 737 N.E.2d 650 (Ill. App. 2000), the court held that the pharmacy, which was aware of the patient's

drug allergies, owed a duty to disclose either to the patient or her physician that the prescribed drug was contraindicated. Similarly, in *Cafarelle v. Brockton Oaks CVS, Inc.*, 1996 Mass. Super. LEXIS 421 (Mass. Super. 1996), the court concluded that the pharmacy had a duty to warn the patient and her prescribing physician that the patient may have overused the medication. These cases suggest that where a state-sponsored pharmacy or other state entity dispenses Canadian drugs known to be potentially problematic, it has a duty to warn the patient of the particular harm that users of those drugs might incur.

D. Fraud, Misrepresentation or Unfair Trade Practices

For reasons similar to those discussed above with respect to failure to warn, Illinois and Massachusetts could be found liable for common law fraud or misrepresentation or for violations of those states' unfair trade practices acts if they provide Canadian drugs to patients later injured by them. While the elements of these causes of action vary slightly, they can all be fairly described as requiring a plaintiff to prove that the defendant made a false representation of a material fact with knowledge of its falsity for the purpose of inducing the plaintiff to act thereon, and that the plaintiff relied upon the representation as true and acted upon it to his damage. See, e.g., *Damon v. Sun Company, Inc.*, 87 F.3d 1467, 1471-2 (1st Cir. 1996); *Capiccioni v. Brennan Naperville, Inc.*, 791 N.E.2d 553, 558 (Ill. App. 2003). An omission as well as an affirmative representation may give rise to a claim of fraud, although in Illinois the concealment must have been done with an intent to deceive. *Stewart v. Thrasher*, 610 N.E.2d 799, 803 (Ill. App. 1993). Massachusetts law, however, does not require an intent to deceive. *Damon, supra*, 87 F.3d at 1479.

Applying the foregoing criteria to states supplying Canadian drugs, liability could potentially arise where the states conceal the fact that the drugs provided are from Canada and

are not FDA-approved, or where states make affirmative representations that the Canadian drugs are equivalent to their American counterparts when FDA has made known to them that this is not the case. Recipients of these drugs would have fairly relied upon representations by the state, either in its role as employer or as the holder of police power for the benefit of the public health and welfare. Plaintiffs could potentially show that they acted upon the state's representations to their detriment, and that they would have refused the drugs if they had known of their foreign origin or of the distinctions between the Canadian and American versions.

E. State Collective Bargaining Agreements

Separate and apart from the risk of tort liability, states could face liability for violation of collective bargaining agreements with state employees if the supply of Canadian drugs were considered not to meet the quality or other requirements of the healthcare provisions in a collective bargaining agreement. Further evaluation of this issue would require specific examination of the terms of the agreement in a given state.

* * *

In sum, states that provide or facilitate the distribution of Canadian drugs could potentially face substantial liability under a number of tort and other theories. Cases could be brought by individual plaintiffs, or conceivably by class action, depending on the circumstances. The risk is heightened given that some of the drugs specifically identified by FDA as problematic are fairly widely used, such as Zocor and Glucophage. While the likelihood of plaintiff recovery will vary with each theory and the specific facts regarding the state's involvement in the provision of the drug, FDA's recent announcements of the serious safety concerns presented by Canadian drugs make it more likely that courts or juries would find states liable for harm resulting from such drugs.

Federal Food, Drug, and Cosmetic Act**A. The Statutory Scheme**

It is unlawful under the FDCA for anyone to introduce a new drug into interstate commerce that is not covered by an approved new drug application (NDA) or approved abbreviated new drug application (ANDA). FDCA §§ 301(d) & 505(a); 21 U.S.C. §§ 331(d) & 355(a). When a product is introduced into interstate commerce that does not comply fully with an approved application, it is considered an unapproved new drug in violation of section 505 of the FDCA. 21 U.S.C. § 355. It is also misbranded under section 502 of the FDCA. 21 U.S.C. § 352. These basic rules cover importations, since importing is a form of introducing a drug into interstate commerce.

There is no exemption from the requirements of the FDCA for importations of a version of a drug obtained in Canada or another foreign country. *See, e.g.*, FDCA § 801(a); 21 U.S.C. § 381(a) (an article shall be refused admission into the United States if it is “in violation of section 505”). Thus, any importer must demonstrate that the imported product is in full compliance with an approved NDA or ANDA in the United States for the product to be admitted to this country. This includes a demonstration that the imported product was manufactured in a facility covered by an approved application, is labeled in full accordance with the United States approval, and otherwise meets all NDA or ANDA requirements (for example, manufacturing specifications, storage and handling requirements, etc.).

In addition, the reimportation of drug products by anyone other than the original manufacturer is expressly prohibited even if the products are in full compliance with a United States NDA or ANDA. FDCA § 801(d)(1); 21 U.S.C. § 381(d)(1). This prohibition on the

reimportation of products previously manufactured in the United States and exported abroad guards against the entry of counterfeit and adulterated products into this country.

B. Proposed State Imports

Published reports of potential state importation plans contain no assurances that any of the requirements of the FDCA for importations and reimportations will be followed, and it would be virtually impossible as a practical matter for the requirements to be met. For example, even if a drug is manufactured in Canada by the same company that holds the approved NDA in the United States, there is no assurance that the Canadian product is precisely the same as the product manufactured in the United States pursuant to the specifications of the NDA. If the product deviates in any respect from the approved NDA (e.g., in some manufacturing process or specification), it may not be imported. Similarly, it is not clear how any state plan could provide safeguards to prevent the unlawful reimportation of products manufactured in the United States.

States would thus be violating the FDCA if they were to import drugs from Canada or other countries, and would be liable to FDA enforcement action. Potential state liability would exist whether the states were to structure an import program with the states as the actual importer, or with some other entity as the importer. This is because it is a violation of the FDCA not only to introduce a violative drug into interstate commerce, but also to *cause* the introduction of a violated drug into interstate commerce. FDCA § 301; 21 U.S.C. § 331.

If states structure a program so that patients themselves are importing drugs for their personal use, it would still violate the law. FDA has adopted an informal personal importation policy under which it will exercise enforcement discretion and not take action against unlawful importations under certain circumstances. *See* FDA Regulatory Procedures Manual, ch. 9-71. This personal importation policy is commonly misunderstood. The policy

applies only to the importation of small quantities of a drug for personal use *when there is no effective treatment lawfully available in the United States*. It does not apply to importations of foreign versions of drugs approved in the United States, or to reimportations.

If a state (or anyone else) attempts to import products in violation of the FDCA, the Customs Department and FDA are required under section 801(a) of the FDCA to refuse admission of the products at the border 21 U.S.C. §381(a). For products that somehow enter the country illegally, FDA could take enforcement action. For example, FDA might go to court to seek an injunction against violative importations, or seek to seize products that have improperly entered the country.

C. FDA Prouncements

The above legal analysis has been unequivocally confirmed by the FDA. Only a month ago, FDA responded to an inquiry from the State of California in an August 25, 2003 letter making clear that imports of drugs by California from Canada would violate the law. The letter is available on FDA's web site at <<http://www.fda.gov/opacom/gonot.html>>. Following are verbatim quotes from FDA's letter, which leaves no doubt about the illegality of any state import plan:

- [V]irtually all drugs imported to the United States from Canada violate the FFDCA because they are unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 353), or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Importing a drug into the United States that is unapproved and/or does not comply with the labeling requirements in the FFDCA is prohibited under 21 U.S.C. §§ 331(a), and/or (d).
- FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. Generally, drugs sold outside of the United States are not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a

drug, the version produced for foreign markets usually does not meet all of the requirements of the United States approval, and thus it is considered to be unapproved. 21 U.S.C. § 355. The version may also be misbranded because it may lack certain information that is required under 21 U.S.C. §§ 352 or 352(b)(2) but is not required in the foreign country, or it may be labeled in a language other than English (*see* 21 C.F.R. § 201.15(c)).

- [W]ith respect to “American goods returned,” it is illegal for any person other than the original manufacturer of a drug to import into the United States a prescription drug that was originally manufactured in the United States and sent abroad (21 U.S.C. § 381(d)(1)). This is true even if the drug at issue were to comply in all other respects with the FFDCA. *Id.* Importing a drug into the United States in violation of section 381(d)(1) is prohibited under 21 U.S.C. § 331(t).
- Practically speaking, it is extremely unlikely that any program in the state of California could ensure that all of the applicable legal requirements are met. Consequently, almost every time a city, county, or state program imported a drug from Canada, that program would violate the FFDCA. Moreover, individuals or programs that cause illegal shipments also violate the FFDCA. 21 U.S.C. § 331 (“The following acts and the causing thereof are hereby prohibited . . .”). Thus, neither the public nor private entities mentioned in Mr. Lilyquist’s letter can avoid jurisdiction under the FFDCA by merely “facilitating” the sale of Canadian drugs to California citizens through a third-party internet service.

FDA’s response to the State of California follows and reinforces equivalent statements FDA has made to private entities involved in Canadian import schemes. For example, on March 21, 2003, FDA issued a warning letter to Rx Depot explaining that shipments of regulated products from Canada to the United States are illegal, and on September 16, 2003 FDA issued a similar warning letter to CanaRx Services. Copies of the warning letters may be found on FDA’s web site at <http://www.fda.gov/foi/warning_letters/g3888d.htm> (RxDepot), and <http://www.fda.gov/foi/warning_letters/g4291d.pdf> (CanaRx Services).

FDA has also demonstrated its resolve to stop illegal import programs. After Rx Depot refused to heed FDA’s warning letter, FDA directed the United States Department of Justice to bring suit and seek an injunction to shut down the company’s import activities. A

press release announcing FDA's actions may be found on the FDA web site at

<<http://www.fda.gov/bbs/topics/NEWS/2003/NEW00939.html>>.

Medicaid and Medicare

Because drugs imported by a state from Canada or elsewhere would be unapproved and misbranded under the FDCA, they should not be eligible for federal coverage under the Medicaid or Medicare programs. The Centers for Medicare & Medicaid Services (CMS) has yet to address this issue to our knowledge. However, the plain provisions of the Medicaid law suggest that there would not be federal assistance for illegally imported drugs. The same is true under the Medicare law.

Only FDA-approved drugs and certain other grandfathered products meet the definition of "covered outpatient drug" in the Medicaid drug reimbursement provisions. 42 U.S.C. § 1396r-8(k)(2) (covered outpatient drug means a drug "which is approved for safety and effectiveness as a prescription drug under section 505 (21 U.S.C. 355) . . . of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act (21 U.S.C. 355(j))"). For the reasons explained above, prescription drugs imported from Canada are in almost all cases considered unapproved under the FDCA, and thus do not meet this Medicaid definition. As such, these imported drugs would not be covered by a Medicaid drug rebate agreement (42 U.S.C. § 1396r-8), and it is thus not clear whether or how federal payment would be made. *See, e.g.*, 42 U.S.C. § 1396b(i)(10)(A). In addition, the CMS regulations would prohibit federal payments for any drug not prescribed and dispensed by a licensed physician and pharmacist. 42 C.F.R. § 440.120. This very likely would not be the case for many drugs coming from Canada.

The analysis under Medicare is similar. Section 1862(a)(1) of the Social Security Act contains a general provision prohibiting payments under Medicare Part A or Part B for any expenses incurred for items or services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” 42 U.S.C. § 1395y(a)(1)(A). For use of a drug or biological to be found “reasonable and necessary,” such use also must be safe and effective. Medicare Carriers Manual § 2049.4. CMS considers drugs or biologics approved for marketing by the FDA to be safe and effective when used for indications specified in the drug’s labeling, but the drugs at issue here have no FDA approval and thus would not meet the Medicare coverage requirements.

Public Health Considerations

Compelling public health and public policy considerations exist for FDA and others to take action against illegal import programs. The laws governing the importation and reimportation of prescription drugs are carefully crafted to protect patients from illegal, contaminated, and counterfeit drugs. Any failure to enforce these laws fully and faithfully risks exposing American consumers to very real dangers. Outright counterfeit products could be imported, masquerading as bona fide United States products. Alternatively, patients might receive drugs that have been manufactured at unregistered and uninspected facilities, or that have been distributed by wholesalers without compliance with the pedigree requirements of section 503(e)(1) of the FDCA. 21 U.S.C. § 353(e)(1). These drugs may have been made and stored according to unvalidated procedures and specifications, and may not comply with current good manufacturing practices (cGMPs). Any such deviations from the rigorous standards contained in an approved NDA or ANDA could produce adulterated products that are impotent, subpotent, superpotent, or even toxic.

If FDA or other agencies unilaterally relax the existing import laws, and make an exception for state programs, it would establish a dangerous precedent. Similar import programs might be established elsewhere to bring drugs in from Canada, Mexico, or other countries. FDA would be hard-pressed to prevent this expansion after effectively blessing a state program through inaction. The ultimate result could be the creation of a new and essentially unregulated drug distribution channel that could be used to circumvent the basic protections that exist under United States law to protect the safety, effectiveness, and integrity of the drug supply.

Michael S. Labson
Miriam J. Guggenheim



AUG 25 2003

Mr. Gregory Gonot
Deputy Attorney General
State of California
Department of Justice
1300 I Street
Sacramento, California 95814

Re: Opinion No. 03-601

Dear Mr. Gonot:

I write in response to the letter of July 28, 2003, that your colleague, Rodney O. Lilyquist, sent the United States Food and Drug Administration (FDA) regarding the importation of prescription drugs from Canada into the State of California.

I. QUESTIONS PRESENTED

Mr. Lilyquist's letter asks nine separate questions about the potential liability associated with importing prescription drugs from Canada. All nine of the questions relate to one of three basic issues:

- Questions 1 – 6 query whether it is legal to purchase drugs from Canada and import them into the State of California.
- Questions 7 – 8 query whether the federal law in this area preempts the State of California (or a county or city within the state) from enacting a law that would legalize the importation of prescription drugs from Canada.
- Question 9 queries whether public pension funds such as CALPERS or CALSTRS can negotiate for Canadian prescription drug prices for their members.

II. SHORT ANSWER

FDA is very concerned about the safety risks associated with the importation of prescription drugs from foreign countries. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S.- approved prescription drugs have been of unknown quality. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA. For example, an American consumer recently ordered an FDA-approved anti-seizure medication called Neurontin from a website that purported to operate in

Canada and ship FDA-approved drugs from Canada into the United States. Nevertheless, the drug the consumer actually received had been manufactured in India, shipped from India, and was not approved by FDA for any use in the United States. In another instance, a website that purported to operate in Canada mailed insulin into the United States for use by an American with diabetes. Although the drug originally had been manufactured in the United States, it had not been appropriately refrigerated when shipped back into the country. The failure to refrigerate insulin promotes the degradation of the drug and renders it less effective. Unfortunately, however, the failure to refrigerate the product may not change its appearance, so American consumers may have no way of knowing their insulin has been mishandled abroad.

These safety concerns are reflected in the import provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), which strictly limit the types of drugs that may be imported into the United States. Congress enacted these provisions to create a relatively "closed" drug distribution system, which helps ensure that the domestic drug supply is safe and effective. Accordingly, if an entity or person within the State of California (including any state, county, or city program, any public pension, or any Indian Reservation) were to import prescription drugs into the State of California from Canada, it would violate FFDCA in virtually every instance. Furthermore, the drug importation scheme set forth by Congress preempts the State of California (and any city or county within the state) from passing conflicting legislation that would legalize the importation of certain drugs from Canada in contravention of the FFDCA.

III. ANALYSIS

1. Questions 1 – 6: The importation of prescription drugs from Canada

General Legal Framework

The starting point for our analysis is the legal framework applicable to imports of prescription drugs from Canada.¹

First, virtually all drugs imported to the United States from Canada violate the FFDCA because they are unapproved (21 U.S.C. § 355), labeled incorrectly (21 U.S.C. §§ 352, 353), or dispensed without a valid prescription (21 U.S.C. § 353(b)(1)). Importing a drug into the United States that is unapproved and/or does not comply with the labeling requirements in the FFDCA is prohibited under 21 U.S.C. §§ 331(a), and/or (d).

FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. Generally, drugs sold outside of the United States are

¹ We will limit our discussion to drugs imported from Canada because your request is so limited. The legal analysis is the same for drugs imported from any foreign country.

not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the United States approval, and thus it is considered to be unapproved. 21 U.S.C. § 355. The version also may be misbranded because it may lack certain information that is required under 21 U.S.C. §§ 352 or 352(b)(2) but is not required in the foreign country, or it may be labeled in a language other than English (see 21 C.F.R. § 201.15(c)).

Second, with respect to "American goods returned," it is illegal for any person other than the original manufacturer of a drug to import into the United States a prescription drug that was originally manufactured in the United States and sent abroad (21 U.S.C. § 381(d)(1)). This is true even if the drug at issue were to comply in all other respects with the FFDCA. *Id.* Importing a drug into the United States in violation of section 381(d)(1) is prohibited under 21 U.S.C. § 331(t).

Thus, to ensure compliance with the FFDCA, any state or private entity that intends to import prescription drugs into the United States must ensure, among other things, that it only imports FDA-approved drugs that comply with the FDA approval in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. The importer must also ensure that each drug meets all U.S. labeling requirements, and that such drugs are not imported in violation of the "American goods returned" language in 21 U.S.C. § 381(d)(1).

Practically speaking, it is extremely unlikely that any program in the state of California could ensure that all of the applicable legal requirements are met. Consequently, almost every time a city, county, or state program imported a drug from Canada, that program would violate the FFDCA. Moreover, individuals or programs that cause illegal shipments also violate the FFDCA. 21 U.S.C. § 331 ("The following acts and the causing thereof are hereby prohibited..."). Thus, neither the public nor private entities mentioned in Mr. Lilyquist's letter can avoid jurisdiction under the FFDCA by merely "facilitating" the sale of Canadian drugs to California citizens through a third-party internet service.²

With respect to questions 4 and 5 of Mr. Lilyquist's letter, please note that the preceding analysis applies also in the case of sovereign Indian nations located in the State of California. FDA considers Indian Reservations to be possessions of the United States within the meaning of 21 U.S.C. § 321(a)(2). Accordingly, FDA asserts complete jurisdiction over products within the purview of the FFDCA that are imported, purchased, or sold by an Indian reservation. See *FPC v. Tuscarora Indian Nation*, 362 U.S. 99, 116 (1960); *United States v.*

² The issue of whether persons may broker the sale of Canadian drugs through an internet operation is discussed more fully in Warning Letters that FDA sent to Rx Depot (March 21, 2003) and CanadianDiscountDrugs (June 30, 2003). A copy of those letters is enclosed and can also be obtained through FDA's website at www.fda.gov. They are particularly responsive to question number 6 in Mr. Lilyquist's letter, which queries whether an Indian nation may sell Canadian prescription drugs through a website to other residents of California.

Baker, 63 F.3d 1478, 1484 (9th Cir. 1995), *cert. denied*, 116 S. Ct. 824 (1996); *United States v. Funmaker*, 10 F.3d 1327, 1330 (7th Cir. 1993); *EEOC v. Fond du Lac Heavy Equipment and Construction Co.*, 986 F.2d 246, 248 (8th Cir. 1993).

With respect to question 6 of Mr. Lilyquist's letter, please note also that the preceding analysis applies to persons who import drugs into the United States on their person or on a bus. In those cases where the FFDCA prohibits the importation of a prescription drug, it makes no legal difference whether that drug has been imported through the mails, delivered by a private shipping company, or carried across the border on one's person. *See* 21 U.S.C. §§ 331 and 381.

FDA's Personal Importation Policy

There has been some recent confusion in the press about whether FDA's Personal Importation policy changes the law with respect to personal imports of pharmaceuticals. Recent advertisements in certain domestic newspapers and magazines have implied that Congress has made the personal importation of drugs a legal practice. Other advertisements and certain Internet sites have stated that personal importation of up to a 90-day supply of prescription medications is legal. Neither of these messages is true.

The Personal Importation policy is used to help guide the agency's enforcement discretion with respect to imports by individuals of drugs for their personal use. Under certain defined circumstances, as a matter of enforcement discretion, FDA allows consumers to import otherwise illegal drugs. Under this policy, FDA may permit individuals and their physicians to bring into the United States small quantities of drugs sold abroad for a patient's treatment of a serious condition for which effective treatment may not be available domestically. This approach has been applied to products that do not present an unreasonable risk and for which there is no known commercialization and promotion to persons residing in the U.S. A patient seeking to import such a product must also provide the name of the licensed physician in the U.S. responsible for his or her treatment with the unapproved drug product. *See* FDA Regulatory Procedures Manual, Chapter 9, Subchapter: Coverage of Personal Importation.

However, this policy is not intended to allow importation of foreign versions of drugs that are approved in the U.S., particularly when the foreign versions of such drugs are being "commercialized" to U.S. citizens. (Foreign versions are often what Canadian pharmacies offer to sell to U.S. consumers.) Moreover, the policy simply describes the agency's enforcement priorities; it does not change the law.

Potential Liability

There are many sources of civil and criminal liability for parties who violate the FFDCA. A court can enjoin violations of the FFDCA under 21 U.S.C. § 332. A person who violates the FFDCA can also be held criminally liable under 21 U.S.C. § 333. A violation of 21 U.S.C.

§§ 331(a), (d), or (t) may be prosecuted as a strict liability misdemeanor offense. *See United States v. Dotterweich*, 320 U.S. 277, 284 (1943); 21 U.S.C. § 333(a)(1). Any such violation that is committed with intent to defraud or mislead or after a prior conviction for violating the FFDCA may be prosecuted as a felony under 21 U.S.C. § 333(a)(2). Separately, it is also a felony to knowingly import a drug in violation of the "American goods returned" provision of 21 U.S.C. § 381(d)(1). *See* 21 U.S.C. § 333(b)(1)(A).

Those who can be found civilly and criminally liable include all who cause a prohibited act under the FFDCA. 21 U.S.C. § 331 ("The following acts and the causing thereof are hereby prohibited"). Those who aid and abet a criminal violation of the FFDCA, or conspire to violate the FFDCA, can also be found criminally liable under 18 U.S.C. §§ 2 and 371.

To date, FDA has focused its enforcement resources on those who commercialize the practice of importing drugs into the United States from abroad.³ With respect to question 6 in Mr. Lilyquist's letter, please note that, as a matter of enforcement discretion, FDA generally has not seized drugs from those who have taken buses across the border and then brought foreign drugs back into United States for their own personal use. Instead, FDA has attempted to educate such citizens about the safety risks associated with consuming foreign drugs. Nevertheless, FDA retains the authority to bring an enforcement action in any case in which a provision of the FFDCA has been violated.

Please also note that, under current California law, state-sponsored importation of drugs from Canada for use in the state's Medi-Cal program may violate the statutory and regulatory requirements for this program. *See* West's Ann. Cal. Welf. & Inst. Code, § 14100, *et. seq.*; Cal. Admin. Code tit. 22, § 50000, *et. seq.* For example, the importation of drugs from Canada may violate the Prudent Purchase of Drugs Program, 22 CCR § 51513.6, because the drug products are not "handled in accordance with the provisions of applicable federal and state law." In addition, we question whether the state would be potentially liable in tort if a California citizen were injured by a drug that the state purchased in violation of federal law. FDA has not researched and does not here advise you of any tort liability that may arise under state law, but we cite the issue as a possible concern.

2. Questions 7 and 8: Federal preemption

Federal preemption of state law is grounded in the Supremacy Clause of the United States Constitution. U.S. Const. art. VI, cl. 2. The Supremacy Clause states that: "This Constitution, and the Laws of the United States which shall be made in pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

³ *See, e.g.*, the Warning Letter that FDA sent to Rx Depot on March 21, 2003, the Warning Letter that FDA sent to CanadianDiscountDrugs on June 30, 2003, and the letter that FDA sent the Kullman Firm of New Orleans, Louisiana on February 12, 2003. A copy of the Kullman letter has also been enclosed for your review.

The Supreme Court has held:

under the Supremacy Clause, the enforcement of a state regulation may be preempted by federal law in several circumstances; first, when Congress, in enacting a federal statute, has expressed a clear intent to pre-empt state law; second, when it is clear, despite the absence of explicit preemptive language, that Congress has intended, by legislating comprehensively, to occupy an entire field of regulation and has thereby left no room for the States to supplement federal law; and finally, when compliance with both state and federal law is impossible, or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Capital Cities Cable, Inc. v. Crisp, 467 US 691, 698-99 (1984) (quotation marks and citations omitted); see also *English v. General Electric Co.*, 496 US 72, 78-79 (1990); *Association of Int'l Auto Mfrs., Inc. v. Abrams*, 84 F.3d 602, 607 (2nd Cir. 1996).

Courts have thus held that federal law preempts state law when, *inter alia*, Congress has intended to occupy a field of regulation comprehensively (termed "occupation of the field preemption") and when the federal law and the state law actually conflict (termed "implied conflict preemption"). See *English v. General Electric Co.*, 496 US at 78-79; *Choate v. Champion Home Builders Co.*, 222 F.3d 788, 792 (10th Cir. 2000).

Occupying the field

Congressional intent to occupy a field comprehensively can be shown any of three ways: 1) when, based on the pervasiveness of the federal regulation, it may be inferred that Congress "left no room for the States to supplement it"; 2) if the federal statute "touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject."; or 3) when the state regulation "may produce a result inconsistent with the objective of the federal statute." (emphasis added) *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 US 707, 713 (1985), quoting *Rice v. Santa Fe Elevator Corp.*, 331 US 218, 230 (1947).

In the instant matter, Congress set forth a comprehensive importation scheme in the FFDCA that strictly limits the types of prescription drugs that are allowed to be introduced into domestic commerce. For example, the "American goods returned" provision (21 U.S.C. § 381(d)(1)) was enacted in 1988 as part of the federal Prescription Drug Marketing Act. PL. 100-293 (April 22, 1988). In enacting the law, Congress cited the explicit goal of limiting the flow of drugs into the United States from abroad. In section 2 of the bill, Congress found, "[l]arge amounts of drugs are being reimported into the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping." *Id.* Clearly,

Congress enacted section 381(d)(1) and the other import provisions in the FFDCA with the goal of controlling the types of drugs that could be legally imported into the United States. The federal scheme is comprehensive in that it promulgates national standards that are to be applied equally to all ports of entry, regardless of the states in which they are situated. By definition, the scheme cannot allow the individual states to enact laws that erode the federal standards; otherwise, importers could simply circumvent the federal law by routing all their unapproved drugs into the state (or states) that allowed such imports. If the state of California were to enact a law that contravened the scheme, there is no question that the result would be inconsistent with the plain objectives of the FFDCA.

Implied conflict preemption

Implied conflict preemption can be shown in two ways: (1) where it is impossible to comply with both federal and state law; or (2) where the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. *See English v. General Electric Co.*, 496 US at 79.

In the instant matter, if the state were to enact import legislation that contravened the provisions of the FFDCA, those importing the drugs would find it impossible to comply with both the state and the federal law. Indeed, the drugs imported pursuant to the state law would still be illegal under federal law (*see* 21 U.S.C. §§ 331, 352, 353, 355, and 381), and those importing the drugs would be subject to civil or criminal liability in the federal courts (21 U.S.C. §§ 331, 332, and 333).

In addition, a state law authorizing the importation of certain drugs would frustrate the Congressional objectives enshrined in the import provisions of the FFDCA. As noted, Congress clarified the purpose behind 21 U.S.C. § 381(d)(1) when it passed the Prescription Drug Marketing Act. It concluded that American consumers are best protected by a "closed" drug system that strictly limits the types of products that may be imported into the United States. Any effort by the State of California to pass legislation conflicting with that scheme would stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress as expressed in the FFDCA.

3. Question 9: Public Pension Funds

As noted above, the import prohibitions in the FFDCA apply to both public and private entities. *See* 21 U.S.C. §§ 321(e) and 331. Thus, a public pension fund would be subject to the same liability as a private citizen for a violation of the import provisions of the FFDCA.

I. CONCLUSION

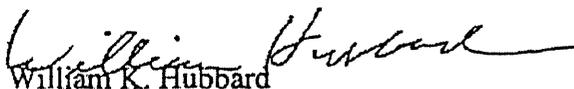
I hope that the preceding discussion is helpful to you. From a public health standpoint, FDA is very concerned about the kind of scenario described in your letter. In our experience, many

drugs obtained from foreign sources that purport and appear to be the same as FDA-approved prescription drugs have been of unknown quality. FDA approves a drug based on scientific data submitted by the drug sponsor to demonstrate that the drug is safe and effective. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA. Accordingly, the FFDCA strictly limits the types of prescription drugs that may be imported into the United States. Any state law that would legalize imports in contravention of the FFDCA would be preempted by federal law. Moreover, those importing drugs in violation of the FFDCA would be subject to liability under that statute, regardless of whether the importation was otherwise sanctioned by the state.

Nevertheless, we are aware that the high cost of some prescription drugs is a serious public health issue, and we have taken several steps in recent months to help reduce the cost of drugs in the United States without opening our borders to the potential dangers of foreign unapproved pharmaceuticals. These steps include new initiatives to accelerate approval of innovative medical procedures and drug therapies, changes to our regulations to reduce litigation that has been shown to delay unnecessarily access to more affordable generic drugs, and proposals to increase agency resources for the review and approval of generic drugs – products that are often far less expensive than brand name products and generally no more expensive in the United States than the generic drugs sold elsewhere in the industrialized world. The Administration is also working with the Congress on landmark legislation to provide a prescription drug benefit that will enable millions of America's seniors to receive coverage for their drugs in Medicare.

Thank you for your interest in this matter. If you need additional information, please feel free to contact me.

Sincerely,



William K. Hubbard

Associate Commissioner for Policy and Planning

Encl: FDA letter to the Kullman Firm (February 12, 2003)
FDA Warning Letter to Rx Depot (March 21, 2003)
FDA Warning Letter to CanadianDiscountDrugs (June 20, 2003)

March 31, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

**RE: Task Force on Importation (21 CFR Chapter D)
[Docket No. 2004N-0115]**

Dear Sir or Madam:

On behalf of McKesson Corporation, we are pleased to submit comments to the U.S. Department of Health and Human Services for the Task Force on Importation. McKesson commends the agency for undertaking a study of drug importation and we appreciate the opportunity to share our perspective.

McKesson is the largest pharmaceutical supply management and health information technology company in the world. We are also the largest pharmaceutical distributor in North America, through our ownership of McKesson Canada, the leading wholesale distributor in Canada, and our equity holding in Nadro, a leading distributor in Mexico. We provide a broad array of products and services to over 5,000 hospitals, 35,000 physician practices, 10,000 extended care facilities, 700 home care agencies, 25,000 retail pharmacies, 600 payors, 450 pharmaceutical manufacturers and 2,000 medical-surgical manufacturers. McKesson also repackages over 1.5 billion doses of drugs annually and provides analytical testing services in support of these operations.

For the past 170 years, McKesson has led the industry in the delivery of medicines and health care products to drug stores. Today, a Fortune 16 corporation, McKesson delivers vital medicines, medical supplies, and health information technology solutions that touch the lives of more than 100 million patients each day in every health care setting. We understand the critical importance of medication safety and the need to protect the integrity of the pharmaceutical supply chain. McKesson has strict policies and procedures in place that both ensure the safety of the products we distribute and exceed the safety requirements of the countries in which we operate. We source 99.5% of our products in the U.S. and 100% of our products in Canada directly from the manufacturers.

We also understand that many people do not have adequate access to the pharmaceuticals they need. As the administrator of the Together Rx™ card, McKesson has actively promoted a safe and workable solution to high drug prices for low-income seniors. As of

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Comments for HHS Task Force on Importation, FDA Docket No. 2004N-0115
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March 28, 2004, over 1.2 million seniors are enrolled in the Together Rx™ drug savings card and have obtained demonstrated savings of over \$318 million.

McKesson has also been an industry leader in the development and application of technology in health care supply management, in pharmacy automation, and in bedside barcode scanning of pharmaceuticals to assure patient safety. We were the first drug distributor to fully automate our distribution process by implementing radio frequency and scanning technology throughout our entire warehouse and distribution network. Today, we are engaged in a joint innovative effort with Wal-Mart to beta-test RFID (radio frequency identification) technology for use in tracking inventory and assuring product safety.

Evaluation of Drug Importation

Our long history and expertise in the pharmaceutical distribution business in both the U.S. and in Canada, combined with our steadfast commitment to a safe and cost effective drug supply, provide us with unique insights on many of the questions that have been raised concerning the importation of pharmaceutical products.

McKesson has serious concerns that a broad-based importation system may not assure both product safety and cost savings to the American consumer. However, it is possible that the safety and cost savings issues could be addressed through a narrower “closed distribution” system. Under such a system, pharmaceutical distributors with the appropriate technology, experience, and distribution networks on both sides of the border could safely transfer products between their distribution centers in Canada and their distribution centers in the U.S. To assure safety, these distributors must source 100% of their products directly from the manufacturers. Clearly, such a system would depend on the availability of product in Canada, the cooperation of key members of the supply chain, and the development of an allocation system to ensure equitable distribution to the American public.

It is important to recognize that U.S. demand for lower-priced pharmaceuticals will always exceed the available supply from Canada or from any other exporting country. The U.S. pharmaceutical market is the largest in the world, amounting to almost half of the world’s pharmaceutical spending. In comparison, the Canadian market is less than 1/20th of the size of the U.S. market. This imbalance in demand will require an allocation system to ensure equitable distribution of the available imported pharmaceutical products. McKesson recognizes that any allocation policy will be highly controversial and will require government intervention.

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If an importation system is devised, we believe there are significant challenges that may make it difficult to safely provide an adequate supply of lower priced product. Addressing these challenges will add costs that could negate any potential savings. To ensure a secure and cost-effective supply chain, the Task Force must address the following issues of product safety and costs.

Safety

The preservation of a safe pharmaceutical supply chain is essential. There are several factors affecting the safety of imported products that merit particular attention.

1) Regulatory Oversight

As we have previously noted, demand in the U.S. will far outstrip the available foreign supply of pharmaceuticals. This disproportionate demand may create financial incentives for legitimate and illegitimate operators to seek alternate sources for prescription drugs and increases the threat of a gray market for vital medicines.

While Canada has strict policies in place to ensure the safety of pharmaceuticals for its citizens, the Canadian government has stated that it cannot guarantee the safety of drugs shipped to the U.S. At the same time, the U.S. lacks the resources to adequately monitor products shipped directly to patients over the border. Actual or alleged trans-shipment of product through Canada could result in the development of a gray market that is difficult to monitor. Adequate regulations and supporting resources are needed to prevent the shipment, through Canada, of pharmaceutical products that are improperly stored or handled, sub-potent, expired, adulterated, or counterfeit. Additionally, the institution and enforcement of severe criminal penalties are needed to deter those who knowingly distribute compromised pharmaceutical products.

Internet and international mail order pharmacies provide another channel for the importation of foreign product which is unregulated by U.S. authorities. McKesson believes that the lack of international, federal and state regulations has left consumers vulnerable to unsafe drugs. We have previously recommended that the FDA ban domestic and international prescription drug sales via the Internet unless those transactions and businesses are held to the same regulatory and licensing standards established by the Prescription Drug Marketing Act, state Boards of Pharmacy, and Departments of Health, and currently applied to U.S. distributors and pharmacies.

2) Product Testing, Packaging and Labeling

Appropriate testing of imported products may be required to ensure safety and potency. While resources exist at McKesson and elsewhere to test imported products, questions

Comments for HHS Task Force on Importation, FDA Docket No. 2004N-0115
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remain as to the parameters of the testing, ability to access patented information to assure adequate testing, liability and costs associated with the testing.

Under current federal regulation, most foreign labels and packages do not comply with the Food, Drug & Cosmetic Act, as required for legal sale in the U.S. Lack of barcoding or NDC numbers on foreign products may require additional repackaging to enable rapid and efficient distribution of these products from wholesalers to pharmacists to patients. Country of origin labeling and language requirements for package inserts must also be considered. Should patient or product safety concerns necessitate relabeling or repackaging of imported products, additional costs will ensue.

3) Inventory Tracking

McKesson has been an advocate and leader in the adoption of technology to track and trace products through the supply chain. The use of electronic technology to track products from foreign countries would help to ensure that products are sourced in FDA-approved facilities and shipped through legitimate wholesale channels prior to sale in the U.S. The effective implementation of such a system for importation, however, poses significant challenges. Pharmaceutical manufacturers must agree to tag products globally at the time of manufacture, and approved foreign intermediaries must adopt the electronic reading technology. Despite wide spread support for such technology, harmonized standards to facilitate broad adoption of these technologies are still under development.

Tracking products without such electronic documentation could compromise the integrity and the efficiencies of the pharmaceutical distribution network. Paper pedigrees that are designed to document the source of the product and its movement through the distribution chain are subject to counterfeiting. McKesson has previously submitted comments to the FDA in opposition to the use of paper pedigrees, which can be easily forged and which cannot be effectively transmitted through our currently paperless and virtually automated distribution channel.

4) Recall Mechanism

Product recalls are currently initiated by the manufacturer and facilitated by wholesalers and pharmacies. Most recalls are national in scope, not global. It will be necessary to establish a process for recalls in the absence of a single governing body that has jurisdiction on both sides of the border. In order to execute a recall of foreign products, systems will have to be developed and instituted to monitor and track foreign-sourced products. It is also likely that segregated inventories of foreign-sourced and domestic-sourced product will have to be maintained at the wholesaler and pharmacy level. Questions will arise as to responsibility for initiating and overseeing the process and subsequent liability for such recalls.

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Costs

Ensuring the safety of the supply chain will add significant costs to imported product. Regulatory oversight, testing, repackaging/relabeling, tracking and recall mechanisms will reduce any available cost savings. In addition, other factors could further increase the cost of importation and reduce savings to U.S. consumers:

1) Proper Importation Documentation

Well executed importation has associated costs, including import/export licenses, customs broker fees, tariffs, bonds, and documentation fees.

2) Product Pricing

The economic principles of supply and demand, as well as currency fluctuations, will also impact any cost savings available through importation. In Canada, national and provincial bodies currently set and regulate prices for pharmaceutical products. These regulations apply only to products dispensed in Canada. Canadian price controls exist for Canadian citizens, not for the export market. In a legalized importation environment between the U.S. and Canada, we would expect the prices at which Canadian entities sell to the U.S. to rise as demand exceeds available supply. In fact, drugs exported from Canada are already sold at prices above domestic Canadian prices.

3) Generic Substitution

Generic pharmaceuticals are generally less expensive in the U.S. than in Canada and account for approximately 45% of the unit volume of drugs consumed in the U.S. American pharmacies today actively promote generic substitution. Under legalized importation, consumers may ultimately pay more to import a branded product than they would for a domestic generic product that is readily available.

4) Reimbursement

Reimbursement for pharmaceutical products by third party payors will need to be thoughtfully addressed in any importation system. Pharmacies and payors will need systems to track different channels of product acquisition in order to accurately reflect their average acquisition costs, upon which reimbursements by Medicaid are based. Foreign-sourced drugs will not have NDC numbers, which are the basis for most pharmacy management and reimbursement systems. Furthermore, it remains unclear as to what extent health insurers and government payors, including CMS, would reimburse pharmacies and patients for foreign-sourced products. Administrative complexities, and resulting costs, would increase as insurers implement systems to track and reimburse foreign-sourced products and provide adequate medication therapy management, drug utilization review, safety and counseling efforts for these products.

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5) Liability

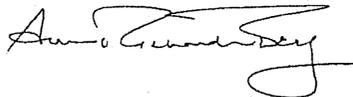
The importation of pharmaceutical products is also likely to entail the assumption of additional liability. Without regulations governing liability for imported product, it is unclear who (e.g. manufacturers, importers, government, payors) would bear liability for any adverse drug events associated with products sold outside their country of intended use. Additionally, since September 11, 2001, security concerns coupled with the rising cost of insurance have made it increasingly difficult for companies to attain adequate liability coverage. Liability insurance covering imported products is likely to be costly, thereby further reducing available cost savings.

Conclusion

Given our unique capabilities in Canada and the U.S., we stand ready to share our expertise to help the Task Force better understand safety and cost issues associated with drug importation. McKesson is committed to removing unnecessary costs from the health care system as we ensure the timely delivery of safe, cost-effective products. We remain concerned about the safety, cost and allocation issues which we believe could present significant barriers to the successful implementation of any importation system.

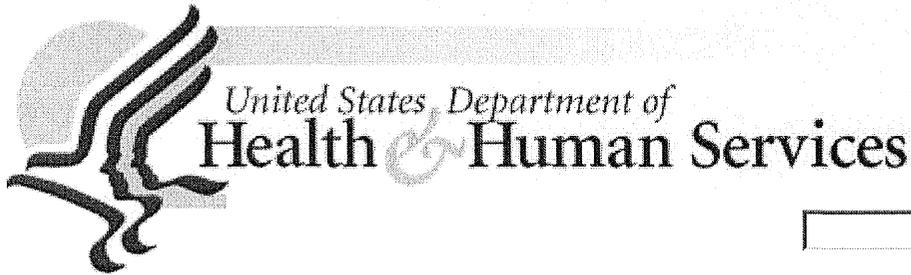
McKesson appreciates the opportunity to provide comments and recommendations based on our distribution experience within North America and the strict policies and procedures we have implemented to assure product safety. We applaud the FDA's commitment to providing a safe channel for lower cost drugs, and look forward to ongoing collaboration and cooperation to ensuring the safety, efficiency and effectiveness of the pharmaceutical distribution system.

Sincerely,



Ann Richardson Berkey
Vice President, Public Affairs

ATTACHMENT C



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- [Listening Session #6: Professional Medical Groups - May 14, 2004](#)

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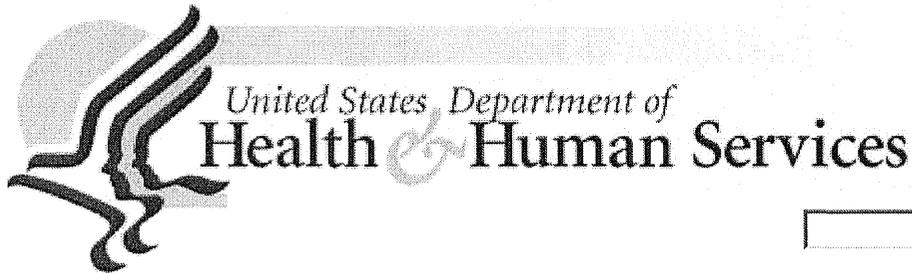
- [Submit an E-comment To the Docket](#)
- [Detailed Drug Importation Questions For Task Force Public Docket and Meetings - April 5, 2004](#)
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Consumer Stakeholder Meeting - March 19, 2004

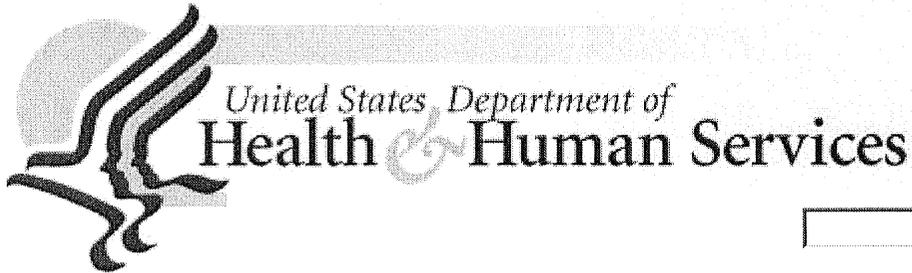
- [Listening Session #1: Consumer Groups, Welcoming Remarks, Surgeon General Richard Carmona](#)
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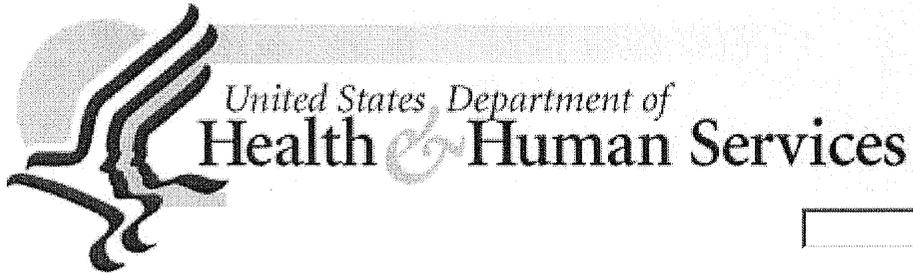
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HHS Task Force on Drug Importation

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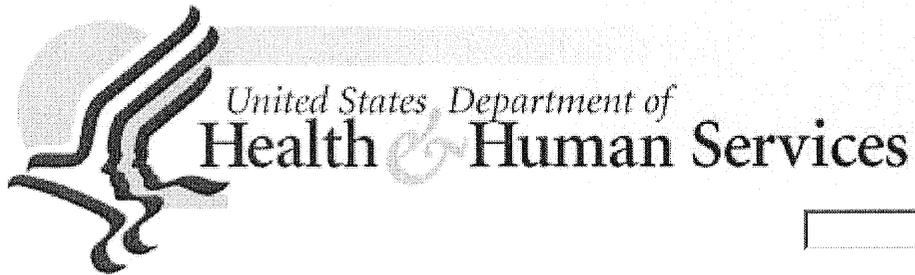
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HHS Importation Task Force

Public Meeting

Wednesday, April 14, 2004

**Natcher Auditorium, National Institutes of Health
Bethesda, Maryland**

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I. Opening Statement – Task Force Chair, Vice Admiral Richard H. Carmona, M.D., M.P.H., FACS

Good morning, ladies and gentlemen. I would like to call meeting to order and start the meeting. I am Richard Carmona, the U.S. Surgeon General. I would like to welcome you to this public meeting of the Task Force on Drug Importation. Today we will hear from members of the public who have indicated that they would like to make presentations to this task force.

Secretary of Health and Human Services Tommy Thompson formed this task force to explore whether and how drug importation might be conducted safely and its potential impact on the health of American patients, medical costs, and the development of new medicines.

On behalf of Secretary Thompson, I want to thank the members of the task force for your willingness to work on this important issue. It's an extraordinarily complex topic that challenges the best minds in the field.

The past two weeks, we have held the first two listening sessions of this task force. We heard presentations, in the first session from consumer and advocacy groups, and at the second session from pharmaceutical development and distribution companies. Those presentations were very useful to this task force. I thank the presenters not only for their thoughtful presentations but also for their responses to our follow-up questions.

The safety and efficacy questions related to importing prescription drugs into our country are very important to the nation's health.

As a trauma surgeon, the former CEO of a health system, and now doctor the American people, I understand the critical role that prescription drugs have in our public health system. The miracles of modern medicine are often found in a pill. It's truly wonderful that science has brought us medications that can unclog arteries, lower blood pressure, cure infection, and save or enhance life.

Millions of Americans have come to depend on prescription drugs to keep them healthy. The biomedical research that has led us to the development of these drugs is truly awesome.

The task force is first and foremost about the facts and the science. And we will go as far as the facts and the science will lead us. I thank everyone, in advance, for keeping this in mind.

Together, this task force, the members of the public, and the stakeholders are exploring whether prescription drug importation can be done safely and effectively. And if so, what resources are needed. Our mission, outlined in the Medicare Prescription Drug Improvement and Modernization Act of 2003, is to determine whether there is a safe structure for prescription drug importation.

As I did at our first two sessions, I want to promise all of the presenters today and in the future meetings, the opportunity to be heard. I expect this process to be completely transparent, with frank, open, and honest discussion about the health implications of drug importation. I expect that diverse ideas will be presented, and I ask everyone to be respectful of that diversity.

These meetings are being conducted in an organized manner, in an effort to produce the best possible information. As with previous sessions, each of today's presenters will have up to five minutes for prepared remarks. Please note, in the front is a timer; goes from green to yellow to red. I'd ask speakers the speakers to be cognizant of it, when you see the yellow light, you have about a minute left, and I'd ask you to begin summing up at that point. After a presenter has concluded his or her remarks, the task force members may follow up with some questions for that presenter.

I ask each presenter to be mindful of the five-minute limit for presentations so we can ensure that everyone has an equal opportunity to be heard. In addition, the task force will welcome all written and supporting materials that parties would like to submit.

Those materials, along with the transcript of each listening session, will be available to the public. The Department of Health and Human Services has developed a web site for the task force that can be reached through www.hhs.gov

One last bit of business; is there anyone in the audience that would require signing for any of their presentations this morning? Because we want to make sure that's available. Nobody is identified; OK, thanks so much.

With that, let's get going with today's business. I would like again to thank my fellow task force members for their time and we will now welcome the first presenter and that would be Rick Roberts. Mr. Roberts, thank you and Mr. Roberts let me just mention for you and any of the speakers, that you have the option to come to the podium on the stage if you like, or use one of the three microphones -- the one you're at or either at the two aisles -- so, whatever makes any of the presenters the most comfortable to you, please make the selection of where you'd like to be.

Presentations from Registered Speakers

Rick Roberts, Consumer

Great, thank you, and I'm just going to move this, if that's OK, 'cause I can't see the light from here and I want to try to stay to my time.

My name is Rick Roberts and I feel very fortunate to be here today. And I'm glad to have the opportunity and I thank you for the chance to share my experience, what I have learned through those experiences, and my concerns about importation and reimportation.

I started college as an 18-year old in 1981 in San Francisco. I was infected with HIV in the early 80's. As you know, HIV was later discovered and in 1988, I became ill and was diagnosed with AIDS Related Complex, which progressed to AIDS. I'm going to kind of fast forward 12 years from that time to the year 2000. Those 12 years were an interesting time; had some ups and some downs, but in the year 2000 I was diagnosed with AIDS wasting syndrome, although it doesn't look like it right now, I was wasting at that time. And I had failed on a couple of therapies and my doctor said our last try was going to be a drug called Serostim recombinant human growth hormone. And that cost four to six thousand dollars a month, and I was fortunate enough to have the insurance company approve a 12-month supply.

I started injecting that and had very good results. More than half way through my time of injecting Serostim, I noticed a stinging at the injection sites that I hadn't noticed before, and some subtle differences in packaging and in the amount -- or the dose -- of the power itself. What... I wasn't alarmed. I've had lots of drugs change size, shape, color. I just a note I wanted to ask my pharmacist, so I went into the CVS pharmacy where I got my Serostim every month and I asked the pharmacist. And, I told him what was going on and I asked him if I was doing something wrong or if something had changed? And he nonchalantly commented that "You should go home and check, because you may have received some of the fake stuff."

So, I did go home, and by the time I got off the bus and got home I had convinced myself I must have misunderstood what he said, because how could that be? I went to the CVS pharmacy in my neighborhood and it was the box just as it was supposed to be. I was wrapped in plastic, it has the label on it. Fake stuff. I went online and, sure enough, found an article in the *Boston Globe*. Three paragraphs saying that fake Serostim could be found in seven different states. And that the FDA was doing an investigation. Went to the FDA website, found the notice there; went to Serono, the manufacturer's web site and they said were cooperating with the FDA.

I called my doctor. She hadn't heard about this. Went in to talk to her and she said, we have to find out if it wasn't growth hormone what it was you were injecting, because we need to know if there's something we should be doing if you have done some harm, we want to counter that -- we need to find out. We couldn't find out. Nobody knew what was in those vials. Which started, for me, a really difficult time of not being able to sleep, I became very preoccupied. Couldn't focus; I teach at the University of San Francisco, and found it really difficult to do what I was supposed to do. I started having anxiety attacks. For 12 years, we knew who the enemy was, we were fighting HIV. For the first time, I had no idea what we were up against.

In my mind, though, I kept going to the thoughts that they had put Hepatitis-C in those vials, and I had injected myself with Hepatitis-C. And, that's what I thought. It took three months to find out that it wasn't Hepatitis-C in those vials. I had been injecting HCG – Human Chorionic Gonadotropin -- which is the hormone women make when they are pregnant and it's used as a fertility drug. It's not meant to be injected subcutaneously, and it's certainly not meant to be injected every day. It does explain why I was an emotional wreck for a while. So, I, though, discovered that I had received two different batches perpetrated by two different persons or groups. The second batch, I found out three months later, had contained that form of growth hormone but, based on the contaminants, it was probably produced outside of the U.S. and it was 1/6 the dose I was supposed to be receiving.

How does this relate to reimportation or importation? I had gone through an American pharmacy. It turns out that this was distributed through the secondary market, through a licensed wholesaler in Florida. As far back as I know that it's been traced, who sold it to a licensed wholesaler in Las Vegas, Nevada, who sold it to a secondary licensed distributor in New York. This is much like money laundering to clear the pedigree, because once they put it through an authorized dealer, the pedigree doesn't have to be included in the next sale. And then it was sold to the major distributors who had contracts with the major pharmacies and that's how it got to the seven different states.

I have since worked with – talked with the FDI, to the manufacturers, the Nevada Board of Pharmacy the law enforcement agency for the state of Florida (who investigates counterfeit medicine), and even the FBI. I have testified against these bad guys. They are really bad – they don't care. They found \$47 million of bad medicine in Florida in one year: cases of insulin, not refrigerated in the Florida sun. These are bad guys, and they know what they're doing and they do it really well.

I have learned that the longer the distribution chain, the more likely -- or the more doors are opened for these bad guys to do what they want to do which is to make money at the expense of sick people. So, I need to sum up. I am afraid... these are my concerns: that as we elongate and go outside the jurisdiction of the FDA, and we go with links in this chain of distribution, that we create opportunities for the bad guys.

So, the safely issue, I don't think, is secondary or a smoke-screen, as people have told me. I think it is a primary concern. My concern is that, people like me, who may receive a counterfeit, what recourse do we have? What do we have – where do we find relief? Who would we find responsible? If we're having trouble paying for our medicines – and I've been there, maxed out my credit cards buying AZT in the 80's, and borrowed money to get my medicine – I'm not going to going to be able to afford an international tort lawyer to represent me in some other country. Who will be responsible if this happens and why would we open the doors that would allow this to happen? I don't know of any savings monetarily or discounts that could be offered that would make it worth jeopardizing people's health, or allowing the bad guys to do to you or anyone in this country what they've done to me. Again, thank you. I feel fortunate to be here, and thanks for listening to my story.

Carmona – Thanks very much Mr. Roberts. Would you hang on just a second in case any of our task force members have any questions of you?

Roberts – Yes, sorry.

Carmona – Thanks. We'll all get used to it as we go through the day. Members, anybody have any questions for Mr. Roberts? Yes, Dr. Crawford.

Lester Crawford, DVM, PhD, FDA deputy commissioner – I'd just like to thank you for that testimony and for your courage in being here. Since the event in the year 2000, obviously you have educated yourself about this problem. Are there special steps you could share with the group

that you yourself take in order to ensure against this happening again?

Roberts – Yes. I am now well-known to my pharmacy, I go to another pharmacy. I go -- it's a 24-hour pharmacy -- I usually go after midnight. They know me by name; they know I won't leave the counter until I've gone through every prescription. I look at every drug before I leave the counter, because once you take it away from the counter they can't take it back. They're used to me calling with questions and asking questions. And I question everything that's different. I have a bottle of Lipitor at home that we can't track to the Lipitor recall and I'm not going to take it. I don't know what the odds of getting three counterfeits are, but I'm not going to take a chance. So, that's what I can do, I just think the responsibility shouldn't fall on the patient. Cause I don't know what else we can do except to ask the pharmacist or our doctors. But I do recommend, if anyone feels anything different they hadn't noticed before, or notices any changes, they should check, and the FDA website is a useful place to look, too.

Crawford – We would invite everyone to do that, on behalf of the FDA. Thank you.

Carmona -- Other questions?

William Raub, HHS deputy assistant secretary for public health emergency preparedness -- Just to follow up on that, when you went back and found the drug with the burning sensation – you said there were subtle packing differences. Can you describe those and the quality of the product in terms of the sophistication and the comparison?

Roberts – Would you like to see them? I have them with me.

I would, I would. Did in fact, the pharmacist that gave it to you, that gave you the product, did they in any way realize that the product was counterfeit? Even when you brought it back and looked at it, could they tell that it was a counterfeit product?

Roberts -- I don't think so, and I'm glad to share it. I actually have the counterfeit and the real. I understand how the pharmacist passed it one. I don't think that they are necessarily looking for counterfeit all the time, and you can tell for yourselves if you could be able to identify the difference or not. And I certainly didn't; only because I was looking at it so closely -- each vial -- because I was injecting it, I noticed some subtle changes. But I don't think... I mean, it's such a good counterfeit, I don't think the pharmacist would be able to pick it up. What was surprising to me was that when I got home, the FDA knew, the manufacturer knew and the pharmacy knew -- because they had received a letter saying the product had been recalled and they had sent everything they had on their shelves back. That's how he knew to tell me to go home. But, nobody ever notified me. And, I've said this before, when I've had a car part recalled, they have had to track me down, notify me, track that part, remind me that I didn't get it fixed. But for some reason, there's no policy like that for pharmaceuticals, so I found out by chance. I have no idea how many people might think they just failed on the Serastim, and got the fake stuff.

Carmona – Any other questions?

Raub – It would be nice if we could see the product, if he's got it.

Roberts – I'll just point something out, if I can, and then I'll have you take it, look at it. It comes in a seven-day supply box, it comes with a diliant bottle and a powdered drug bottle. This, well, top one is real; the bottom one is counterfeit. And you can look at the vials and decide. After it happened, Serono put a hologram on the box to help identify the real stuff, but within a couple of months, the counterfeiters were able to make the boxes with the holograms as well and there were two more counterfeits of this drug a year later with the holograms on it. The one with the hologram, the way I can tell, is because this blue is a little bit darker on the fake one. So, when you get it, look really closely, and this blue that's a little darker is the fake one

Carmona – So what you're saying is – I hadn't seen those before – is that those who made this provided countermeasures in effect to make it look the real thing, and when we got a hologram on it, they also put a hologram on it?

Roberts – And there's another difference. You can tell that the labels are slightly rounded on the corners on the bottle on the vials, that's the real drug, and the more square corners are the counterfeit. They weren't real good at cutting the labels out. But very small, subtle differences, as you'll see. And, with laser printing and scanning, they were able to – they had the package insert and the instructions to the patients, all that they were able to recreate and pass it off.

Carmona – Yes, Ms. Willis.

Elizabeth Willis, chief of the Drug Operations Section, Office of Diversion Control, US Drug Enforcement Administration – Yes, Mr. Roberts, you mentioned that the drug had gone through several layers of the secondary distributors industry. Do you know how many layers it had actually passed through?

Roberts – The FDA may have more answers. When I testified in the case in Las Vegas against the company in Las Vegas, their sole supply of the medicine came from a company licensed under the name Rekcus in Florida. R-E-K-C-U-S, which is that's "suckers", spelled backwards, that was their license name in Florida. And, they were getting medicines from a number of places; expired medicines that were supposed to be destroyed that doctors were sending them from South Carolina so they could reliable with new expiration dates. Things like that. They were getting them from a lot of different places and some that were, apparently, international. So, we're don't know exactly where these started but we can trace it from Florida to Nevada to New York -- the big three. And the FDA is still on-going, so the FDA has a lot of things they say they can't talk to me about.

Carmona – Other comments, questions? No? Mr. Roberts, to echo what Dr. Crawford said, we appreciate your time and also your willingness to expose these very private parts of your life for the benefit to the American public.

Roberts – Yes, thanks for listening.

Carmona – Before we move on to our next speaker, let me... I was remiss in not introducing a new member of our task force. At the very far end on the right, Tracy Hardin, an attorney with the Department of Justice. Her predecessor left because she was promoted to a judgeship, I believe, and Tracy was good enough to come and join us after being nominated by the Department of Justice, so welcome and thank you for being with us. Our next speaker is Dr. Rene Rodriguez, from the Inter-American College of Physicians and Surgeons. Dr. Rodriguez, welcome and Dr. Rodriguez, if you'd like you can use the podium on the stage or any of the microphones on the floor. Whichever you prefer, sir, your call.

Rene Rodriguez, Inter-American College of Physicians & Surgeons

Thank you very much, sir, and good morning. My name is Rene Rodriguez and I am a medical doctor and president of the Inter-American College of Physicians and Surgeons. Since 1979, we have worked to promote cooperation among U.S. Hispanic physicians. I am here today because this great country, and some of its most vulnerable citizens are in grave danger.

We have the safest and best medicine supply in the world but proposals for prescription drug importation could dismantle this system. Those who favor importation have good intentions: to lower costs and increase access to medicine. But that they propose to do with an irresponsible and unacceptable trade-off between price and safety. With foreign importation, the U.S. FDA would not be able to exercise the same safety control over prescription drugs that it does now.

The drugs may be real drugs or they may be counterfeit, they may be effective in treating patients, or they may not.

Even worse, they may actually be harmful. The truth is, we don't know which is which until someone has paid the ultimate price with his life. While some think that imported drugs are somehow OK, because Canada has tough domestic standards, nothing could be further from the truth. Imported medicine – you saw what happened already -- are not guaranteed to have been inspected by Canadian authorities who have stated that they do not have safety responsibility for drugs exported to the U.S.

Doctors know that, when they prescribe a drug for a patient, that they will be able to get real medicine that really will cure the patient. Right now, doctors have that confidence. If this misguided proposal becomes law, no doctor will be able to have this confidence and the health and safety of millions of Americans will be compromised.

The Inter-American College of Physicians and Surgeons plays an important role in minority communities. And I ask you to consider this issue from the point of view of minorities. Minority and low-income and other traditionally underserved populations will likely get a disproportionate share of these bad medicines. As state Medicare programs struggle to save money, it is those who have the least ability to pay who will be hurt the most. They will end up with a two-tier system, where people in the suburbs get safe, FDA medicines, and people in the barrios get medicines of unknown quality and origin. For these reasons, we believe that importation drugs really will end up in the low-income areas, in the barrios, and we believe they are a bad prescription for the good medicine that we have in this country. Thank you, sir.

Carmona – Thank you, Dr. Rodriguez, task force members, does anyone have questions for Dr. Rodriguez. No? Dr. Rodriguez, thank you so much, we very much appreciate your being here. Our next speaker will be Steven Gibson, from the ALS Association. Is Steve Gibson present? OK, what we'll do then, for a matter of administrative course in these proceedings is, if someone is not present, they'll just move to the end of the list. So if any of you know Mr. Gibson and he comes in, we'll just take him at the end of the list. We'll move on to our next speaker, who will be Mr. Noel Curb, SPC Global Technologies. Mr. Curb, are you OK standing there?

Noel T. (Tom) Curb, SPC Global Technologies

Yes, I came up here; this [podium] will help hold me up. I just wondered, did ya'll start timing me when I started up the stairs? I told the chairman that I'm from Texas, I can't introduce myself in five minutes. I asked for 30 or 40 minutes for my comments. (Laughter.) I'm going to parse this down, but it will be complete in the hard copy and a CD for you guys.

My name is Tom Curb, I've been a resident pharmacist for 41 years with more than 38 dedicated aspects of managed care pharmacy benefits related to hospitals, HMOs, PBMs, retail pharmacy networks, development of prescription claims processing, pharmaceuticals purchasing and as an independent consultant on matters pharmaceutical.

My background and experience qualify me to allow me to make the following comments and observations. The challenge before this commission is to assess the potential for a cost effective and safe system for the importation of Canadian prescription drugs.

I will describe such an importation program with documented cost-effectiveness and patient safety. First, necessary elements must be defined and addressed. Lowered drug cost is a given; informed Americans know they can obtain cheaper drugs from outside the United States. The effectiveness and safety, appropriate therapeutic response and patient safety demand two primary considerations: product efficacy and real-time electronic safeguards; the former being affected by accountability of source, and the latter by applications of proven, technological edits.

Product efficacy. Dire government and industry predictions about unsafe or substandard drugs from licensed Canadian pharmacies have proved invalid. Documentation of more than 38,000 Canadian source prescriptions subjected to the below-described safeguards reveal that there were no reports of counterfeit drugs, substandard drugs, or adverse drug events. These statistics are especially important because the majority of patients had affiliated medical benefit programs and thus were subject to consistent and routine physician oversight.

Real-time electronic safeguards. Although there is no validated evidence of product-related death or injury to Americans importing drugs from licensed Canadian pharmacies, tens of thousands of patients obtaining drugs from within the U.S. system die or are seriously injured from adverse drug events. To help prevent these, U.S. pharmacists are required to maintain patient profiles with their drug utilization histories that interface real-time with technologies that identify potential medication-related problems. Also, prescription benefits managers, or PBMs, require claims processors to maintain a central profile of each member's drug utilization within the provider network, and for the profile to be linked to similar patient-protective technologies.

The primary purpose for these patient-protective technologies is the prevention of adverse drug events caused by drug-to-drug interactions. An essential deterrent for which is a comprehensive patient profile. Obviously, even within the internal U.S. system, applications of these patient-protective measures are not universal. Many Americans do not consistently trade at one pharmacy, and an out-of-network situation will occur if a customer obtains a prescription from a non-technologically linked pharmacy, or if a prescription is not submitted to a PBM claims processor.

An out-of-network prescription permanently contaminates the patient's profile with respect to that medication and all subsequent medications. Without appropriate technological monitoring, imported prescriptions will also meet this out-of-network criteria. Increasing public awareness of cheaper foreign drugs, and ease of acquisition via the Internet, cause perceptive health care providers to recognize an imminent danger to their members' health from potential out-of-network prescriptions.

To alleviate risks due to omission of data about imported drugs from members' drug history, and in an effort to fulfill their obligations to protect members' health (and in many cases the plan's resources), proactive benefits plans took preemptive actions to incorporate proven protective measures into benefit's designs. Also, recognizing the danger from data omission in customers' drug profiles, visionary retail pharmacist retailers have tried to fill that obvious void. Facing the increasing threat of reduced revenues, they offered to supplement their in-house patient profiles with imported drug data, to inform their importing customers or safer mechanisms, to advise them of the relative cost of domestic versus imported medications and to answer customers' questions about the products that they may choose to import.

I emphasize this technological aspect of a safe mechanism because some regulators seem to misunderstand the process or they underestimate its importance. Despite the irrefutable need for these universally acclaimed and professionally endorsed safeguards -- and ignoring evidence that the lack thereof is a much greater threat to citizens than unsupported, product-related concerns -- the federal government, in concert with state officials and regulatory agencies, is attempting to prevent application of these safety measures to imported prescriptions.

Hopefully, theirs is just not another effort to placate a narrow but influential constituency. For, by discounting the necessity of such measures, regulators will create a preventable and yet grave and imminent danger to American consumers. If regulators do not ensure to these safeguards, they will have abandoned their mission to protect Americans' health and, instead, create a deadly environment that is diametrically opposed to the safer one of application of universally endorsed and proven health care technologies.

Carmona – Mr. Curb, would you please sum up now?

Curb -- Yeah. Under the safe and cost effective mechanism, licensed Canadian pharmacies would be certified or subject to an acceptable professional criteria. In the absence of this reciprocity and our dual licensure, Canadian prescribers would be credentialed based on accepted, professional criteria that would include review of requirements. U.S. prescription benefits plans, and all other PBMs, would be allowed to coordinate with credentialed Canadian pharmacies to obtain medical and drug data that have been supplied to them by their importing members, and to electronically processed Canadian prescription claims for these members. U.S. retail pharmacy would be allowed and encouraged to establish cooperative relationships with Canadian pharmacies and/or U.S. PBMs that would enable them to become involved in their customers importation processes. The technologies, safeguards and processes that could accomplish these programs have been developed, prototypes can be demonstrated and positive results validated. For those 38,000 prescriptions that were mentioned earlier, the Canadian savings were in excess of \$6 million, when compared to already-reduced prices in the U.S. pharmacy network – an average saving of \$150 per prescription, more than 50 percent. I have answers to all of your specific questions, but I guess you'll have to get them off of the CD.

Carmona – We'll certainly look at your record that you've provided to us. I appreciate it. Task force members, anyone have any questions for Mr. Curb? Thank you, sir, for your testimony. Appreciate it. Our next speaker is Peter Neupert of drugstore.com. Mr. Neupert.

[Peter Neupert, drugstore.com](http://www.drugstore.com)

Good morning, and thank you for the opportunity to speak today. I'm Peter Neupert, Chairman of Drugstore.Com, a leading online of health, beauty, vision, and pharmacy products. We were one of the first fully licensed online pharmacies, back in 1999.

The Internet has empowered consumers to comparison shop for their prescriptions. For example, Drugstore.com was the first to make all of our prescription drug prices available online to any consumer. Because we believe that empowerment is a positive thing. However, it is the same medium, the Internet, that has made it so easy for unscrupulous, unregulated and untouchable entrepreneurs to put U.S. consumers at real risk for their health.

Since 1999, our safety and privacy claims have been substantiated by a thorough audit, conducted by a trusted, independent organization – the NABP, the National Association of Boards of Pharmacies. Trusted verification is especially important on the Internet, because the consumer does not have the visual cues available in the physical world; things like which neighborhood it's in, the cleanliness of the site, the licenses, the orderliness and the like.

As cross-border importation of prescription drugs becomes more popular and widespread, the problems will only get worse, exponentially. This is the nature of the Internet; trends accelerate at a breakneck pace. Consumer demand will create supply, while more marginal players that exist will set up shop to tap into the bigger and more lucrative markets. Many problems that exist with the current *laisse faire* approach to cross-border importation will increase, from therapeutic failures to life-threatening events; all will be exacerbated. An uncontrolled free-for-all, without mandatory certification and enforcement, can never claim to put patients' interest first.

By harnessing the Internet, we believe that Drugstore.com is onto something quite important and possibly revolutionary. Today, we have safely dispensed more than 2.5 million prescriptions to consumers in all 50 states. We leverage the power of the Internet volume to offer discounts of 10-25 percent off prices of traditional brick and mortar pharmacies. Moreover, we are providing important health information that can improve health outcomes, and we have an e-med alert service that proactively goes out and alerts consumers when the FDA has recalled a drug, or any other agency has recalled a drug -- which would solve the problem noted by the first consumer this morning. And we do all of this while conforming to applicable federal, state and local regulatory controls. For the safety of consumers and the viability of the Internet as a lower cost drug delivery channel, it is critical that all Internet pharmacies – whether here or outside the

United States -- play by the same rules. Without appropriate standards and enforcement mechanisms in place, opening our borders undermines the confidence in the safety and reliability -- and affordability -- of the Internet distribution channel. Health Canada, for example, does not regulate pharmacies catering to U.S. citizens.

A spot check on the popular search engine, Google, identified over 250 websites that dispense drugs. Over 25% of those are outside the U.S. or Canada, and those are only the ones that we could identify. Over 167 of those 250 provide medications without a prior prescription, and over 40 more without a prescription at all. Many dispense compounds that are illegal, or subject to special controls. The average consumer cannot say, with certainty or any degree of confidence, which sites are safe and which are not. Right now, the situation is "buyer beware."

(Displays TropicRx site.) Here's a site that I got in my email two days ago. I venture to say that we've all received such things. This one is particularly interesting because of all of the various things going on. I would venture to say this site is not FDA-approved, although it says it is, although the [FDA] logo is there. This site undermines the doctor-patient relationship and patient safety by requiring no prescriptions. It showcases the U.S. flag, but gives a Canadian address. There are thousands more suspicious sites like this.

So, what do we do? I recommend that we adopt the uniform standards, similar to the NABP -- VIPS program. Once such a uniform standard has been adopted and introduced, I recommend the following three-tiered approach to help enforce that standard.

One: make it illegal for on-line pharmacies to advertise on search engines, unless they meet the approved certification standards and prohibit search engines from accepting advertisements from on-line pharmacies that are not properly certified. Two: stop credit card payments to pharmacies that do not meet the certification standards, and stop the funding at the source. And, third, motivate third party shippers to refuse shipments from pharmacies that do not meet the certification standards.

Buying drugs online should be a superior experience: convenient, affordable and private. But in today's world, purchasing drugs on-line is fraught with peril. I see the red light is on. I would say that all Americans deserve a system they can trust, this means finding a solution that combines safety with affordability. We deserve to be protected from fly-by-night operations and unscrupulous providers that set aside all safety concerns to make a buck.

Carmona -- Thank you, sir. Task force members, Dr. Raub?

Raub -- You mentioned mechanisms to reach out to customers in the event of, say, a recall of a product or, by extension, the discovery of a containment product. Would you elaborate on what that mechanism is?

Neupert -- We harness the low-cost, two-way communications of the Internet. We keep a database of our customer name and every drug they received, even by lot number. So, if we get a recall, we monitor the FDA website. If we get a recall, within less than 24 hours, we send an email to each customer who has received anything from that lot number or from that drug. We also do it for non-drug products, you know, we sell baby products and things like that. If they get recalled, we also send notices to those customers. We sent over 30,000 when, I can't ever say it, when phenyl propylene was taken off from market for some reason, we send out over 38,000 emails to customers within 24 hours.

Alex Axar, HHS general counsel -- Mr. Neupert, have you all done any kind of comparison of prices available through your website versus the prices that would be available through websites that offer drugs for importation? And, by that, I mean particularly brands and generic drugs, how they compare.

Neupert – Absolutely. Typically, on generic drugs, we’re cheaper than foreign sources, because there’s a much more robust generic drug market here in the U.S. On brand drugs, my favorite example is that we typically sell Lipitor for \$73; probably the traditional retail price is in the mid-80s. Our foreign competition from Canada sells it typically for \$32.

Axar – And what would you say are the major safety concerns? Since the way Drugstore.com is, if I understand your testimony, it operates, you work solely with FDA-licensed and approved drugs and distribution channels. What is your perspective of what the major risks would be with imported drugs, where are the points in manufacture, distribution, where in that chain where you would have the greatest safety concerns?

Neupert – Well, I think that the major risk is that consumers don’t know who they are going to be doing business with. That, if you really think of mass scale importation, it’s going to happen largely on the Internet. There’s no physical way to make it happen from a consumer perspective, and when you’re doing business on the Internet, you don’t know -- unless there’s some uniform, certification standard – if that person is in Canada, even if you think they are in Canada, you have no way to credential them. And there’s no remedy, if it’s not what you think it is, there’s no way for any U.S. authority to go out and deal with it. In terms of the drug supply, if you could have some sort of regulated system, certainly drugs manufactured in other parts of the world are as of good a quality (if FDA-approved) as if manufactured here. I think the issue is, how do you have a controlled system once you leave the border? We have a controlled system, because it’s the only way we can ensure the end results. Once you leave the borders, how do you end up with a controlled system? That, I think, is the ultimate challenge.

Axar -- Thank you.

Carmona – Dr. Crawford.

Crawford – You’ve basically called for a regulatory system geared towards policing the Internet pharmacies; do you see a role for the states in the U.S., as well as the federal government, or by the very nature of Internet pharmacies is it only the federal government that should be involved?

Neupert -- In 1999 and 2000, I testified in front of Congress on this very issue. States of course, currently certify pharmacies. We preferred voluntary regulations at the time, we didn’t see a particular role for federal government at that time. I’d have to say that my experience since 1999 suggests that that was probably the wrong approach. That certainly, there is a role for states, but the issues about enforcement, about location, about how do you solve all that. I think the Internet has changed the rules. Bottom line, and that you need some national, federal, specific certification capability with enforcement behind that. And that... it’s not just a problem outside the U.S., but inside it as well. Of the 250, the over 40 that sell drugs without a prescriptions – hydrocodine, OxyContin, Vicodin, all that stuff – many of those are inside the U.S. And, so I think that the Internet drug distribution issue is a big issue both internal and external.

Jayson Ahern, assistant commissioner in the Office of Field Operations, US Customs and Border Protection, Department of Homeland Security – Actually, Dr. Crawford asked part of the question, but I was going to ask if you could elaborate a little bit more on your three-step process for certification of online pharmacies, particularly on the importation aspect?

Neupert – What we have been focused on is how do you control something that has been, in effect, the Wild Wild West so far. And, try to do it in a way that enables innovation and takes advantage of the low-cost Internet business model while still providing consumers with some confidence? So, we start by saying you have to have some sort of national certification system that can be secure. When we designed VIPPS with the NAPB, we had to make sure the shield – the certification -- couldn’t be stolen by any entrepreneur and put up on their site just like a fake state license could be. So it has to be a secure certification, which means that the link is controlled by a single person and that you get, through this certification process whatever set of

standards you want, but then it's controlled by a central server. So, that's step one. Once, then, you have a definition of a what a good pharmacy is, what a legitimate pharmacy is, then you can call the "arms dealers to the Internet's ecommerce companies" and say, "You can only do business with the good guys." It's unfair today to tell Fed Ex or UPS that you shouldn't be accepting all of these packages coming into the U.S. They can't tell who the good guys are from the bad guys. Visa, MasterCard and the payment systems can't tell good guys from bad guys. But once you have a certification standard, one that defines here are the good guys, then you can tell the search engines, the payment systems and the delivery systems that they can only do business with good guys. And I think that is a potential way to control 90-95 percent of the problems – the no prescription issues, and the importation issues. And that would work even if you want to make, to enable someone outside the U.S. to do it, if they had the same set of rules. And that's the only system that I've been able to think of, in five years, that would be able to accomplish it.

Raub – Mr. Neupert, on your slide that you put up, it looks like some of the products that you have on that slide are pain control products. And, you mentioned some other pain control medications, some of which are controlled substances. You also talked about a survey that you did in which you characterized, you know, 167 of 250 sites as not requiring a prescription. Can you tell us what you are seeing from your evaluation, from your expert evaluation of the Internet, in terms of the types of products that people are trying to get to order? Is it a lot of controlled substances and other products?

Neupert – Absolutely. Go do a search of Vicodin at Google. You'll see over 50 different websites that will sell you Vicodin without a prior prescription. Deliver it overnight, to your door. It used to be, when I started in 1999, it was all about Viagra; then it was about Zenecal, then it was about some other things. It's very quickly accelerated, in the last year, to OxyContin and Vicodin.

Raub – Can you elaborate about why that is, when a consumer has the alternative to go to a pharmacist or an on-line pharmacy, or a non-VIPPS on-line pharmacy?

Neupert – Well, our number one drug at drugstore.com is Propecia, because we're low cost and it's a cash drug; no benefits, in general. Our second big one is Lipitor, which would be traditional with other pharmacies. The reason that you have so many illegitimate pharmacies pushing controlled substances is that people want them. Bottom line is, they don't want to go to a doctor to get a prescription, and they want to be able to self-medicate and the Internet's a good way to self-medicate and it's more convenient than trying to find a street corner.

Willis – In regard to the controlled substances, do you find that the majority of them offered over the Internet are coming from domestic sites or from foreign pharmacy sites?

Neupert – It's difficult to tell exactly where they are coming from. Many of the sites will hide their contact information. I spent a couple hours trying to figure it out: called the 800-number, wouldn't identify what site it was. You couldn't figure it out, you go to the domain registration, couldn't figure it out because they use some third party registration. I'd say it's about 50-50 right now. I'd say the problem is probably bigger inside the U.S., because, frankly, there is very little enforcement because it's hard to find.

Willis – As a follow up, and you've answered part of that, how is a consumer to know exactly where the drugs are coming from? While this advertisement has the American flag and has a street address in Canada, is there any assurance that the drugs are actually coming from Canada, for the consumer?

Neupert -- Without some certification system, there's no assurance. I mean, I'm a professional and I've had engineers try to figure it out. There is no assurance. And that's why I think you have to have some form of certification, both for the benefit of U.S. citizens using U.S. pharmacies, and for anyone who might try to take advantage of lower prices outside the U.S.

Elizabeth Duke, PhD, administrator of HHS' Health Resources Administration Services – You've several times said, "some form of certification". Do you have a picture in your mind of what that certification system would look like and what it would take – you've identified it as a federal responsibility – what it would take for us to produce such a thing?

Neupert – I think that the work that we did with the NAPB, building the VIPPS – the Verified Internet Pharmacy Site -- is a good model. There may be some additional things that people want to layer onto it. It's basically what, the similar types of things you go through to get licensed as a mail-order pharmacy. And what this goes as an extra step is an on-going, regular audit to make sure you're up-to-date, and you make certain agreements to follow all the rules from HIPAA on through whatever the state- of-the-art is with regards to pharmacy practices at the time. We just went through our second audit, in November/December of this prior year. They spent two days at our site, visited our facilities, made sure our pharmacists were properly doing the right thing, looked at our exception reporting, looked at all kinds of stuff. It's that kind of thing. There are, today, 13 VIPPS-certified pharmacies, largely because it's voluntary. But, when you think about the work that has to get done to regulate the 50,000 pharmacies in the U.S., I don't think it's more work than is already happening. It just has to get transferred from the people who are doing it today to some other agency in a way that has this secure capability that the VIPPS situation does, on-line.

Duke -- Thank you

Carmona -- Dr. McClellan.

Mark McClellan, PhD, incoming Administrator for HHS' Center for Medicare and Medicaid Services -
- Would this require international participation to conduct the inspections abroad, to monitor the drug supplies abroad and that sort of thing? I'm just trying to understand what additional authorities in the U.S., but perhaps also ...

Neupert – I understand your questions, and I'm not here proposing that we accept drugs from overseas. I think this would be a good step for the U.S., to improve its U.S. system. Should the Commission, in its wisdom, say we want to do it outside the U.S., and we want to enable Canada, then yes -- those pharmacies should have the same rules that we have here in the U.S. And that would require that whoever the authorities are – whether they're provincial or federal in Canada -- accept the same sort of standards and the same sort of oversight that a U.S. pharmacy does. The next point, that I didn't mention is that there needs to be some sort of a consumer awareness campaign; that there is good guys and not good guys. And that is one thing that has never been funded, that the VIPPS program never got off the ground, frankly, because as the Internet bubble burst, we couldn't afford it.

Carmona – Ms. Hardin.

Tracy Hardin, Department of Justice – If importation was allowed, is this something you would use? Would you use Canadian drugs in your business to pass along greater savings to the consumer, or is this something you would not want to be involved in it?

Neupert – I've always, in participating in this debate over the last few months, I've thought it was a mistake to have consumers try to figure out how to import products from around the world. That, it would make much more sense, if you wanted to allow importation, that you would have commercial importation fit into all of the controls and safeguards of the U.S. system. As the prior speaker mentioned, the DUR, the patient profile, all of the sort of linked in networked claims, these issues that happen, could occur if you allowed commercial importation. As opposed to expecting consumers to try to figure out who the good guys are and who the bad guys are throughout the world. And the one issue that I'd like to mention in that regard is, if you empower consumers, and encourage them to go off-shore to go shopping, I don't think that there's any way to control it. To think that it's just going to stop in Canada is just naïve. People are shopping

around the world, and there're going to go to where the lowest prices are, because, hey, if it's safe to get drugs from Canada, why isn't it safe from New Zealand? Why isn't it safe from Thailand? And they're not going to be able to tell the difference. And if two million people have done it so far, and everyone's telling their friends, or ten friends, how they saved \$100 a month, there's going to be four million people this year and ten million people next year. This is going to go like this, because it already has from a very small base.

Carmona – Any more questions? Mr. Neupert, thank you so much for providing this information, particularly your comments on informing the consumer, which has been a challenge for us. Because, in our first meeting, I spoke about the aspects of health literacy, that is consumer awareness. And, you know, to the average person, looking at a website like this, you feel very secure. As you said, you see the American flag, you see "FDA", and yet there's a whole sinister operation below that, that has nothing to do with safety or efficacy. And we keep seeing more and more of that, yet the American public has this false sense of security by seeing their flag and seeing FDA and so on. And we are struggling with how to breach that gap and instill that body of knowledge into the American public so they will understand and recognize that there is a risk. Thank you very much for bringing it to our attention. Next speaker is Kurt Hilzinger, from HDMA.

Kurt Hilzinger, HDMA

Morning, Mr. Chairman and members of the task force, and thank you for allowing me to participate in today's important meeting. My name is Kurt Hilzinger, I am President and Chief Operating Officer of AmerisourceBergen Corporation. However, I am here today in my role as a member of the Board and Executive Committee of the Healthcare Distribution and Management Association.

HDMA is a national trade association representing full-service distribution companies responsible for ensuring that billions of units of medication are safely distributed to tens of thousands of retail pharmacies, hospitals, nursing homes, clinics, and other provider sites across the United States.

In our presentation last week to the Industry Roundtable, convened by this task force, HDMA stressed that assuring patient safety is of paramount importance when considering the feasibility of importation. With this in mind, we focused on the top three safety issues we believe must be addressed: product authentication, product liability, and product availability. Each offer significant challenges that cannot be overemphasized.

While these remain at the top of our list, I would like to turn today to two additional safety issues HDMA believes are critical for the task force to consider. Specifically, these are recalls and repackaging and re-labeling.

I'll start with recalls. One of the key safety features incorporated into U.S. policies and regulations is the current FDA managed system for "recalls." Systems are in place today to facilitate domestic recalls that are initiated by the manufacturer and processed by wholesalers and pharmacies. When dealing with foreign imports, it will be critical to ensure that the FDA has the authority and resources to apply the same level of oversight to international product recalls as they have to domestic product recalls. Foreign manufacturers should be held to the same standards for evaluating when a product should be recalled as is currently done in the U.S.

This leads to a number of questions, such as: Who will have responsibility for initiating, regulating, and monitoring international recalls? Will FDA have the jurisdiction and oversight over a foreign firm's recall plan? How will post-marketing complaints and adverse event reports be gathered and assessed? What will happen if foreign originated product is recalled but its domestic counterpart is not: will this require wholesalers and pharmacies to maintain separate inventories? If so, this implies a whole new set of procedures and costs that should be factored into your study.

Next is the issue of repackaging and relabeling. Imported products may have to be repackaged to meet FDA specifications. This, in turn, means they should also have to be assigned a new National Drug Code or NDC. This number is used throughout the U.S. health care system to identify products in support of such wide-ranging activities as product ordering, drug recalls, and reimbursement of pharmacies under public and private sector insurance programs. The imported drugs may also have to be bar-coded to meet the newly promulgated regulations and to enhance distribution efficacies. They also should be marked as to the country of production and be accompanied by patient package inserts that meet FDA-approved language requirements. All of these steps are critical, but they will result in additional time in getting drugs to the patient and have costs associated with them that will need to be factored in.

If a decision to move forward with importation is made, patient safety must be the paramount consideration. Wholesalers are best positioned to help maintain the safety and security of the national drug supply. However, importing product from foreign sources introduces significant challenges and must be addressed to ensure the broad safety of imported products while maintaining the desired cost benefits for consumers. Before the green light is given to importation, the three safety issues HDMA outlined last week – product authorization, integrity and availability – as well as the ones we raised today – processing recalls and repackaging and relabeling – should be thoroughly evaluated by this task force. There are still other important issues that remain to be addressed and discussed for your evaluation, but we will cover those in extended remarks that we will submit to this task force by June 1.

Thank you again for allowing me the time to speak today. I would be happy now to take any questions.

Carmona – Thank you. Any questions from the task force? Mr. Azar.

Amit Sachdev, acting FDA deputy commissioner for policy – Mr. Hilzinger, I'm not sure if you were here earlier and got to hear Mr. Roberts' testimony about the counterfeit drugs that he received from a CVS store in his neighborhood?

Hilzinger -- I did hear it.

Sachdev – Could you explain, from the distributor's perspective, what you might know about how – how could something like that happen in the distribution system. How could someone end up going to a CVS that's here in America and receiving a drug that's counterfeit, multiple counterfeit drugs? It sounds like different drugs that he had purchased ended up being counterfeit. How can that happen?

Hilzinger – Well, there are a lot of ways that it can happen. As a primary way it can happen, we, today, take returns from our pharmacy customers in part for product recalls – which obviously go back to the manufacturer and their FDA guidelines – but we take returns for good product, for in-date product. We would like to believe that our pharmacy customers today buy all of their pharmaceutical products solely from us, but pharmas today are under tremendous pressure in their own businesses. They do procure product from other sources; sometimes that product is, in fact, counterfeit and when we take a return back from a customer, it is very difficult for us to tell – virtually impossible for us to tell -- if it is counterfeit or authentic. As witnessed by the product packaging today. So, we have... we can... We do a superb job of controlling product from the manufacturer down to our pharmacy, but there is a reverse distribution function that we perform as well. And our pharmacies will buy product from other sources than ourselves. There is also an issue, obviously, with the number of distributors that have been licensed in this country. Florida was an extreme example, with over thousands of wholesalers licensed at the state level. And I think, you know, additional regulations need to be put into place to control the number of licensed wholesalers who are approved at the state level.

Carmona – Other questions, Dr. Raub.

Raub – You had mentioned the prospect of increased costs for the wholesaler with respect to the recalls and the repackaging and the relabeling. Could that be of a magnitude that would virtually wipe out the theoretical savings of importation?

Hilzinger -- Theoretically yes. I think we would need to know, you know, what the model is that would be contemplated by the task force. How broadly importation would be allowed in the U.S. If there are multiple sources around the world from whom product could be welcomed in to the United States, then it could be significant costs to repackage and relabel the product to make sure it's safe for U.S. consumers.

Raub – Of course, as one of earlier presenters testified this morning, the longer the chain or, by extension, the more complex the web, the potentially greater costs for you.

Hilzinger – I would agree with that. I think the task force should be assured that there will significant additional costs to reimport product and repackage it to make sure that it's safe.

Raub – Thank you.

Hilzinger – Yup.

Carmona -- Other questions from task force members? Ms. Hardin.

Hardin– I was just wondering if you could give a brief description of what liability issues distributors face in situations like the one Mr. Roberts described with counterfeit drugs in the distribution chain, and if you've given any thought to how that issue might change if importation was allowed?

Hilzinger – Well, we've not... in a world where importation was not allowed, we've really not thought about our liability until we know what kind of model will be approved by the task force and the government. Clearly, we feel that, you know, we have a moral and ethical responsibility to safeguard the supply chain as best we physically can today. We do have, we have been asked to participate, we've been part of the lawsuits, have been named in some of the lawsuits for situations like that. And obviously, we have our own views as to what we can control and what we can't control and we'll have to defend ourselves accordingly. Historically, wholesalers and distributors have been indemnified by manufacturers for most of our liability in the marketplace. We provide a logistics and distribution function for our manufacturing partner, that's our primary role.

Carmona – Other comments? Mr. Azar.

Azar -- We've heard testimony from others that for importation of prescription drugs, that you can import drugs that are FDA-approved drugs that meet FDA specifications. Your testimony appears to support that type of implication if we go in that direction. But, others have suggested that you could import drugs that are FDA-equivalent or like FDA-approved drugs. Do you have a sense of how, of how much more difficult, how that would compare to FDA-approved importation?

Hilzinger – You know, you're out of my area of expertise. The industry association is very comfortable with a closed system, where if we were to have an importing situation in this country, it would come from an FDA-approved manufacturing site, to an FDA-approved importer and then obviously down to pharmacy. When you're dealing with FDA-equivalent products, today I would tell you that our systems and our technologies are not set up that we could determine the difference between an FDA-equivalent and an FDA-approved. Now, unless of course there was ID tagging of some sort and we could get very specific identification of the source of that product.

Carmona – Other questions? No. Thank you sir, appreciate it. Our next speaker will be Governor Doyle, the Governor of Wisconsin. Welcome Governor, thank you for taking the time to be with us.

The Honorable Jim Doyle, Governor of Wisconsin

Thank you again Mr. Surgeon General and members of the task force. I appreciate your giving me -- and other members of the public -- the opportunity to come and speak about an issue that is so important, and certainly one that -- as Governor of the state of Wisconsin -- I hear about daily from citizens from our state. Citizens who really are struggling, as you well know, truly struggling to afford the costs of basic medical care.

There is no doubt that medical science has yielded enormous discoveries that have extended and improved the quality of our lives. But, it is equally true that the skyrocketing cost of prescription drugs threatens to deny many of our citizens in Wisconsin and across this country with access to these lifesaving cures.

Like most Americans, like most people in Wisconsin, we are disappointed that the federal government has not done more to address this dramatic inflation, or to provide meaningful prescription drug coverage to those who need it most. And we appreciate the work of this task force in looking into this very important issue, and hope that the result is going to be one that truly provides some relief to the citizens of our state.

As I have often said, there is one thing the federal government could do tomorrow that would make prescription drugs more affordable for every American, and that's to allow the safe reimportation of U.S.-made and -approved prescriptions from Canada.

Every day, I meet citizens of Wisconsin who struggle with the high cost of these drug, and are often forced to make the inhumane and unbearable choices between food and medicine, or skipping a dose here or there. I know you are hearing testimony from citizens who are in that predicament and I know that you have all heard those stories about people who are making those difficult decisions.

But just across the border, Canadians can walk into their corner drug store and buy prescriptions for a fraction of what we pay. These are the same medications available here, but may be as much as twice or even more for Wisconsin consumers.

Wisconsin has acted and we have been forced to take a lead. In February, in response to overwhelming demand from the people of Wisconsin, we launched a website which is on the screen -- www.drugsavings.wi.gov -- this site empowers our citizens to order these lower-price prescription drugs from pharmacies that our state has visited and has found to be safe, reputable, and reliable. For example, just one of the most common pain relievers, Celebrex, the state of Wisconsin for hundred doses, as the state, with the discounts that we receive, we pays \$106.71, but through our website, an individual can purchase the same drugs for \$72, a savings of 58 percent.

The response to our website has been remarkable and I hope should provide some measure to you of what the demand is out there among American citizens. Over the last six weeks, we have had 87,000 visitors to the website, an average of 2,000 visitors a day trying to find help with affordable drugs. And here are some of the stories they have shared with me.

Connie sent an email to tell me that the only way she and her husband can afford the drugs he depends on is to buy them from Canada, since there are no generic substitutes.

Cari is 48 years old, disabled and has no prescription drug coverage. She hopes that the website will help her with the costs of the nine prescription drugs that she takes.

Clare wrote to tell us that her husband is a transplant patient and his anti-rejection medication costs \$1,000 to \$1,300 per month, depending on the pharmacy used. Her husband is 65 years old and still working, and she wonders how anyone except the wealthy can afford this medication.

Mary from Brookfield says that she has been ordering drugs from Canada for over a year for herself and her husband. They are senior citizens, they take multiple medications and just can't afford the high prices.

The emails come to me from Wisconsin and around the country make one thing very clear to me, and I'm sure that it's clear to this panel -- people are going to Canada. Whether we like it or not, people are going to Canada. They are going in bigger and bigger numbers, because the simple dollars demand it and it is the only option that many of them have. We have, we hear from people not only from Wisconsin but from all over the country, writing the same thing, emailing through the website, saying, telling us that in many cases they have been going to Canada for a year and a half. They appreciate the fact that some body has checked the pharmacies out and has negotiated some prices and that they can deal with those pharmacies.

Now, I can understand that the pharmaceutical companies don't want us buying safe prescription drugs from Canada, because it cuts into profits. But I really hope that the federal government gets on our side, trying to help the citizens of Wisconsin.

This Administration has the authority -- right now -- to allow the safe reimportation of U.S.-made and --approved prescription drugs from Canada. And I hope that this task force will recommend that the Administration use its authority to do just that.

The drug companies have waged an expensive, highly coordinated scare campaign to try to convince people that buying from Canada is unsafe. But do any of us really believe that the Canadian health system is more dangerous than our own? If we were in Canada, and got sick, would any of us really think twice about going to a Canadian hospital or a Canadian pharmacy for prescription drugs?

If the FDA has concerns about the safety of these drugs, then I would encourage the FDA to do what our state has done. Put some inspectors on a plane, send them to Canada, and check out these pharmacies for yourself. You will find what we would find, that the ones on our website are reputable, long-standing, highly regulated pharmacies in whom we can have confidence.

It's time, I believe, for the federal and state governments to stand together on this issue, not do the bidding of the drug lobby, but stand up for the people of our states and implement a safe system of prescription drug reimportation. I have found it amazing in these recent months that the FDA has time to send out press releases attacking our website, it has had time to send staff to Wisconsin to hold press conferences criticizing our efforts, but not to actually work with us to put this system into place. It is a story of missed opportunities and misplaced priorities, and it is a disservice to the people of this country.

One thing is clear: someone has to stand up to deal with the incredible soaring prices of pharmaceutical drugs. And somebody in this task force is in the position to do it, to say that we are going to look out for the people of the United States, the people of the state of Wisconsin. U.S. drug manufacturers have threatened to blacklist Canadian pharmacies and cause shortages in Canada if they move ahead with reimportation. I have asked Attorney General Ashcroft to investigate these companies for violations of anti-trust laws.

But, unfortunately, no action has been taken. And, unless some action is taken, the 25 largest on-

line Canadian pharmacies have said that they may not be able to do business with citizens of Wisconsin or any other state.

Even more recently, we have heard that several merchant credit card payment processors have been scared off from providing their e-commerce credit card services to Canadian mail order pharmacies. Three weeks ago, Visa and MasterCard announced that they will not service Canadian mail order pharmacies because they have been under pressure from the FDA to cease their support of the payment processing. They cited pressure from the FDA and have warned their member financial institutions to avoid so-called "illegal" transactions.

The simple fact is this: people in Wisconsin – and all over America – need relief from the high price of prescription drugs. Reimportation holds the promise of significantly lower prices, and expanding access to life-saving medicines. It's time for the federal government to stand with us against to move past the scare campaigns and heavy handed tactics, and to start being on our side in making prescription drugs affordable for all Americans.

Not only does the federal approval of prescription drug reimportation holds the potential for huge savings for citizens, it has huge savings for Wisconsin taxpayers. Our state spends more than \$700 million annually on prescription drugs for Medicaid recipients, employees, inmates and others in our state institutions. If we could just save a fraction of that amount by purchasing drugs from Canada with federal approval, it would mean savings to the taxpayers of our state in the tens of millions of dollars.

Again, I truly thank the task force for your attention to this matter. As I said earlier, this is happening. No matter what I do, as the Governor of a state, no matter what you do, as the task force, people -- particularly in the Northern states and I assume this is happening all over the country, but particularly in the Northern tier states – are going to Canada. And they are going to Canada in increasingly large numbers and nothing is going to stop that, given the price differential. It is going to happen, it is going to happen in greater and greater and greater numbers. And I am proud of the fact that we in Wisconsin have taken some steps to protect our people.

We have checked out the pharmacies that are on our website, and I feel confident that if the FDA goes to those pharmacies, you will come away fully satisfied with the safety of the prescription drugs that come from those pharmacies. They are exactly the same drugs that people are buying at pharmacies in Wisconsin at prices that are 30, 40, 50 and 60 percent higher than what they can purchase through Canada.

So, again, I thank you very much for your attention to this. I look forward to the findings of this task force. I hope that you are going to help work with us to provide some relief for the taxpayers of the state of Wisconsin. Thank you very much.

Carmona – Thank you, Governor. Governor, would you have a moment to answer some questions from the task force?

Doyle – Yes.

Carmona – Dr. Crawford.

Crawford – Thank you, Governor. Taking into account that the past two Secretaries of Health and Human Services – Secretary Shalala and Secretary Thompson – have been unable to guarantee or assure the safety of products coming in from Canada, and none of us want something like this to be a permanent solution to a permanent problem, what do you see as the long-term solution to this? I mean, what you're doing, and what other states are contemplating, and some municipalities, may not, with all due respect, get to the root cause. Could you enlighten us as to

what you see that as being?

Doyle – Well, I believe pretty much in the marketplace. I believe that what we're doing in Wisconsin and what I hope that reimportation will do, is actually to bring competition in a way such that the drug companies will have to start moving the prices down in the U.S. I would strongly prefer an internal system in which we are working not through a website but through Wisconsin pharmacies, but one where there real, competition in place. And world-wide competition. I mean, the fact is, if you believe the drug companies -- and I think that given the amount of money being spent on advertising it's little hard to believe it, but if you believe the drug companies -- we as American consumers are footing the bill for all of the research going on, essentially, in the world. And, I think what has to happen is that they have to see that there is not a safe haven for just whatever profits they want to make in the U.S. That's what Canadian reimportation does. It introduces real competition into the marketplace, and it's going to make the drug companies have to find a better structure of pricing world-wide that will help American consumers. People in Wisconsin shouldn't have to pay for all the advertising and all the research in the world. And that's why I believe what we are doing here is trying to introduce a level of competition into the marketplace.

Carmona – Dr. Raub.

Raub – When your inspectors go on a visit with pharmacies in Canada, is there an involvement with your counterpart provincial officials or with Health Canada?

Doyle – The involvement; there was some contact, but primarily this was our inspectors going right to the pharmacies and making same kind of inspections of the pharmacy that they would of a Wisconsin pharmacy.

Sachdev – Governor, I have a follow-up question. The witness before you testified about concerns with regard to what would happen in the event that there were adverse events that resulted from purchasing drugs from a Canadian pharmacy where U.S. domestic authorities don't have regulatory authority. What is the state in terms of its responsibility for that possibility?

Doyle – Well, obviously, this is where we'd like to have the FDA involvement and a national agreement between the U.S. and Canada. I mean, Wisconsin can't do what the federal government can do in the relationship with Canada. Our recourse would be, and I don't think this will happen, because I feel quite confident with the pharmacies that we have chosen, but we would take the pharmacy off the list. But we do not have... again, this is why it is so important for the FDA to get involved in this – the ability to have the government to government, U.S.-- Canadian government kind of arrangements that would help ensure the effectiveness of system. But, I do believe, again, if anyone went to look at the three pharmacies that are on our site, that they would walk away from those pharmacies with any significant concerns that they wouldn't have with any American pharmacy.

Sachdev – As a follow-up to Dr. Raub's question, on the comment you just made. So the, what you're suggesting is that, if there were a product that was purchased from a Canadian site that was problematic in that there was an adverse event seen, the state would investigate and take down the website. Would it do so with the Wisconsin Board of Pharmacy? And, to what extend was the Board of Pharmacies involved in assessing these Canadian sites?

Doyle – The Board of Pharmacy does not have jurisdiction, obviously, over a Canadian site, would not have jurisdiction over taking it down. They were not involved because they have no jurisdiction in Wisconsin over a Canadian pharmacy.

Ahern – Governor, a couple of very quick questions about the certification or the inspection on the three pharmacies in Canada. First part is, how did you select those three for inspection by your state officials? And, tow many did you actually consider and why did you discount the others and

just focus on the three that were inspected?

Doyle – I can get you the exact numbers of how many we considered. Part of this, I give due credit to the state of Minnesota, which had done some of the preliminary work, and obviously we were able to benefit from the work that they had done. Still have a number of them soliciting us to get on the website, as you can imagine. There are a variety of ways that these came to us and, again, I'd be happy to provide the task force with that information. And we have looked at a number of them, and did not include every one we looked at in making the decision about what we were going to put on the website. We may still add more to website as well, further inspections are made.

Ahern – Were there any pharmacies that were either contemplated for inspection that were dismissed because of concerns, and was that posted, and would they be posted; kind of "buyer beware" outreach?

Doyle – We would not post ones we had concerns about.

Carmona – Mr. Azar.

Azar – Governor, thank you for your testimony. As I understand it, you had found that these pharmacies that you posted on the website, that they are safe, reputable, and reliable. That was your testimony, right? And that the consumer can buy the same safe prescriptions that we have here in the U.S., also, is what you have concluded?

Doyle – Well, in fact, the ones that we list, if anyone uses the pricing on the website, are all named prescription drugs, that are manufactured and approved in the U.S. We don't have any prescription drug on that list that is not a prescription, named drug in the U.S.

Azar – And again, because we don't know what your inspectors did with these pharmacies, how do you all know that the particular drugs were, in fact, manufactured in the U.S. as opposed to manufactured elsewhere? The drugs that would be bought on these Canadian pharmacies

Doyle – Our inspectors looked at the drug lots and so on, as they went. I suppose people could have been hiding bad drugs in back rooms, and so on. I mean, it's the same thing that we do in Wisconsin, and we rely on the representations that were made. We also looked historically at these companies, these pharmacies, we looked at what their history was, the extent to which the Canadian and provincial governments in the state relied on them for their various prescription drugs programs. I mean, all of those things were looked at – these are good, reputable, long-standing pharmacies in Canada.

Azar – So, the state of Wisconsin is very confident that these drugs are safe for importation into the U.S. for people? Like you, I'm a lawyer. So, I went to your website, and on your website there is a disclaimer. And the disclaimer says that the state of Wisconsin, as well as its officers and employees makes no representation as to the legality of the importation, or reimportation of pharmaceuticals from Canada. And it expressly disclaims any and all liability for such importation or reimportation or the use of any product so acquired. And then, there's a separate lengthy list of disclaimers: a disclaimer of liability, a disclaimer of warranties and accuracy of data, a disclaimer of endorsement, a disclaimer of for external lengths and a disclaimer of duty to continue provision of data. I'm just wondering, if the state of Wisconsin is encouraging people to buy these drugs from these pharmacies, why there would be the need for these types of disclaimers? Because it seems like your lawyers must have decided that there is some significant litigation risk to the state here, from people getting unsafe drugs, and that they needed to put these disclaimers on there. I just wanted to get a sense from you, of why there needs to be these types of disclaimers if things are so safe.

Doyle – In the first place, we are not encouraging people to buy drugs from this website or any other. What we have done is to provide them with alternatives that they have been demanding in Wisconsin. If they buy from this website, or using the prices on the website from those pharmacies, they make the purchase themselves. It's a direct purchase from the consumer to the pharmacy. And, we don't assume any liability for purchases that are made in Wisconsin pharmacies. The state does its best to regulate that, as the FDA does. But, go to the FDA website and count the number of disclaimers on the FDA website. This is... we do not pretend to be at the site of every drug purchase, making every... looking at every single drug and testing every drug, making sure it's exactly what it is. What we have done on the site is to say, these are three pharmacies we have visited, that are reliable, reputable, long-standing pharmacies, and that these are drugs that are approved in the U.S. That's what we tell people, and they will make their own decisions if that is what they are going to purchase or not. The FDA certainly doesn't, the state of Wisconsin does not accept liability for every drug purchase that is made in the U.S. by a consumer in a pharmacy.

Azar – I know you weren't here earlier today, but Mr. Roberts, our first witness today, testified about counterfeit drugs that he had received for his AIDS treatment. And the question that he had asked that I found fairly significant was, "Who will be responsible?". Who does he go to, to get compensation, and is he going to have to hire an international tort lawyer to go after compensation and trace down the source of the drugs that he's gotten – the counterfeit drugs? It's something that I think consumers – as we think about importation -- are concerned about and very worried about. Another thing that has come up, Dr. Rodriguez testified earlier today, and we had a witness at the first hearing also, representing a Hispanic group also, that testified expressing concern that, if we simply allow importation of drugs that are not FDA-approved, that haven't been subject to the distribution controls throughout the entire process, that we really would be creating a two-tiered system of drug safety in America. One for people who can afford the gold standard FDA drugs, and one for people who can't – a lower standard of safety for drugs. I was wondering because I think position is that we ought to just let the importation of drugs as they are now, occur, under the existing assumption that the drugs are safe, so we ought to just let them in. What is your perspective on this idea that there's a two-tiered system of safety?

Doyle – We believe that the reimportation should be of FDA-approved drugs, and every drug on our list is one that is FDA-approved. Now, you may argue that the reimportation of that drug is not approved, but the drug itself, you could walk into ... every drug on our list, you could walk into an American pharmacy and purchase in an American pharmacy, fully-approved by the FDA. I believe that the FDA has a very important role in this, and that's why I'm here with respect for the FDA and the process that you're all in. I believe, if we really get on this, and we all work together to develop a reimportation system, we can do something really good that's going to drive the costs down and answer many of the questions that you're asking right now. But to just say, you know, there are all these problems, and we're not going to do it, plays right into where drug companies want us all, and doesn't help us with the basic issue. That's why I am.. but, as I say, what we have on our list are FDA-approved drugs.

Azar – Thank you, Governor.

Carmona – Dr. McClellan first, then Dr. Duke.

McClellan – Thank you for testimony and I want to thank you as well for your deep concern about the problems of drug affordability in the U.S. This is obviously a major issue that all of us who are involved in health policy for the nation should have at the front of our agenda. And, clearly, this commitment is behind your work on the website. Just following up on some of the other questions from other task force members. I'm wondering if, in addition to the task force itself, if there are other steps you are interested in pursuing – in addition to the website, if there are other steps that you are interested in pursuing, beyond referring Wisconsinites to three Canadian pharmacies that your staff has visited? I guess, on this point, I do think that all of the drugs on that list are probably not FDA-approved, in the sense that they were manufactured in U.S. facilities and subject to U.S. manufacturing processes and the like. It may have the same name of the drug, but very often, drugs that are sold in other countries are not subject to the same FDA review for

bioequivalence and evaluation of whether the drugs meet – have the same effects on the body as drugs that are approved in other countries. So, I don't think that's generally the case, but that's something we'd like to find out more about as part of this task force effort. My question, though, goes to whether you regard this as doing enough in itself, and whether there might be other things that might be necessary. For example, bipartisan members of Congress are interested in finding a way to give FDA and U.S. government more authorities to assure the safety of imported drugs. Authorities like requiring foreign sites to register with us; allowing inspections to occur without advance notice and sort of the full level of government authority that they can be done in the U.S.; steps like making sure that the products that are coming into this country have a reliable pedigree, something that we've heard a lot about from other presenters before this task force. These ideas are more in line with what the U.S. has for food inspection and food imports coming into the country, and they don't really exist today for drugs. Is that, do you have any views on this kind of legislation and whether it's an important part of assuring the safety of imports and preventing that kind of two-tiered system that we've heard about from other presenters?

Doyle – Yes, let me just talk about, if I could mention the first and, Dr. McClellan, I don't presume to have your level of expertise on this. But, I will say this, the FDA could take care of that first issue for us in three days as to whether these are American manufactured or FDA standards. There are many Canadian pharmacies that are ready to give you any assurance you want that they were manufactured in perfect accordance with FDA standards. All it would take would be for you to go you there and work it out. So, that could be done very easily and very quickly. On the other steps, I'm willing to look at anything, but not if, if what the condition is that you are going to prohibit people from going to Canada. I mean, this has now been going on for ten, twenty years and it's growing and growing. I think the American public, like the Wisconsin public, would be very cynical about some of the efforts that you have discussed which might be fine on their face. But, if the condition that comes with them is that you are going to cut off the ability of all of the people who are currently going to Canada, of their ability to go there.

McClellan – So, you wouldn't support legislation like that introduced by Senator Kennedy or Senator Grassley? You think that would be too restrictive, or?

Doyle – Well, what you laid out. ... I'm interested in working on any option, and working with you on any option that we can come up with. But, what I'm saying is that legislation that conditions those options on shutting off Canada for Wisconsin consumers, I couldn't support.

McClellan – And, in terms of working with us, on other steps, in my current role as the Administrator of the Center of Medicare and Medicaid Services, we are trying very hard to implement some other new programs. So, that will bring relief to seniors who need help the most, those who are choosing between food and drugs, or rent or other urgent needs, and taking the prescriptions they need. Starting next month, there will be a new Medicare program that provides financial assistance and discounts to all seniors with limited incomes who don't have drug coverage now. And in addition can be used by seniors – like those in your state – who qualify for Wisconsin's low income program, to add to that and make sure they don't have to make that impossible choice between meeting their medical needs and meeting their other basic needs of living. We are launching a major website, we are engaged in a major outreach effort to get people enrolled in these programs which can provide literally billions of dollars through financial relief directly and through lower prices for drugs right away. I'd be interested in finding out a way to work more closely with the state of Wisconsin to get people enrolled in those programs to help meet the needs that they have now.

Doyle – We would look forward to that. And let me also say, we very much appreciate your efforts and those of your new agency. We do, in Wisconsin, I believe, have probably the best senior care program, under a waiver, in the U.S. And it is really significant. Most of our low and even low to moderate income seniors do not go to Canada, in Wisconsin, because we have such an effective senior care program. Now I would like to be able to buy those drugs for the senior care program from Canada, it would sure save us all a lot of money. But the program itself, and again, we have worked very well with your agency on that waiver and I appreciated it – it really is a life-saver for

many seniors. One point, though that – I know you know this, but I want to emphasize it -- this discussion often quickly turns to seniors. And, at least low-income seniors do have some options available to them. Many younger people have nothing available to them and for their children and to themselves. And, if we were just dealing with seniors, which is a huge issue, Canada would be a very important option, but there are some other options as well. For many of the non-seniors, there really is no option for them right now, except Canada.

McClellan – That’s right. And we are concerned about that in our Medicaid programs and our other state programs, to work with you on the waivers, as you mentioned. And I think there’s even more we can do to make our dollars go further in helping those low-income populations (other than seniors), through generic substitution programs, through drug management programs and other steps to help states get lower prices for their drugs through negotiation. We stand ready to work with you on all of those steps and I am very pleased to hear about this interest in collaborating in finding a whole set of solutions to people who most need them. I agree with you that people in this country should not be forced to choose between food and other needs – especially those with limited incomes, and I agree completely with you that we have an unfair system of drug pricing around the world that is putting too much of the burden on Americans. I am very much looking forward to working with you on some of these other steps that can be taken to address these concerns in addition to endorsing websites.

Doyle – Does that mean all our waivers will be granted? (Laughter.)

McClellan – Ah, we’re doing all we can.

Carmona – Dr. Duke?

Duke – You have mentioned that your website directs the citizens of Wisconsin to three drugstores that you found to be safe, reputable, and reliable. The question I have is, as you said there are more firms that would be willing to sign up for your website. Were the other 49 Governors to chose the same route, would there be sufficient supply of drugs and drug stores available in Canada to meet that need?

Doyle – Well, it depends on whether the American drug companies are prepared to sell to the Canadian pharmacies. There will be as many drugs available as they are prepared to make. Unfortunately, even while it is now Wisconsin and Minnesota that have websites up, Rhode Island has linked to our website, I believe New Hampshire has announced that they are going to do it. I may be missing some here, but, even with those limited number of states, the threats are already being made to restrict the sale of drugs to Canadian pharmacies. You know we are dealing with some pretty hardball tactics when you shut down MasterCard and Visa and you threaten the supply of the Canadian drugs over this. But, you know, I don’t see that I really have any other choice. As I say, in Wisconsin, people have been doing this for years and they are going to continue to do it. We have actually introduced a way that they can have some assurances on what the price is and they can have some assurance of the pharmacies that they are going to. Again, the supply is going to be for the drug companies to decide.

Carmona – Ms. Willis.

Willis – What you have described is at the state level. At a national level, if this task force were to recommend importation of prescription drugs, do you think it would be more feasible to have importation at the wholesale level, direct to the retail pharmacy level, or direct to the consumer? And, as a follow-up question, if you think it is most effective to go directly to the consumer, would this importation pertain to all types of prescription drugs, or should there be any restrictions on the availability directly to the consumer?

Doyle – My great preference for this is that you would approve wholesale purchase, and then we could go back, in Wisconsin, to the way I’d like it to be. I’ve often said that there are two sets of

victims of the situation that have right now that the drug companies are putting on us. One is the biggest number, and the one I have to look out for most importantly, are the citizens of the state of Wisconsin, the consumers. But, the other is the pharmacists. They're not the ones – they're just caught in the middle in this thing. My preference would be, if we're all sitting down with a goal, is that there would be Canadian importation; that we would be setting up a system that every one of those drugs are FDA-approved and it would be done at the wholesale level. That would be my, if I could just sit down and design it, that's how I would do it. But, right now, I have to make a very hard choice and it's not, in many ways, a fair choice, between pharmacists in our state. And... by the way, in our system, on our website, if you are filling out one of the forms from our website, it is only for... it is not for the original prescription. You have to go to a Wisconsin pharmacist and get an original prescription; these are for refills. But, I would prefer that that be done through Wisconsin pharmacists who are good, local businesspeople who I would like to make sure are part of this. But, they are caught in the squeeze. I can't say, my interest right now has to be the consumer; that's who I have to look out for, as Governor of Wisconsin.

Carmona – Governor, last question. Clearly, it seems, you've thought through this quite a bit and you are serving your constituents as best you can under these difficult issues before you. Certainly, this is a short-term remedy, assuming that it can be done safely as you say. Have you given any thought to the long-term consequences of such a policy of importation for the U.S., not just for your state, but for the U.S. We're looking at this more globally; Southern states also might want to be dealing with Mexico and other countries in South and Central America. And so, the future consequences – intended or unintended -- of such a policy, where we become more dependent on other countries for our pharmaceutical supplies. Have you given any thought to that?

Doyle – Well, I believe we can become significantly less dependent if we introduced some competition here. And, I can't speak about other countries; Canada's the one I know best. I will tell you, this whole sell that's trying to be made, is not going over. People in Wisconsin do not believe that the Canadian system is unsafe or unreliable. They just don't believe it, as much as that stuff is getting put out there, it just doesn't sell in a state like Wisconsin. You know, we know Canada pretty well and we don't believe it. I believe that the long-term effect of reimportation, as I said earlier, is really a market effect. It's going to say to these companies that you have to respond to the consumer demand to bring the prices down. If it means taking those ads off the air -- I which they are trying to convince me to go to my doctor to convince my doctor that he should prescribe a drug to me -- to help lower the prices, then that's what they should do. They've got to start responding to the consumer pressure. If what we're talking about is always government responses, the FDA working hard at this, trying to figure out ways to do it... what we have to do is to figure out ways to put pressure on the drug companies to start bringing their prices down. That, I believe, is the long-term benefit that comes from the policy that we've adopted in Wisconsin and that other states are moving pretty rapidly to. My guess is, by the way, that if you were to hold these hearings six months from now, you won't be seeing two or three Governors up here; you're gonna be seeing 30 or 40 governors up here. Only ones that have major drug companies in their states might you not find here.

Carmona — Thank you, Governor. I appreciate your testimony, thank you so much.

Doyle – Thank you very much, thank you all. I appreciate the work you do. Thank you.

Carmona – Our next speaker, Mark Barondess.

Mark Barondess; Christensen, Miller, Fink, Jacobs, Glaser, Weil & Shapiro, LLP

Good morning. My name is Mark Barondess and I'm sure that most of the members of this Commission have no idea whatsoever who I am. I am an individual who looks at themselves as someone that has what a lot of people don't have. I have two living, loving parents; I have a great wife; I have two wonderful children. And, I was blessed enough that I was able to have an education and go to law school. And, today, I'm able to represent some very famous people from

Olympic gold medalists to people that you probably watch on TV every single night.

So, that being the case, what could possibly be wrong? Well, what's wrong is that I suffer every day with a disease – the disease I suffer with is called multiple sclerosis. Now, some of you obviously, as doctors, know what that disease is, but for the benefit of people in the audience, multiple sclerosis is basically your own immune system attacking your nervous system. It attacks it to the point of affecting the conductivity of the signals that your brain sends.

And when your brain doesn't send the right signals what ends up happening is that you can become cripple, you can lose feeling, you can end up in a wheelchair. I'm not the type of person that likes to take medications. I just, the idea of a prescription, I always want to know, do I really need to take it? I found out that when you're diagnosed with a disease like MS, you don't have a choice. You have to take the medicine. I'm fortunate that there are various medicines available that can help abate some of the conditions. The bad news is that the main medicine that I have to take, I have to inject three times a week into my stomach. Now, I don't know how many of you have ever done an injection into your stomach, but it can be the source of what I would call considerable anxiety. It's not a fun thing to do, and not only that, the type of medicine that I take gives you the sensation that it's like a bee sting. So, I psyche myself up three times a week to get my bee sting, and I know that another side effect of the medicine is that I'm going to get a fever every week, three times a week, for four or five hours a week following it. It's just not fun.

So, the last thing in the world that I want to worry about now, is whether or not what I'm injecting into my body is real or whether or not it's going to hurt me in some way. I'm frankly shocked that the government is considering this issue of reimportation. I'm shocked that we would consider, as a means of cost savings, to open up our borders to what could potentially be one of the biggest terrorist threats this country has ever seen. The drugs that come Canada are not coming *from* Canada – they're coming *through* Canada. With all due respect to the Governor, if he's still in the room, I think he understands the basic understanding of that and I would be more than happy to discuss it with him, so that he can hopefully educate his own constituents as well as himself as to what he's actually putting out.

In this particular day and age, we saw last night on TV, all the concerns about terrorism. You can't walk anywhere in Washington, without suffering and dealing with the effects of 9-11. Coming into this building today, our driver had his steering wheel swiped, his trunk swiped with the little bomb detecting mechanism, and we're going to open up our borders to millions and millions of pills? Do you all remember, a couple of months ago, a cow from Canada got in that had mad cow disease supposedly. And everyone was up in arms, my God, how did the cow actually come into the country? Imagine trying to trace the millions and millions of pills, syringes, tablets and other medical devices that would be allowed under this proposed legislation.

I don't believe that our citizens should have to place their own life at risk in order to achieve cost savings. I think that there are options that the government can explore to assist in medical programs such as, Dr. McClellan, the new Medicare bill, the Medicaid bill -- these are all intelligent, effective ways to deal with the high costs of medications.

I know I'm probably running short on the time, so I have to go to what Governor Doyle was just talking about, and I don't mean to be so harsh. But, I know, Admiral, you said to please be polite to the other people. But, it was just intellectually offensive to me, in every sense, for that gentleman to stand right where I was standing and say that he's not encouraging people to go and buy drugs in Canada. When I've got a copy of his website right here, the same one that Mr. Azar has, that specifically says, "Since the federal government isn't going to take on the drug companies and fight for more affordable drug prices, states like Wisconsin will have to lead the way. This website gives the ability to buy your prescriptions at significantly lower prices, directly from the site."

Let me tell you, if that's not encouraging people to buy from your website, what is? And then he proceeds to tell you that all the medicines are safe. Well, I'm not going to read you the entire

thing; there are three pages of disclaimers. Three pages, where he specifically says, we have checked out the pharmacies. Well, let me read you only one sentence. "Although the data found in Wisconsin's access systems have been produced and processed from sources believed to be reliable, no warranty expressed or implied is made regarding accuracy, adequacy, completeness, legality, reliability or usefulness of any information. This disclaimer applies to both isolated and aggregate uses of the information. The state provides the information on an "as is" basis."

Lemme tell you. If the Governor is not concerned about this issue; you know I feel like President Reagan, "Tear down this wall, Mr. Gorbachev!" Well, Governor Doyle, take off the disclaimer. If you really mean what you're saying, take the disclaimer off. Make it so Mr. Roberts has someone to go to - if he gets the bad medicines from your "safe" website that your pharmacists have gone and visited and performed the same inspection in Canada that they would have performed in Wisconsin. I mean, that is utterly ridiculous.

We cannot take the chance that we will be terrorized by someone who infiltrates our medical supply system. Each one of you has information today which says that these counterfeit drugs are out there and they're dangerous. This isn't a Louis Vuitton purse, these are things you inject into your body. They can kill you if they're bad. So, I would ask each one of the members of this Commission to think to yourself, would you want your own child taking this medicine? I mean, when your own child had an ear infection, and needed amoxicillin, or whatever it may have been, do you want to give your infant medicine you don't know for sure if its' real or not. You think it is, but, you know, we'll see. And then, finally, how many people in Wisconsin have to die before Governor Doyle says, "well, maybe that's not such a good idea."? I'm glad I don't live in direction, if that's the kind of direction the Governor is taking. I apologize for being a little caustic, but it just got me.

Carmona -- Thank you sir, as I said in the beginning, we want to have open and frank discussions on both sides of the opinion, so we appreciate your comments. Task force members, do you have any questions? And thank you for the remarks, the terrorism angle is certainly something to consider. I assure you that the burden of this rests with us every night, when we go to bed and when we get up in the morning -- recognizing the importance of the tasks that are before us. And foremost in that is the safety and the health of the American public. And, I appreciate your comments as it related to your understanding. We recognize that this is extraordinarily complex and that's why appreciate the frank comments like yours.

Ladies and gentlemen, we're going to take a ten minute break right now and then reconvene in ten minutes and continue through our list.

OK, ladies and gentlemen, would you please take your seats. We'd like to begin in a few minutes. Our next speaker is Sharon Cohen, from Biotechnology Industry Organization.

Sharon Cohen, Biotechnology Industry Organization

Good morning. My name is Sharon Cohen and I am Vice President for Government Relations for BIO -- Biotechnology Industry Organization. We are very appreciative of the opportunity to talk with you today about the issue of drug importation.

BIO members develop and manufacture life-saving prescription products that

are often administered either intravenously or by injection. Most biotechnology products are extremely sensitive to changes in manufacturing parameters, temperature, light, pressure, shipping and handling conditions.

Many biologics are actually clear liquids, and it is extremely difficult to detect when products have been opened and thus contaminated, diluted, exposed to improper handling conditions, or simply

replaced with in a vial with water or worse. Indeed, many of these things have happened to our members' products over the course of the last several months. And you've actually heard two very personal and telling stories from some of the presenters today about these situations.

Because of the sensitivity of biotechnology products, the existing importation provisions within the newly enacted Medicare law, as well as new Congressional importation proposals, generally have exempted many biologics from these provisions that would legalize the importation of prescription drugs.

However, one need only look at the astonishing number of prescription drug products entering the U.S. via the mail or inside containers every day to know that the legality or exemptions merely could be words on paper. For unscrupulous vendors, the fact that importing some of these products is illegal, or unsafe, is no deterrent at all.

That's why notwithstanding the well-intended exemption for most of our member companies' products, BIO continues to remain opposed to legalizing of expanded drug importation. BIO believes, and we believe that we share the views of most American patients, that the U.S. system of drug regulation is the world's gold standard. In many other countries, patients literally cannot know whether the prescription medications they receive are pure, or adulterated, potent or ineffective, real or fake. That reality is one that we have not had to face in America until now.

In the recent blitz operations by the FDA and the U.S. customs and border officials, they discovered that many of the products they thought were coming in from Canada actually had their origins from countries where more than half of the drug supply is fake. Some of the products were packaged in sandwich bags; some were labeled in foreign language; some tablets were smashed and, more importantly, some of the shipments that contained biologic products that should not have been imported because of their unique handling and shipping requirements, and the fact that these are necessarily administered by physicians. Some of the products which required refrigeration were sent through the ordinary mail with no refrigeration whatsoever.

The U.S. pharmaceutical marketplace is, undoubtedly, the most attractive in the world. That is certainly the reason that it is attractive to counterfeiters and other criminals whose goal is making money without regard for public health or safety.

But the attractiveness of the U.S. market is also one of the reasons that biologic innovation really thrives here in America and it's why patients in America are often the first in the world to have access and benefits from many of the innovative products that our companies make.

Today, the reason for gaining FDA approval is to gain entry into the U.S. market. If products not approved by the FDA can enter the U.S. market legally, there would be an extremely strong incentive to obtain approval where it can be obtained most easily. And the FDA approval system could quickly become an anachronism. The first consequences of that must fall more heavily on patients than on product sponsors, but extensive damage could be done to the drug research and development – and particularly the biotech industry here in America.

Anti-counterfeiting technologies may not be the answer, and that's especially true with respect to biologics because our products are not packaged similarly to conventional pills and tablets. There are critical questions as to whether or to what extent these technologies may interfere with the effectiveness of the underlying product.

Two pivotal questions are really before this task force. One, do U.S. consumers need the imprimatur of the FDA approval system as assurance that their prescription medications are safe and effective? And, two, would loosening the importation controls result in a reduction in safety? BIO strongly believes the answer to both questions is yes. I'll be glad to answer any questions.

Carmona – Thank you very much. Task force members, any questions? Mr. Azar.

Azar – We've gone over this a little bit, but would you be able to explain to those of us who are not biologics manufacturers, a bit about what's unique about how a biologic is manufactured, compared to, say, a normal, chemically compounded pharmaceutical, that makes it so that it's not so easy for another company in Canada or China to simply look up the what the formula is and just re-do it and ship it to Canada or the United States?

Cohen – I'd be glad to, and I'll try not to be overly simplistic. With chemical compounds, it's almost as if you have a recipe for so many bits and pieces that are compounded together. The old way of doing things in a pharmacy. With a biological, it's actually a living material. This material largely is derived either through genetic information or tissue, recombinant technologies that can actually manufacture a protein, an enzyme. These are actually living materials. These items need to be stored, manufactured, handled in very, very unique ways. I'll give you a couple of examples. We have some products that are so photosensitive – light can damage them – that it has to be not only packaged in a dark vial, if you will, but it has to be mixed and administered in the dark, otherwise it becomes non-efficacious. Other products require refrigeration; we're not talking about keeping it just cool. There are some products that literally have to be kept so cold – 60 and 70 minus Celsius – gaseous material that's liquefied by freezing -- that there are only a few entities in the U.S. that actually can receive and ship them. Those materials are actually drop-shipped the night before they are administered.

Carmona – Other questions?

McClellan – In terms of thinking about biotech and how it's different from other pharmaceuticals, and what not. There are some things, though, that seem somewhat similar. It does seem that prices do differ across international markets, particularly some of the countries that we would think of that are already fairly prosperous, places like Australia or Spain. Can you give us a little feel -- because a lot of this discussion of reimportation would not be happening if there were not price differentials viewed as significant enough between countries – can you give us a feel for how your industry makes those determinations of pricing determinations. Of different prices in different markets?

Cohen – Well, let me step back for a minute and say that today, in the marketplace, anywhere from 50 to 60 percent of the biologics approved in the marketplace today are for orphan conditions. These are for very, very small patient populations, sometimes they may be extraordinarily small – you know, 1,000 individuals in the entire world that may have a particular condition. In those situation, there is a greater chance, not always, but there is a greater chance, for what's called "unitary pricing". There are not as many opportunities for price differentials and that's obvious because of the small patient populations. Foreign countries, as we know, do have a variety of price control mechanisms which are imposed and that results in, largely, the differential.

Mike O'Grady, HHS assistant secretary for planning and evaluation – Are there any countries where that sort of price control are so low that you don't offer ...?

Cohen -- Yes, I don't want to name countries, *per se*, but that is accurate. There are some where the price is not at all relevant to meet the need. The actual research and development costs, plus the manufacturing expenses -- and they are extraordinary with respect to biologics, you need to maintain very different facilities than you do with making a pharmaceutical compound.

Carmona – Other questions. I have one, then. It's been said that the U.S. bears the burden of the most of the development costs, the overhead for bringing a products to market and so on. That being the case, and with an inequitable distribution of pricing and the ability of some countries to control and, if you will, be free riders for what the Americans provide to the world, did you have any suggestions as to how that could be remedied.

Cohen – Well, I guess that begs the question of, you know, we've heard Dr. McClellan talk about this before, the issue of this being a trade problem. And are there opportunities through trade negotiations to resolve some of these issues? I think that that's an important endeavor that should be looked into.

Carmona – Thank you very much.

Cohen – Thank you.

Carmona -- Our next speaker is Mr. Pete Sepp, National Taxpayers' Union.

Pete Sepp, National Taxpayers' Union

Thank you. I greatly appreciate the opportunity to be here. I'd like to discuss the dimensions of importation from the economic and fiscal angles here, rather than the safety angle, because that's what the National Taxpayer's Union concerns itself most with.

As you may know, we have long opposed certain government laws and regulations that would manipulate free-market innovation across the board, not just in the pharmaceutical industry. That includes price controls, rationing, and weakened patent protections. And, to our mind, importation proposals are only the latest in this long line of burdensome mechanisms.

I say this for three reasons. We believe that the cost savings from importation may not be as great as advocates suggest. The Congressional Budget Office, for example, in July of 2003, determined that Canadian imports of drugs would not produce any significant savings to consumers or taxpayers on a nationwide basis. They did a second analysis in October of last year, suggesting that the savings would be roughly 0.8 percent to all payors, government and private, totaling about \$40 billion. This seems like great sum of money, but of course that's over an extended period of time in a sector that comprises roughly one-seventh of our Gross Domestic Product.

For all of that, it's quite little in our opinion. The result of importation would be, in our opinion, to starve U.S. drug innovators of the vital capital they need to continue their role as world leaders in development. It's not always popular to state that. It's very easy to say, "Drug companies are making obscene profits." Well, however cheap it is to manufacture pills, someone has to undertake the tremendous risk to formulate a drug breakthrough in the first place. In a truly free-market economy, those odds only make sense when risk-takers can reap the rewards from their hard work. That happens most here, in America; we call it an island of drug pricing freedom.

The third reason, the free-market drug development environment, which occurs here, is already saving taxpayers a great deal of money. We heard from Governor Doyle that he's trying to look out for the taxpayers of his state and hopes that, perhaps, a nationwide plan will do the same for taxpayers across America.

That overlooks the point that drug therapies already exert downward cost pressures on state, local and even federal health care programs. We commissioned a study by Bill Orzechowski and Robert Walker a couple of years ago on the issue of patent protectors for drug manufacturers. They quote a study by Frank Lichtenberg, for I believe the National Journal of Economic Research . He concluded at the time that a \$1 increase in pharmaceutical expenditures is associated with approximately a \$4 reduction in other expenses, like surgeries or therapies.

Even so, if you factor out that kind of cost reduction, there is also the benefit to the overall economy of increased productivity from better worker health. And Lichtenberg said that a one-time \$15 billion expenditure of drug R&D saved about 1.6 million life years, per year, whose value to the economy is 27 billion dollars. So, this kind of development is already working to provide

savings to taxpayers and help keep our economy productive.

I'd like to close with just a personal anecdote about how I think the pharmaceutical revolution is helping not only taxpayers but also consumers and patients. Fifteen years ago, my dad went to the doctor complaining of fatigue and chest pains. Doctors found that all of his arteries were blocked, he was in urgent need of a bypass -- had to get it right away. He went through the procedure; nearly died twice, once on the operating table and once after recovery.

Well, if you fast-forward 12 years, the grafts that were implanted from his leg began to fail -- he needed another bypass. So, they provided him with a very strict regime, leading up in the weeks leading up to the surgery, of prescription drugs, a whole mix of them to help cope with surgery. They had a recovery regime, too, that was very dependent on drugs. Here, my father is 12 years older and he sails through this bypass and he's out of the hospital in two or three days, as opposed to a three-week recovery that nearly cost him his life 12 years earlier. I realize that surgical procedures have advanced over that time, but I credit a lot of the reason to my father's survival and recovery -- over that period of time, over two operations -- to the development of pharmaceuticals, most of which is based here.

And, so I close by saying that Americans won't get a second chance. Prescription drug importation proposals undermines the cost savings or cures that we're all depending on. And, I don't think my father will get a third chance, either. So, that's it; I thank you. I'll be happy to answer your questions.

Carmona – Thank you. Questions? Dr. Raub?

Raub – How would you help Governor Doyle and the other Governor's bridge from macro analysis that says this importation might not be such a good idea, even economically, to the individual cases he deals with of his constituents – who he deals with – saying "I can save \$100 a month by going across the border."

Sepp – I think we need to do more research on a state-by-state basis, perhaps building on Lichtenberg's research and those of others, showing how the state programs themselves are experiencing better cost savings by shifting to drug therapies. If we can demonstrate to them that, look, this is already helping your programs, this may already be taking some of the pressure off of your programs, I think that might sway some of them.

Sachdev – Thank you for your testimony. In your written statement, you describe a study that you all did at the NTU, of the Illinois plan, and you identify savings of between zero and .8 percent, in comparison with the savings that were estimated by the Illinois Governor's office. Can you discuss the differences in these numbers and how you arrived at these calculations from what was presented in the plan?

Sepp – Well, we relied primarily on the CBO methodologies, the July and October 2003 studies. And applied those scenarios to some of the conditions outlined in the Illinois importation plan. So, we were able to compute, based on CBO estimates, some different cost savings and I believe that the savings we came up with was 99 cents per enrollee per month, based on the number of workers and retirees in the Illinois state employees' program. I'm sure you'll hear different opinions on the cost savings involve here. I think our point is that there may be a range of cost savings associated with these programs, and the range may actually begin zero. And, as such, we need to consider that and weigh it against the possible costs of restricted development and discoveries we never had. That's sort of the point that Walker and Orzechowski made in their study of patent laws is, you can't miss something that you never had in the first place. And that's the paradox of so many developments in our free-market economy. If we stifle the development, we never realize the benefits from it. So, it's much easier to have a clamp-down on prices, demand, whatever, and simply say "Well, we're doing the best for consumers", but never thinking about the things consumers *could* have had if those mechanisms weren't in place.

Sachdev – To follow up, and I do expect that we will hear testimony today, later on, about the Illinois plan. So, what I don't understand is that, you're suggesting that the range that we're talking about is from 0 to 1 percent, to 40 percent which, to me, strikes me as a very large discrepancy. Can you describe what accounts for the differences from zero to 40 percent savings?

Sepp – I think that would require a pretty detailed analysis of the CBO reports and that might be the topic of a whole hearing in an of itself. But, I would think that we have to count -- and account for -- some of the economic opportunity costs that come with reducing prices and profit margins to the point where additional R&D expenditures on the part of pharmaceutical companies become less enabled, and almost prohibitive.

Carmona – Mr. Azar.

Azar – To follow up on what Mr. Sachdev was just asking, and I don't know if you have this information. After listening to Governor Doyle and other witnesses come in and talk about the savings that consumers might get by taking advantage of the Canadian price controls on drugs, the bipartisan Congressional Budget analysis, I think, to many people will be, I think, surprising. That, at least according to the Congressional Budget Office, there wouldn't be widespread, significant savings from a wide scale, mass importation policy from Canada. Do you have any idea what the major elements of the analysis by the Congressional Budget Office that would leads to that conclusion? When we're hearing this anecdotal evidence of individual savings...

Sepp – Well, I believe that some of the elements include the additional regulatory cost burdens on the federal government and the private sector. Also, some of the burdens that would result from lost opportunity and R&D, but I'm not familiar enough with all of the CBO analysis to give you all of those points. But, most of them are summarized in the analysis we did, *Issue Brief 147*, called "Planning to Fail", which is on our website, www.ntu.org.

McClellan – It might be helpful if the National Taxpayers' Union could submit that analysis as part of the public record really, because I'm at least curious about the basis for this analysis.

Sepp – Sure, happy to.

Carmona – Dr. O'Grady

O'Grady – One kind of question, but also to continue this discussion a little bit. I haven't seen the CBO analysis, but I've seen other analyses. And, often what underlies them is a notion that an individual is going across the border and purchasing is one thing, but if you're talking about something where the American market is so much larger than the Canadian market, if you really did go to the weighted average price of this new, merged market, that it just -- the American prices in effect overwhelm it and therefore you are not in a situation where you are seeing those kinds of discounts. Now, whether the CBO followed the same kind of methodology or not... now, I wanted to bring it up in terms of, in light of your testimony, that I wanted to get, wanted to understand what I believe are the trade-offs that you are pointing out. If this were successful at dropping prices significantly, then there would be the concerns about stifling of innovations. But, if the other side of that is, there's very little net effect over the system, over both countries, there's really very little effect, I'm not sure I see a stifling of innovation at that point. If the CBO is right and it's really the minimal savings involved.

Carmona – Other questions? Thank you sir, we appreciate your testimony. Our next speaker is Bruce Kuhlik, Pharmaceutical Research and Manufacturing Association.

Bruce Kuhlik, Pharmaceutical Research and Manufacturing Association

Thank you, good morning. I'm general counsel of PhARMA, we represent the nation's pharmaceutical and biotechnology companies. Last year, our members spent more than \$33 billion dollars in research and development; they have more than 1,000 new treatments in the pipeline.

I'm going to limit my comments this morning to a couple of key issues relating to the safety of imported medicines. These questions are vital to the health of all Americans, since the schemes that are being proposed would put imported drugs into any pharmacy in the U.S. where our families, friends, neighbors and others could be given unsafe, unapproved, substandard and ineffective medicines without even their knowledge or consent. I want to thank you for hearing our concerns about these approaches.

I'm going to make three points this morning. First, importation is inherently unsafe. It violates the fundamental public health principles on which U.S. drug regulatory system is based. Second, the purported safeguards offered by importation supporters are a totally inadequate substitute for the genuine protections established by Congress and implemented by the FDA. And, third, there are better solutions already in place to enable more Americans to gain access to affordable pharmaceuticals. We should be looking toward these programs, rather than the false promise of importation, to improve the health of all Americans with safe and effective medicines.

The FDA comprehensively regulates the safety, effectiveness, manufacturing, distribution and quality of prescription medicines, pursuant to extensive authorities granted to it by Congress under the FD&C Act. Two basic principles underlie this system. First, the burden of proof is on the manufacturer to prove that its medicines are safe and effective. This burden must be carried in advance by obtaining FDA approval before a prescription medicine is marketed, and it must be met continually thereafter. Americans can take their medicine with confidence because they know that the FDA – an agency devoted to protecting their health and well-being – has affirmatively determined that these medicines are safe.

The second principle is that safety can only be assured over time through controlled manufacturing and distribution systems that build quality into the product. It is a fundamental tenant of FDA regulations that quality cannot be tested into the product. In other words, that chemical analysis alone is inadequate to ensure that a product is safe and will work as intended.

The proponents of propositions to importation propose to violate both of these principles. They assume that products are safe even if they are not outside the regulatory jurisdiction of the FDA, or even are never subject to that jurisdiction in the first place. They suggest that we should assume that importation will be safe, even without full FDA oversight, unless or until we have proof that Americans have died or been seriously injured under their proposed systems. We have walked that path before, and it has led to public health tragedies, such as the elixir sulfonamide poisonings, that led to the enactment of the review system for new drugs in 1938. In that case, a company used ethylene glycol, better known as anti-freeze, as an inactive ingredient in a sulfur drug, causing more than 70 deaths. We now wisely ask for proof of safety first, not proof of harm later.

They also suggest that tests at the border can distinguish genuine products from counterfeits, and safe products from those that are adulterated. Again, the FDA has opposed this approach and imposed extensive requirements on domestic manufacturers to ensure that quality is built into their products, precisely because of the limitations of end-product testing. FDA oversees the entire process from chemical synthesis of active ingredients, the inactive ingredients, and requires the manufacturing steps for the drug product through its packaging, quality control checks, storage and distribution. Americans considering the possibility of importation need to know that product testing alone – at the border or elsewhere – cannot possibly substitute for this comprehensive regulatory system designed to protect them.

My second point this morning relates to the illusory promises of safety that have been offered by

importation proponents. They suggest, for example, that an importation scheme would be safe if limited to Canada. However, drug products that are not intended for use in Canada fall outside the scope of Canadian health regulations as long as they are properly exported. Health Canada itself, the Canadian FDA, has made clear that it does not regulate the safety and quality of these projects. We should be under no illusion as to what a so-called "Canada only" importation scheme really is – which is an invitation to trans-shipment of sub-standard products from Third World and other countries. Suggestions that FDA could ensure safety through foreign inspections are totally unrealistic; approaches that will work for foods and illegal narcotics (such as visual inspections and field tests) simply would not work for complex prescription drugs. Substandard and unsafe drugs cannot be detected by appearance or smell, for example, and there is no technological silver bullet against counterfeits or to guarantee the accuracy of a chain of custody.

I want to go to my final point this morning, which is that Americans do not want imported drugs; they want access to safe and affordable ones. There are numerous public and private assistance programs already in place to help people obtain the medicines they need. Last year alone, PhARMA's members provided free medicines to more than six million patients through company assistance programs. Other help is on the way, such as through the Medicaid and Medicare Assistance Act, drug discount cards, and drug coverage. PhARMA's members are exploring other ways to help. We urge everyone to look for solutions within the framework of public health protections that have served us so well for so long. I know I'm out of time, I'm happy to answer any questions. If you care to indulge me, I'd like to specifically address some of the points raised by Governor Doyle where, I think it's fair to say, we have a difference of opinion.

Carmona – Thank you, Mr. Kuhlik. Task force members, questions? Dr. Raub.

Raub – Thank you, in your oral statement, you made the important distinctions between products intended for use in Canada, versus those that would be for transshipment and therefore not subject to the same degree of regulation. But in the written summary provided by your assistant general counsel, includes a sentence that says that "foreign drug agencies devote their limited resources to regulating products intended for use in their own countries, not for those being shipped abroad." The implications of that is that no one else's pharmaceutical regulatory capability matches that of the U.S. Is that the intended sense?

Kuhlik – Well, certainly the FDA is recognized as the gold standard. Products that are intended for use in Canada are regulated by Health Canada. A principle concern we have is the trans-shipment concern that I mentioned and others have mentioned. Those products aren't subject to regulation by anyone until they come into the country.

Raub – I understand, but I think the interpretation of the sentence goes broader. I read it as suggesting that Canadian regulation for its own use is not up to the FDA, that that U.K regulation for its own use is not up to the FDA. Is that...

Kuhlik – Each country regulates for its own population. We've certainly never said that, in the U.S., for example, that approval in Canada is tantamount or the same as FDA approval. There may be circumstances where similar requirements are imposed, but we've always counted on the FDA do to what's right for the American people.

Carmona -- Other questions, Amit.

Sachdev – Mr. Kuhlik, if I could start with a request and not a question. The request is that -- since the entire importation debate revolves around pricing in America versus pricing of drugs in other countries – if the task force could get some information about the pricing regimens in other developed countries. How prices are set, or the extent to which they are allowed to be determined by the free market? I don't know if your information has access to at least some comparative information on this. I think that would be helpful for us to know about.

Kuhlik – Thank you. We certainly intend to submit information on that to the docket in our written comments. The short answer is that government price controls are endemic throughout the rest of the world.

Sachdev – The other point; this is a question that I had asked at the other, previous, task force. At least almost everyone has seemed to assume that, if we were to permit the reimportation of drugs into America, only those that meet the FDA's gold standard of safety and effectiveness should be permitted into this country. That would, of course, include not just the product's composition being safe and effective and being subject to a new drug application; but also that it was produced according to good manufacturing practices, which is a very extensive regulatory regimen throughout the entire manufacturing process as well as the chain of distribution all the way up to the pharmacy and then to the consumer. If we have a regimen like that, for just one country – Canada – for Canadian importation, does that not require voluntary cooperation by the pharmaceutical manufacturing industry and the pharmacies, and the distribution entities in Canada – many of whom we may not even have domestic jurisdiction over. To be willing to cooperate with that type of inspection regimen and regulatory regimen. Not to say that Health Canada wouldn't also do that, agree to let us be inspecting and regulating there to get them into this country? And would your member companies be willing to cooperate with such a regimen to ensure that anything that came into the country would conform to the FDA gold standard?

Kuhlik – I think, you are asking a very important question and, essentially, when you get to the root of it, the only way to have an assurance that the products that are coming into the U.S. are fully approved and meet all of the various requirements (from manufacturing, testing, distribution, quality control and all the rest of it) is to ensure that they are within the jurisdiction of the FDA the entire time. Which is obviously impossible once those products are in foreign countries. In the Canadian government and Health Canada want to change their regimen to conform precisely to the U.S. regimens, so that only the U.S.-approved products are available there, and they will inspect and they will enforce, and they'll make sure there's compliance... you might have a different system. But, again, I think that there's this very basic misunderstanding (that you heard earlier this morning) about what is and isn't an FDA-approved product. Just because brand product X is approved in the U.S., and the same brand is available in Canada, doesn't mean that that product, in Canada, actually meets FDA requirements. And there's no simple way to know what the significances of any differences are. Just last week, FDA published 40 pages of small type, three columns in the *Federal Register*, about what kinds of regulatory requirements manufacturers need to go through in the U.S. whenever they make a change in their manufacturing process, of whatever significance it is. A change in mixing time, a change in mesh size, a change in active ingredient or inactive ingredient, a change in suppliers. There are all kinds of levels of controls the FDA puts in place because these products are so complex and have such a potential for harm or for a lack of efficacy if you don't follow these rules. So, to simply say there may be differences but they are diminimous, I think flies in face of everything everybody knows about the science and manufacturing regulation of these products.

Carmona – Other questions, Dr. Duke.

Duke – You mentioned in your remarks that there are many efforts in the industry to provide assistance for those who do not have access to drugs. The Governor, in his comments, talked about the issue of the non-senior working poor. It might be helpful to the commission if we knew more about the kinds of programs that are being provided for that segment of that population.

Kuhlik – We'd be delighted to do that. We have a website called HelpingPatients.org which provides an easy way to access these programs; they are geared toward the needy, not necessarily simply the elderly needy. And, I think that if people had more, if there were more broadly aware of those programs – they already take wide use of them – that would be a very good thing.

Carmona – Ms. Willis.

Willis – You and several other people have talked about the negative impact that importation would have on R&D. Can you explain exactly why the impact is a negative one on research and development, and would importation not encourage R&D in other countries?

Kuhlik – The key facts about pharmaceutical R&D are that they are extremely expensive, very long-term and very risky. And, they typically – in most products -- are much, more than the cost of manufacturing the pill. What other countries have done through their price control regimens has been to try to step away from financing all of that R&D. \$800 million or more per drug; only three drugs out of 10 that actually make it to the market actually recover R&D expenditures. Only 1 product out of 5,000 that's initially tested in the laboratory ever makes it to market to begin with. We've got here, I think a previous speaker referred to it as an "island of pricing freedom", I would characterize the U.S. as an island of competition. We do have competition here. We have very large purchasers who negotiate on behalf of tens of millions of covered lives on pharmaceuticals. Importation is not importing competition; its importing price controls that are specifically designed not to finance the R&D enterprise. If that's shut down here, there's nowhere else for it to go.

Carmona –Dr. O'Grady.

O'Grady – A couple questions. One having to do with a follow-on of Mr. Azar's request for a kind of... you talk about price controls overseas; I'd like to also know, again, along the lines of what asked I asked Mrs. Cohen. Are there specific drugs that are not being offered to consumers overseas because of the price controls that their countries impose? Because I certainly understand and am very supportive of the notion of competition and innovation and whatnot. But, what I haven't seen is, is what it is that the average consumer in Australia, or Spain, or France is not getting access to because of the price controls that their countries have imposed upon? And certainly, I understand the free rider argument, and it makes sense, but what can you do to convince us that that their price controls haven't worked? They seem to get all the same drugs that our people do, and they seem to get them at a much lower price.

Kuhlik – We'll provide comprehensive information on this, as much as we can. Obviously, individual companies make individual decisions on this. But, I'd like to point out that foreign governments impose a variety of controls that work together in ways that very substantially reduce access to products. They have the price controls themselves, they have the fourth hurdle in many countries – where you can't get to market at all, even after safety agency has completed it's review, where you can't get to market until there's a pricing determination that lasts for many, many months and sometimes longer. Even when products get to the market, foreign governments impose many more controls on access, on the provision of information to patients, step therapies and things of that nature where patients can't get the drugs, even if they are on the market. Finally, these governments have a variety of other tools, such as the threat of compulsory licensing, to say that if you do not do what we tell you to do, we'll get it from somewhere else.

O'Grady – Ok, and I guess I understand the intellectual argument. At the same time, the Governor's point, it's hard to tell that little old lady or that little young lady in Buffalo that, somehow, by going to Toronto, somehow she's taking her life in her hands. Now, I understand the concerns, and our colleagues at the FDA's concerns. But it's still not persuasive, I guess.

Kuhlik – Well, I think the safety concerns ought to be. I'd like to point out that in our view, the reasons that these concerns exists with concern to pharmaceuticals, as opposed to (for example) physician services, hospital services, medical imaging, other services and the like, is the lack of comprehensive coverage for these products as compared to others. Remember, pharmaceuticals only represent about 10 percent of all health care expenditures, but for people without prescription drug coverage, they are obviously a much greater out-of-pocket expense. I think if we can do more along the lines of the Medicare drug benefit; other approaches to seeking coverage for uninsured Americans, these are much better solutions than the safety roulette.

Carmona – Amit?

Sachdev – The Secretary was tasked by Congress to look at 11 specific questions and we, as a commission and task force have been asked to shed light on that through these proceedings. We've heard a lot of testimony that touches on many of these issues, but one area in particular that I think it would be very helpful to hear from you and your companies, and that is to assess the impact on drug R&D, and the associated impact on patients and consumers, if importation is required or mandated. That's information that I think would be very important to receive from you and if you have any initial thoughts on that, I'd be glad to hear that now.

Kuhlik – We certainly plan to do that. Again, when you look at importation as a scheme to import foreign price controls, that are designed not to carry the burden of R&D expenditures and investments—I think the only conclusion you can draw (and we'll try to put as much meat on the bones as we can) is that is going to be substantially less R&D and substantially fewer new medicines available for patients.

Carmona – Mr. Azar.

Azar – I certainly understand the R&D concerns that you've addressed. But, is there any even narrow importation system that could be constructed from one or more countries that, at least from the pharmaceutical manufacturers' perspective, would at least satisfy safety concerns?

Kuhlik – I'm glad you asked it in that way because safety remains our principle concern. We have yet to see any type of proposal that would provide the same kind of assurance for the safety of Americans that you get through the closed FDA system. Nobody has been able to come up one and frankly, I can't even logically conceive of how you would do it given that products are manufactured with the intent that they be distributed in particular countries. How will you know – how can you possibly know – whether these products meet FDA standards once they are outside this country? You can't.

Carmona – Dr. Crawford.

Crawford – Yes. Much has been made of fact that the U.S. free-market system fuels R&D of pharmaceuticals. If, somehow or another, that profitability was compromised, so the U.S. no longer contributed to the pool of funds that in fact drives the R&D enterprise, could that enterprise be taken up by any other entity, such as the government?

Kuhlik – I don't see how it would. The NIH, obviously, does a fabulous job of basic science, and elucidating basic mechanisms of disease and pathways and markers and the like that help the companies do work that they need to do to turn those scientific principles into the reality of a safe and effective medicine. It's a process that takes 8, 9, 10, 12 years; it's fraught with risk and uncertainty and the like. It's not a simple matter; I don't know how the government would finance that over the period of time that's needed to do it. Certainly, there isn't an experience with the government taking over some other part of the economy that would give me any confidence that they would do a good job on that.

Carmona – Any other questions? Thank you, sir, we appreciate your comments. We look forward to your other remarks that you'll provide to the docket. Our next speaker, James Green, King Pharmaceuticals.

James Green, King Pharmaceuticals

Good afternoon. My name is James Green. I'm the executive vice president of corporate affairs at King Pharmaceuticals. King manufactures and markets prescription pharmaceutical products that cover a diverse range of categories. We appreciate the opportunity to provide you today with

King's perspective on the importation of prescription drugs.

Foremost, we share your concerns about the safety of imported drugs. Over the last two years, our customers – our patients – have increasingly begun to fill their prescriptions through Internet site with products of unknown integrity, and unknown origins. Many of King's products are maintenance drugs, that is drugs that are intended to maintain patients with chronic conditions – such as hypertension or hyper-thyroidism – within a healthy, normal range. These conditions are often asymptomatic, and a patient who receives a substandard drug may be at serious risk of harm, and may not even know it. Such a situation is of grave concern to us.

In a moment, I will show you some examples of the types of products that are being imported into the U.S. in place of King's FDA-approved products. But, before I do that, I must emphasize this point, and that is that the measure of the safety of imported drugs should not be whether we can point to examples of sudden, adverse events, or acute toxic reactions. When U.S. patients look outside the U.S. for their medications – particularly for these maintenance drugs – the risk of harm may escape immediate detection. And it may not even be recognized until the effect is irreversible.

That said, we want to share with you our own investigation of imported drugs. In particular, we attempted to purchase two of our leading maintenance drugs, Altace and Levoxyl, from non-U.S. pharmacies. We attempted 22 such purchases, finding significant problems with every drug we received. The slides that follow will illustrate some of these problems.

King's product Levoxyl is one of several levothyroxine sodium products for the treatment of hypothyroidism that's approved by the FDA. When we purchased Levoxyl from CrossBorderpharmacy.com, we received this bottle of Synthroid instead. The label clearly said that Synthroid was not interchangeable with other brands and, on the other side, the label falsely states that Synthroid is the Canadian equivalent for Levoxyl. Synthroid and Levoxyl are narrow therapeutic drugs. That means they must be precisely dosed and the same dose must be delivered to the patient each time. Synthroid and Levoxyl are BX-rated in FDA's orange book, indicating that patients who switch brands cannot expect to receive the same therapeutic effect. And here, in this particular case, we have Cross Border Pharmacy.com, who has overwritten the FDA's judgment and deemed the two brands equivalent. Not sure if you noticed on that slide, at the end, that the prescription was filled by Total Care Pharmacy, and on the back side of that bottle where it says it's the Canadian equivalent, and that's one of the pharmacies that appears on the state of Wisconsin's website.

The next slide shows some of the products sent to us when we ordered Levoxyl. Again, none of these products is interchangeable with Levoxyl; the patient may think he is receiving Levoxyl, or a drug that is clinically equivalent. Instead, he is putting his carefully structured dosing regimen at risk.

Some websites provide blatantly false misinformation about Levoxyl. For example, MedCenter Store claims on its website that Levoxyl is known as Synthroid in Canada. Often when the patient proceeds through an on-line pharmacy, it is not until the very last screen that the patient is told that the patient will get a product other than Levoxyl. Clearly, this is a very dangerous bait and switch scam.

We also attempted to order King's product Altace, an ace inhibitor indicated for the chronic treatment of hypertension and to reduce the risk of stroke, heart attack, and cardiovascular death. As you can see, the product we received is not an FDA-approved drug, and is not King's Altace. You can see King's Altace there on the left, the green and white, and there on the right is the product we received. Importantly, because hypertension is asymptomatic, a patient taking the product we received would not know if he is getting the intended therapeutic effect. Also note that the letter that the letter that accompanied this order stated that "your medication may appear different in shape, color or packaging from those you have received in the previously; please be assured that the products are the same and have been manufactured at an FDA-

approved plant." The drug we received has a different color and markings, and was manufactured in a site other than the sites where we manufacture King's Altace. How can the products be the same, if everything is different? Additionally, because there is no lot number, and no identifying information on the bottle, it is impossible to identify who manufactured this product, and where it was manufactured, much less under what conditions.

In another purchase, we received a drug that we did not even order. After ordering Levoxyl and Altace by their brand names, on discountmedsonline.com, we received a drugs known as Eltroxin from Fiji, and Tritace in a handwritten package (shown here on the right) shipped from Pakistan. It gets worse, look to the left. There you see this green package; in the second Pakistani package, we discovered this green labeled box of steroids that we didn't order.

This brings me to a final concern. An important driver in this industry is the ability to contractually leverage the discovery, manufacturing, and market resources of other companies. Some contracts often include negotiation of U.S. rights and companies like King negotiate for these rights with the expectations that U.S. patents and contractual rights will be protected, to protect our investment. For example, King's ownership of Altace is limited to the U.S. and Puerto Rico. The importation of substitutes of King's Altace undermines our intellectual property and contract rights. And, we urge the task force to take this into consideration as an integral pointing the value of drug development.

To add another perceptive, King is headquartered in Bristol, Tennessee; our products are manufactured in more than a dozen U.S. sites including Bristol, St. Petersburg (Florida), Kansas City (Missouri), Rochester (Michigan), and Middletown (Wisconsin). If this fundamental business model is put at risk, we could easily see imported drugs resulting in a loss of U.S. jobs.

In summary, what we have learned from our investigation indicates so far that importation is likely to compromise patient safety, increase patient confusion, undermine U.S. intellectual property and contract rights, and lead to the export of U.S. jobs. I want to thank you for the opportunity to present today, and want you to know that we are at your disposal as you discuss these issues. We would be happy to meet with you privately to discuss our own, on-going investigations.

Carmona – Thank you, Mr. Green. Task force members, questions? Thank you sir, appreciate it. Oh, wait a second.

O'Grady -- I'm sorry, I was a little slow. One question. I'd like to repeat Mr. Azar's question from before – can you think of any importation regimen that would be viable and still have the sort of safety and efficacy concerns that we've always had in this country?

Green – No, I cannot. I can't imagine a regulatory structure that we could put in place that could do that. As you can see right now, what's not supposed to be happening, is happening. If you put some sort of regulation in place to allow the importation of these drugs, I can't see how you are going to prevent the importation of unapproved drugs, or counterfeit drugs. I just don't see how you can do that; I don't think you have the resources to do that.

Carmona – Mr. Azar.

Azar – One more question, if you don't mind. This issue of different licensing arrangements in different countries is a perspective that had not occurred to me, and how an importation regimen could be disruptive of these licensing arrangements that are country by country. If you have information about how prevalent these types of different country licensing and manufacturing arrangements are, that would be helpful and also any information about why that's a beneficial practice. That would be helpful. Obviously, you think it's a good thing; if you have any information about why it's a good thing that should not be interfered with, I think that would be helpful information also. If you or the pharmaceutical manufacturers' association has that information,

that would be useful.

Green -- I'd be happy to see what kind of information we could provide.

Carmona -- Amit.

Sachdev -- I have a bit of a technical question, just to make sure I understand your presentation correctly. The slides we were given don't exactly match the slides you presented so I want to make sure I got it right. You said that one of the pharmacies that you bought a product from was Total Pharmacy, which is one of the pharmacies that is on the website in Wisconsin -- and you bought a product that was said to be the Canadian equivalent. Can you just quickly go over that specific case for us so we can have that right?

Green -- In that particular situation, again, we ordered that product on-line through an Internet website (that was Crossborderpharmacy.com) and that was the spinning bottle where we showed you all sides of the bottle. Of course, on the front side of the bottle it said that it's not interchangeable with other brand, then you turn it around and you see that the label by the pharmacy that filled the product -- when you turn that bottle around -- it says that it was filled by this Total Care Pharmacy, which is one of the pharmacies listed on the Wisconsin website. And they have this statement, you can see right here on the right, it says to "take one tablet daily" and in parenthesis, "Canadian equivalent of Levoxy". And this is put on the label that Total Care Pharmacies obviously put on the bottle when it filled the prescription. So, we ordered it through this Cross Border Pharmacy.com, but apparently, from the bottle, it was filled by Total Care.

Sachdev -- So, what did the consumer actually get? I mean, obviously, you bought it, but what would a consumer be getting? What product?

Green -- It appears to be Synthroid; Synthroid is another branded drug. Both of these products are BX-rated in the FDA's orange book, meaning that there has been no determination that they are therapeutically equivalent.

Carmona -- Other questions, yes, Ms. Willis.

Willis -- Given the situation you just explained, the individuals purchasing over the Internet, do you have any suggestions as to steps that could be taken to protect consumers in this situation, in going onto the Internet and purchasing their pharmaceuticals?

Green -- I can't imagine, again, it kind of gets back to the question I was asked before -- what kind of regulatory structure do you put in place to protect consumers? And the thing is, you can try to establish legitimate pharmacies through whom you can purchase, but once you open the door and have this stream of drugs coming in, how do you control the stream? Already we can't control that stream. So, I can't imagine any kind of regulatory structure that would be able to do that particularly with products coming in from all over the world.

Carmona -- A question on the CrossBorderPharmacy drug that's right before us, the equivalent. Do you have any history, more history as far as where it was manufactured, where it was repackaged, any specific information as we go along. Have you gone back that far?

Green -- I'm not aware of that myself, especially; we might have more information that we could provide to you as far as this specific prescription that we had filled.

Carmona -- If you have it, it would be interesting, because we're hearing so many stories of manufacturing in other locations, packaging and repackaging and distribution and there are so many opportunities to contaminate the system, so it would be very helpful if you have that

history.

Green -- I will check into that and certainly provide you with that. Our investigation is on-going, so we may be able to develop that particular information.

Carmona -- Other questions? Mr. Ahern.

Ahern -- It's kind of surprising, you didn't think you were going to get any questions! But this one will be very simple. You made reference to the exporting of jobs if we allow importation to occur. Certainly, we've talked about health, safety, pricing and those views. But, have you done any analysis that could show as far as, if importation was expanded, what that impact might be on domestic jobs?

Green -- As far as trying to put a number on that, no I haven't done that. However, I know from King's perspective, as I mentioned in my presentation, all of our products are manufactured here in the U.S. All of these others -- I don't know about Synthroid, but -- many of these other so-called levothyroxine sodium ones are not approved products in the U.S. and are manufactured, I would assume, outside of the U.S. by someone else. And, if you are allowing these products to come in through the back door, through importation, you're going to have those products, instead of being manufactured here in the U.S., be manufactured somewhere else, and there's going to be a loss of jobs that results from this.

Ahern -- Do you know of any studies that have been done on this?

Green -- I am not aware of any, but I can check into that and see if we have any information; I'd be happy to provide that to you.

Carmona -- Thank you; other questions? Yes, Dr. Duke.

Duke -- Do you have any data on the volume of counterfeit drugs or improper substitution of your drugs today? You are hypothesizing that there would be a vast increase, but we don't have any baseline data. Do you have that?

Green -- I don't have any data like that today, but I'd be happy to see what I can do to provide you with that.

Duke -- That would be helpful.

Carmona -- Thank you sir, we appreciate your comments.

Green -- You are most welcome, thank you.

Carmona -- Our next speaker is Flora Green, the Senior's Coalition.

Flora Green, The Seniors' Coalition

Good morning, afternoon. I'm pleased to be here. You know, I represent many, many seniors, our group represents over 4 million seniors and I enjoy that classification. I am in my wonderful 82nd year. I spend much of my time visiting with seniors and talking about the problems they are facing. And they are multiple in many ways. Since I only have a few minutes, I'm going to be kind of blunt about some of the things I say.

First, let me say that proposals to permit the reimportation of prescription drugs, ostensibly to allow seniors on fixed incomes access to drugs they need at a cheaper price – is simply political mumbo jumbo. We could make a lot of things cheaper for seniors – and for every American, for that matter -- by allowing for importation of a wide range of products at prices set by socialistic government regulators. But, we don't do that, because we here in America believe in a free market economy where competition sets prices. Preserves quality in the context of an economic system that rewards innovation. We don't permit importation of goods and services subsidized by foreign governments into America because it unfairly undermines the competitiveness of American companies and jeopardizes the working families who rely upon these jobs to make a good living.

You know, the same political do-gooders who promise seniors that drugs will be cheaper if we import Canadian drugs will be the very first to rail against the unfairness of importing products that are unfairly subsidized by foreign governments. They pontificate that they want to protect working families. Well, what about the health and safety of American seniors, and our families? Because time's short, I will only have to state that these politicians are hypocrites. And any one of you, who needs help in understand, just read my complete testimony.

There's another major point that I would like to make: foreign governments like Canada, Great Britain, France, Germany and Italy and many others have, for decades, been artificially suppressing the prices that they allow drug manufacturers to charge their citizens for needed medications. Let's make no mistake, these governments know that in doing so, it will force these drug manufacturers to increase the prices they charge American consumers for these needed drugs, because that is the only way these drug companies will have the incentive to fund research into new, breakthrough drugs.

I enjoy a great benefit from Fosamax; this has stopped my bone loss. I had a serious fall recently, and because I was able to enjoy the benefits of Fosamax (which certainly came at great expense to somebody), I didn't have any broken bones. And I attribute that solely to this great advantage that I have. America has let these countries get away with these unfair subsidies, paid for by the American consumer, that these foreign governments gladly provide to their citizens. It is adding insult to injury to now allow the very government that has been ripping off American seniors -- and all American patients -- to benefit by increasing the volume of drugs purchased in their countries for shipment to the U.S. Let all of those politicians who claim to want to protect seniors from high prices to start with making Canadians (among many others) pay their fair share of the drug costs.

I would also like to give you the highlights of some points that the task force should look carefully at in my testimony. Canada refuses to certify the safety of drugs that would be imported; that's because their borders are like a sieve and they import drugs from countries and facilities that are not FDA-approved manufacturing sites or FDA-approved raw material sources for those drugs. The drugs may be cheaper, but under existing conditions, you have to assume unacceptable and significant risks if you take them.

The key to verifying the safety of drugs is for them to require that all raw materials originate at FDA-approved manufacturing facilities and that they are handled and shipped under FDA-approved protocols. That would require that all shipping and distribution systems must be secure and utilize state-of-the-art tracking technology to protect their product from contamination or introduction of counterfeit or adulterated end-products. All medicines should only be handled by FDA-approved pharmacies that use FDA-protocol in the handling of medicines. The U.S. government could establish a safety validation system to assure these drugs that these drugs are not counterfeit, adulterated or improperly shipped -- that would cost hundreds of millions of dollars just to set up and maintain. You can do the math just as well as I can; if the safety validation system costs as much, or more, than the cost savings than the imported, price controlled drugs, then why do it?

The public policymakers who advocate for importing these price-controlled drug products must account for the safety and economic issues outlined herein that will adversely impact the

economic and health and well being of American seniors. My children and my 19 great-grandchildren thank you. You have my written statement.

Carmona -- Thank you, very much. Task force members, any questions? Thank you so much for your honest remarks, madam. Our next speaker, Scott McKibbon, Special Advocate for Prescription Drugs, State of Illinois.

Scott McKibbon, Special Advocate for Prescription Drugs, State of Illinois

Thank you task force chair, Vice Admiral Carmona. My name is Scott McKibbon, I am a Special Advocate for Prescription Drugs, for the state of Illinois. I have 15 years experience consulting for prescription drugs and medical plans, and I'm here to address the question that affects the lives of millions of Americans every day. How can we safely reduce the costs of prescription drugs in this country? This is not an issue of dry public policy. Every day, people in Illinois and around the states, people with chronic diseases, disease that can be effectively controlled with medication, are forced to choose between filling their prescriptions and paying for the necessities of life. As a matter of public policy, as a matter of public health, I believe the FDA must act as swiftly as possible to give those citizens access to the safe, affordable prescription drugs they need. And, I can assure the FDA and the people of the U.S. that we can implement a well-regulated program that will allow people to benefit from lower prices without sacrificing their safety.

Seven months ago, Illinois Governor Blagojevich called together an interdisciplinary team to study the feasibility of implementing a program to purchase drugs in Canada for Illinois state employees and retirees. The problem was clear: last year, the state of Illinois and the people covered by its health programs, spent \$2.1 billion dollars on prescription drugs. That amount is expected to increase by 15 to 20 percent every year. In Canada, the prices for prescription drugs – as you know – are 40 percent lower than they are here. So our team went to Canada to find out for ourselves whether we could access those lower drug costs and still keep people save.

We met with provincial officials, pharmacists, and executives of mail order and Internet pharmacies in Windsor, Winnipeg and Toronto. We visited warehouses and pharmacies. And we found that the Canadian prescription drug supply is just as safe – and in some ways, safer -- than it is here at home. We found that the provincial regulatory systems in Manitoba and Ontario are substantially similar to consumer protections in Illinois. Although the text of Canadian statutes and regulations is not identical to the FDA's, they are roughly comparable to our own.

When we compared costs, we found that the state of Illinois and the people covered by it's drug plans, could save up to \$91 million by purchasing prescription drugs from Canada. My colleague, Dr. Kamath, will go over highlights of our plan design with you. And, we would be more than happy to go over them and any points that require clarification, with you.

But, in the short time I have left, I'd like to take a moment to talk about safety. In its opposition to Canadian drug imports, the FDA has frequently raised the concern about counterfeit drugs entering the U.S. drug supply. I am also concerned about counterfeit drugs, but I believe it is the current system that puts consumers at risk. The soaring prices of prescription drugs have created a real profit motive for unscrupulous individuals who are willing to take advantage of people's desperation. That's why our email accounts are cluttered with come-ons from fly-by-night operators offering low-prices for superfluous prescription drugs. Again, we saw much evidence of that today. If we can cut the costs of prescription drugs, I believe we can greatly reduce the risk posed by counterfeit drugs. It's not worthwhile to counterfeit a \$1 bill.

I wish we had more time to tell you in detail about the many safeguards in the Illinois plan to give people in our state access to affordable drugs they need. But, I think I can sum it up pretty succinctly. The FDA is required by law to protect the health and safety of the American people. As you assess the safety of our proposed plan, consider this, when we designed this plan, I had five people in mind -- my wife and my four children. They will be covered by the Illinois drug

reimportation program. I am so certain of our program's safety that I am willing – indeed, I am eager -- to work with FDA to launch this program and to begin importing safe, affordable prescription drugs from Canada for my own family and for families all across Illinois who desperately need them.

Thank you. If, the chair would, my colleague would like to come up and present; he has five minutes. As far as Q&A, we can do them now, or it might be easier for us to do them as a group....

Carmona – We'll do it right now, ok, for the task force. Task force members, any questions? Dr. Crawford.

Crawford – Again, getting back to the root causes of the problem that you seek to address here. Would you favor a system of cost controls on prescription drugs in the U.S? If there is a cost problem,

McKibbon – Other than the one we have now, you mean?

Crawford – Well, obviously, you are trying to solve, through these means that you describe, a cost problem with drugs, particularly for seniors and Illinois citizens. So, if there is a price problem, shouldn't you address it head on, rather than bringing these products in?

McKibbon – Well, we want to address all of these issues. As you know, doctor, there are many classes of ways that drugs are priced in this country. There's hospital class trade, there's Medicaid, there's many of those things. And, what we've advocated in this program is to allow the citizens of Illinois access to the market, and that is a market in Canada, which currently doesn't exist. We have made numerous requests to request a waiver to do such as that. In fact, that's why you are here today, because Congress has mandated that a study be conducted. Our governor and other governors have made numerous requests in writing and finally had to go so far as to file a citizens' petition to compel the FDA to answer the questions. So, we want to work within the system. We have not, as you know, but up a website. The Governor, as a former Congressman, wants to work within the system and has pledged to do so.

Azar – You actually didn't get to the answer to Dr. Crawford's question, which I thought was an interesting one. That the whole concern, and the concern of many individuals, is the cost of drugs in America. The solution that a lot of people seem to be proposing is to import drugs from, say, Canada, to take advantage of the price controls that the Canadian government imposes – where they set the price that can be charged for a drug, rather than a competitive market setting it. So, the question was, why doesn't -- does the Governor of Illinois favor setting price controls, in Illinois, for pharmaceutical drugs?

McKibbon – Right. The Governor has said in numerous press conferences that he wants the citizens of Illinois to have access to Canadian drug prices. And, I can't give you a better answer than that. You'd have to address that question to the Governor.

Azar -- So, the Governor of Illinois favors price controls and setting the price of drugs. What impact would that have on either access to drugs for Illinois citizens, or research and development?

McKibbon – Well, those were your words, not mine, and as I said earlier, if you'd like to address those questions to the Governor, I'm sure that he would love to sit down (as he's offered on more than one occasion) with Secretary Thompson and go ahead and have that kind of a dialogue. The question on R&D, and other speakers have addressed it and Dr. Kamath will that also in his remarks. We believe that R&D occurs, it is occurring, it occurs not just in our country but in other countries as well, and that we can import these drugs from Canada, our largest trading partner, and do so in a safe and effective manner.

Azar – But if R&D is occurring in other countries right now, is it occurring because there is the availability of America, where the free market actually allows the prices to be set by supply and demand, rather than being price fixed? And, if you take away that, will R&D continue to occur in other countries? Don't we have the need, as Dr. Carmona mentioned earlier, to think about the long-term impact – not just the short-term issue of the cost of drugs?

McKibbon -- All things have to be considered. At those 15-20 percent trend rates per year, our costs are going to double... without our revenues doubling by 15-20 percent per year. Are we going to be able to continue to pay those prices? The answer is no. Our state, when our Governor came in, he inherited a \$5 billion budget deficit; we're now at a \$1.5 billion deficit. Can we continue at a 15-20 percent drug trend? The answer is no. It's obviously a complex question; otherwise the 13 of you would not be sitting here and we wouldn't have taken the time and energy to present. So, it is going to be a situation where we can sustain the cost, and we also have to sustain the R&D, there's no doubt about that.

Carmona – Other questions, Ms. Carbonell?

Josefina Carbonell, HAS assistant secretary for aging – Mr. McKibbon, if importation is permitted, what liability protections – if any -- will the state Illinois take in administering its drug programs for state employees and retirees?

McKibbon – Sure, well, that's a good question and I'll admit right away that I'm not an attorney. There were several attorneys that did follow and work on this particular project. We've said repeatedly, in our waiver request to Sec. Thompson and in our citizen's petition, that we would not require anyone in our program to sign a blanket waiver. We have talked about those kinds of issues with the pharmacies we visited – in Canada – and, as far as the attorneys would say and, again, I'm just going to give you the answer that I have heard them say and use, is that the liability protections that the citizens and the members of our plan have are consistent. There is nothing that we would ask them to waive. They do have their rights, both in the U.S. and, if the situation occurs as described by your very first witness, or if were to occur in another locale. So, that's the way we look at it. There isn't any increased liability. The other thing I would say is that we have attempted on numerous occasions to work with the FDA. The Governor does not want to do anything to violate federal law. So, we presume that any system that is done, and any importation, is sanctioned and approved by virtue of a waiver or by virtue of a change in federal statute or some other mechanism.

Carmona – Thank you, sir. Other questions?

Dr. O'Grady.

O'Grady – I have one in terms of the way your system works and the way that you did your analysis kind of leading up to it. We know, with drug prices in U.S. anyway, there is a wide variation in what different groups pay for... full retail, different types of discounts. Now you have a population where, it sounds like, anyway (and correct me where I'm wrong), you're hoping to offer these sorts of this access tests to certainly people who have no insurance coverage, but is it also state employees who would be involved? I mean, you mentioned yourself, I kind of assume...

McKibbon – Right, doctor. What we studied was state employees and retirees; we have very comprehensive data from our PBMs on what the costs were. We know exactly what the co-pays are and we know exactly what the ingredients are. That was the basis of our study. So, when we put out an estimate of savings, it is on a very selected list of drugs and Dr. Kamath will speak more to this when he comes up – but a very selected list of brand name medications that we found clinically appropriate for inclusion in the program. And, we can calculate, cause we had the data from our various vendors, how much those drugs were and how much it would be if we purchased those exact same drugs in Canada. And that was the basis of the work that we did. Certainly, you know, I've been asked many times, "How will that be translatable to a general citizen?" Certainly, if we set up a system in Illinois that was designed to save the taxpayers' and the employees and the retirees money -- in the form of no copay, which is what we proposed in

our program, going from a co-pay of currently \$28 for a non-formulary branded drug to zero (which was what we suggest in the program) – as well as some savings to the taxpayer -- that if we set up a system that was safe and effective in that way, then certainly, we don't want people to access the Internet in an unregulated way, either. We feel that safety is important and that we can extend those same types of inspected programs and pharmacies, if indeed we are able to do so, to the general population of our state.

Carmona -- Dr. Duke?

Duke – Well, I'd like to build on that, if I could. In the sense that the state Medicaid program and one of the issues of one of our earlier speakers talked about the issue of the non-senior working poor. If I understand your system, you require one month of an Illinois retail pharmacist review and filling of the prescription on a restricted list of drugs. My question actually has two parts. One is the impact on small businesses in your state; in the sense that you are asking them to do the up-front work for a system that, in a sense, then takes away their work in the future. And, you're sort of creaming the market, in the sense that you are taking a restricted list of drugs and leaving that business line to then be filled by a now weakened small business community.

McKibbon – Actually, a very excellent question and I will answer it to you specific to the study and also in the waiver request. The waiver that we made, and the Governor on numerous occasions has supported House Bill 2427, which was the Gutknecht bill, which would have allowed retail pharmacists and wholesalers to bring their product in. And, indeed, we would continue to want to do that, if that was available. Were it not available, and we would use what we continue to call in our report the Canadian mail order system, Dr. Kamath will speak about a couple of the safety components of this in more detail. One of the things that we suggest in our program is an Illinois primary care pharmacy model for safety purposes. In that, we would pay a retail pharmacy to manage the total pharmacy care for that particular patient. So, that every time a scrip were to go through the domestic mail order system, or the Canadian mail order system, that that primary care pharmacist would be paid an amount to help manage that patient. And that primary care pharmacist would have access to the patient data for all the fills – the domestic fills and the non-domestic fills. So, that is one way, actually, that we, in talking with the Illinois retail pharmacists association, the Deans of the Pharmacy school, with the retail pharmacists and with members of the Board of Pharmacy (and again, Ram as a pharm MD will talk to this in more detail), we found that to be a way to take some savings that were going to be generated in our program and put it back into the domestic system. Because, as you all know, there have been an immense number of prescriptions (particularly maintenance prescriptions) that have shifted to mail order. So, that, indeed, even in the way we put it in our report, often times, the first fill – which is, as you all know, is the most expensive fill – is done at retail setting. And then, the mail order facility, owned by a PBM or another entity, then picks up the delta. So, in our report, our model and our proposal (and again, this was just for the employees and the retirees that we developed this for), we would take some of those savings and put them back into the system on the retail side.

Carmona – Sir. We heard earlier from Governor Doyle about a program that he set up that he feels fairly secure with. That he had no problems with his citizens accessing those pharmacy companies in Canada. After his testimony, we heard testimony from another gentlemen that showed us, in fact, one of those pharmacies did provide medications that were either repackaged or were something that they were not supposed to be. So, there were a lot of issues that were brought up. How can you ensure the your citizens in Illinois are safe?

McKibbon – That is a very good question, Admiral. And, I think that Governor Doyle and Governor Blagojevich had done a great job, and I know that it's a passionate issue for both of those gentlemen, as well as my Governor. When we selected our sites to visit, we went out and, of course, as Governor Doyle has gotten, we were beseeched with requests to visit. We had 11 people go on this trip; we spent four days in three Canadian provinces. We selected the pharmacies that we were going to visit based on information that we had been given, and research that they were able to do by our team in advance. What we found was that, the sites that we went to go visit had been operating in a way for a number of years. And, in a couple of cases, the city of Springfield, Massachusetts, for example, had been using with success. We went

and looked at those pharmacies. There was also another program that had used a facility in Toronto and that we were aware of had a good safety record. Those were the pharmacies that we went to go see. When we visited those pharmacies, we took our chief pharmacy inspector from the Illinois Department of Regulations, which is the regulatory agency in our state that regulates pharmacy. The prosecutor (who by state statutes has to be both a pharmacist and a JD), Dr. Kamath, who's a pharm-MD, a gentleman from our public health department who is also an RPH. And, we basically turned these guys loose and said "Pretend it's Peoria, as opposed to Manitoba. Do what you would do in any state facility. You get to go for as long as you want, get access to anything you want, and have at it." And they did. And, when they came back, they were able to write the report in such a way that we felt that, as I articulated in my comments, that it was equal to or superior the practice pharmacy in my state.

Carmona – Ok, my concern is that we heard a similar presentation by the Governor, by the assurances and yet we had, apparently something that slipped through with the same type of assurances that said, we checked it, we sent our best people, this meets the standards. And yet, we have a medication – again, apparently – based on the testimony after the Governor, that got through. So, aside from the economics, I want to deal with the safety now.

McKibbon – I think that's a very good point and when we met with the Manitoba provincial officials, for instance, we talked about a lot of things. We talked about supply, effectiveness, about inspections. In fact, our folks talked on a colleague-to-colleague basis about how can we make both systems safer and more efficient? And we continue, to this day, to have concerns with the Manitoba provincial folks, who would be our contemporaries in the state of Illinois. So we agree with you, Admiral. Safety is paramount for all of us; it's paramount for my wife and kids; it's paramount for the governor, for his wife and his two young daughters. And, we would do what we think is reasonably appropriate for safety.

Carmona – Other questions, Mr. Sachdev?

Sachdev – To follow up on the comment that you just made and ask a question... We've heard a lot of testimony and heard you testify that you felt confident that the drugs being purchased from Canadian pharmacies are as good as the ones purchased in this country. But we also know – what we've heard in prior testimony is – that the government of Canada (Health Canada in particular) has said that they have a different regimen for regulating products that are intended for export from Canada than for import. And so, products that Canadian citizens are getting from licensed Canadian pharmacies are not necessarily going to be the same, and Health Canada can't vouch for safety of the products that are being intended for export back to the U.S. market in the same way they would for those products. So, that question has raised concerns for us about trans-shipment and, in particular, whether they can (in the context of importation into Canada for export), whether the Canadian regulatory entities -- whether it be the provincial pharmacy regulators or the Canadian government -- can adequately police trans-shipment? How do you see that concern?

McKibbon – Yes, we see that concern. We would not advocate the trans-shipment. I will tell you that, as we went up and took pictures and picked bottles off of shelves, we saw "manufactured by Abbot" which is a manufacturer in our state, we saw "manufactured by Taft", "manufactured by Takeda". We looked at those things and we don't disagree with respect to trans-shipment. The Governor and we have said all along – and I don't want to get into semantics about whether it's an FDA-approved facility or it's a Health Canada-approved facility. I believe Health Canada has been very clear about their certification for their own citizens, that they have not found issues. I know CRS (the Congressional Research Service) did a memo in May on comparing the systems. So, that I'd just suggest to you that, as we went up there and took a look at it, it would be product that would be approved and made in the equivalent of an FDA facility. We looked at the list and we restricted it to 92 products that we felt were appropriate – we're not putting generics on the list that were not available in this country. We were being sensitive to the patent laws and those kinds of things, so we were very careful. As far as we were concerned.

Sachdev – And can you also, just as a follow up, check for us, was one of the pharmacies that

you looked at the Total Care Pharmacy that was on the Wisconsin website?

McKibbon -- No. We did not look at Total Care. No, they were not on. I can put up the list, these are the list of the pharmacies that we went to look at, on your screen now. And Total Care was not one of those pharmacies.

Carmona -- Thank you. Any other questions? Thank you, sir, appreciate that. Let me just make an administrative remark right now, that we have not forgotten about lunch. I know my task force members are probably wondering, but I am concerned because I have been told by staff that are some of you who have planes or special transportation arrangements this afternoon. So, that's why I decided to push through. We've got three more, and I'm going to cut lunch to half an hour. I'm going to ask the task force members, we had originally scheduled it for an hour, I'm going to ask them to cut it to half an hour so we can get to all of our speakers, because that's what we're here for. So, we will expedite it as much as possible. So, I think we have Dr. Kamath now, as our next speaker, and he is also a special advocate for prescription drugs in the state of Illinois.

Ram Kamath, Special Advocate for Prescription Drugs, State of Illinois

Mr. Chairman, members of the task force. My name is Ram Kamath; I am a special advocate for prescription drugs for the state of Illinois. I am a doctor of pharmacy with 20 years of experience in the pharmaceutical field. As a pharmacist, I know the power and the dangers of prescription drugs. The right drugs have the ability to save lives; the wrong ones, or the right drugs taken the wrong way, can have disastrous consequences.

However, affordability plays a major role. A prescription drug that is not affordable and not taken by the patient, is not effective. We do not know how many diabetics skip their medications today and, as a result, lose a toe or go blind. A growing body of research suggests the scope of the problem. For example, the journal *Diabetes Care*, published a study of older Americans with diabetes. In a national survey of 875 people, 19 percent had to cut back on their medications at least during the last year to save money. 28 percent reported that they had to forgo their medication so they could afford food or other essentials to pay for drugs; 7 percent reported skipping their doses at least once a month for financial reasons. This is frightening to me. I firmly believe that a milligram of prevention is worth thousands of dollars of cure.

Our Canadian drug reimportation program has the potential to extend and even save lives. Our plan will give the people of Illinois access to the exact same medicines -- by the exact same manufacturers -- at a significantly lower cost. The drug supply in Canada, we feel, is safe, and in some ways is even safer than it is here. Canadian manufacturers ship drugs in stopped bottles, bottles that are manufactured and sealed by the manufacturer, sent to wholesaler and sent to the retailer, directly to the patient's home. This means that the consumer receives the product in bottles sealed by the manufacturer. This substantially reduces the risk of human error in dispensing. In comparison, as we heard this morning, prescription drugs in the U.S. can go through several layers of wholesalers, retailers and packagers from Florida to Nevada to New York before reaching the consumer.

This difference in the supply chain is one of the reasons that our proposed pilot deserves the FDA's approval and attention. We designed this program, top to bottom, with patient safety in mind. Under our program, the patients would be required to submit their medical histories, allergies, lists of drugs they are currently taking, to the pharmacy prior to receiving the drugs. The list approved for import will be restricted to those that are clinically appropriate and unlikely to spoil during transit. Customers will not be allowed to import habit-forming pain medications, generic medications that are a lower cost here, or antibiotics for acute illnesses.

After receiving a prescription from a U.S. organization, the drug needs to be filled in a local pharmacy for one month. Then, only, they can be imported from Canada. I would like to stress that each patient will select a primary care pharmacy to manage his or her total drug therapy

obtained from domestic or non-domestic sources. This is an important safeguard of our plan. With the soaring prescription prices in the U.S., it makes sense for consumers to shop around for the lowest price. As a result, the patient may be buying five different prescriptions from five different pharmacies within the U.S. This increases the risk of adverse drug interactions. Our plan to create a primary care pharmacists reduces that risk. We also provide a toll-free number where a pharmacist would be available 24/7 to address any questions or concerns.

Finally, our plan would be completely voluntary. If consumers are not comfortable, they would be free to continue getting their prescriptions from a local pharmacy. We are confident that our drug reimportation plan will decrease patients' out-of-pocket expenses and reduce costs for the taxpayers of Illinois. And we are fully confident that our program will give access to safe, reliable prescription drugs that they need. I look forward to working with the FDA to make our plan a reality. Thank you very much.

Carmona —Thank you, sir. Task force members, any questions? Dr. Raub.

Raub – Thank you, just one quick one. Do you feel confident that the costs associated with the patient pharmaceutical oversight, the call line, and the others, won't soak up the savings?

Kamath -- We considered the cost for the primary care pharmacist and that cost was taken into consideration in our calculations of cost savings. We feel that a pharmacist should manage all of the prescriptions a patient is taking, and not just the ones that are filled in his store. Because some of the current systems don't talk to one another here, if you buy a prescription from a pharmacy that is within the network, then you buy a prescription out-of-network, those systems don't talk to each other. And, you know, if there is a significant interaction, it can be missed. Whereby Internet technology has given us the accessibility of email and can provide all information to a pharmacist that is designated by the patient. It may be his local pharmacist. So, this pharmacist will have all the information, can check for all the interactions, and adverse effects, and warn the patient accordingly.

Carmona – Other questions, Mr. Reilly.

Tom Reilly, public health branch chief at the White House office of Management and Budget – Why the need for the no first fill in the first month in the Illinois retail system, if the Canadian system is the equivalent?

Kamath -- Safety. As a clinician, I know when a prescription is given to a patient and taken to their pharmacist, the patient may encounter some adverse reactions; all drugs do not suit all patients. There may be having a condition, the drug might help them, but if you might have an adverse event or reaction. Say, all statins, Lipitor, all of them, in some patients it can cause muscle pain. These are chronic medications, but somebody may take it and then feel, "This is causing me too much pain," then go back to his doctor and be switched. So, we want to avoid those situations. Once the patient receives that prescription at least for one month, and the physician is confident that the patient is comfortable with it, then and only then can they get in refilled Canada.

Carmona – Dr. O'Grady, did you have one?

O'Grady – yes, I've got a couple of questions and was hoping you could provide the task force with information on, having to do with, as you've done your analysis of this, and you've looked at the various sources of what people are currently paying – whether it's state employees or state Medicaid program, or your uninsured folks – that we could start to get a feel for just... your analysis of what you think the effective net discount would be among different subpopulations.

Kamath – Our analysis was limited to state employees, where we can get full cost information

from our PBM. We compared net-net, what the state is paying today, for the top 400 drugs. And we took out all of the drug antibiotics, generics, everything we took out, then it was just the brand name drugs. There are 91 drugs listed in our report. Just those drugs, how much would it cost us from our current vendors? And then we said, if we were to buy the very same drugs, from Canada, on that same date, how much would it cost us? And then we came up with our savings numbers, and that's what we reported.

O'Grady – But, is there something that would block you – other than time and resources – to comparing what you would pay under the Medicaid program?

Kamath & McKibbon – Yes, we could do that. We could do it and we certainly have access to the Medicaid data. I will say that in our particular case, in our state we get supplemental rebates as well as the over 90 rebate. I don't believe, quite frankly, doctor, that we would save very much money by moving many of those drugs over to Canada, so we didn't study that. I mean, intuitively, we knew that between the over –90 rebates and the supplemental rebates that we've been successful in negotiating, that that wasn't the focus. With respect to the uninsured and other populations, yes, we were the first state to get a waiver for this. And we know how much, and those folks are getting access. In our program, we have 186,000 who are under 200 % of FPL -- we also have a state-only program for those that are between about 200 and 240, where we spend about \$175 on ten disease states. We have information on those individuals and we also have some linked information about the uninsured, because we initiated our own discount club buying card as of January 1, so we know how much those folks are savings. So, again, if we could work together with the FDA, we would gladly share that kind of information.

O'Grady – Right, I guess my only point is that I'm trying to get to the point of the analytic aspect of what the net effect is? Is it basically that you can take your state employees and your retirees and you get them... when you take into account all of the appropriate kind of netting out of costs... have you got them down to about what you pay for your Medicaid population? And that was more of an analytic issue of whether you were looking to sort of... As a follow up to that, some notion is, are there other mechanisms that are on the table that would not have this sort of safety issues -- that I know you're not concerned about but I know that our FDA colleagues are fairly concerned about – that would allow you to look at this same bottom line?

McKibbon – One suggestion was that we could extend the Medicaid pricing and the supplemental rebate negotiations that we have been able to do for the Medicaid population to the state employees and retirees. Yes, that would absolutely be a savings. Would it be equal to the Canadian amount? We haven't run that calculation, but it would be an interesting calculation to do.

Carmona – Other questions on this side? Yes, Mr. Reilly.

Reilly – You had, these are projections, I guess, an estimated net savings of \$90 million in a year. What are the gross savings and then the cost? Do you have that and can you provide that? And does that the work you've done up-front work, you know visiting and inspecting the pharmacies? Does it presume an on-going revue of the pharmacies that you deal with in Canada?

Kamath – The total cost for our trip was something like less than \$12,000; that was not considered as a savings.

Reilly – Right. But they can change; do you envision some regulatory or some oversight over time?

Kamath – Yes.

McKibbon – As I said, earlier, when I did my remarks, the Department of Professional Regulations,

if we were to put together a pilot program, would go ahead and do inspections on a periodic basis. With respect to our staff time, we didn't net those costs into the savings projections, but we did have, as I said earlier, the ingredient costs, the co-pays. We did factor in primary care pharmacy costs, certification of primary care pharmacists and setting up the system to do that. So, we can provide some additional information.

Carmona – I think we have one... yes, Dr. Sachdev?

Sachdev – Yes, you mentioned a department, I've missed the acronym there, but is the Illinois Board of Pharmacy involved in what you're proposing and have they taken a position on it? But, also, in the system that you set up, what would be the role of the Board of Pharmacy in policing the drugs that were coming in?

Kamath – The Illinois Board of Pharmacy is an advisory committee to the Department of Professional Regulations, and we continue to seek their advice and guidance, if we are allowed to proceed in this direction.

Sachdev – Have they so far given you any advice or guidance on this program?

McKibbon – No. We met with individual Board of Pharmacy members, and there's a gentleman by the name of Phil Burgess, for instance, from Walgreens. We went into our stakeholder's discussions and tried to meet with anyone and everyone that we thought was important to meet with. I mentioned earlier the Illinois merchants association; we met with Walgreens, which is also a very large drug store and employer in our state; we did meet with pharmacy groups and pharmacists' groups, deans of boards of pharmacies, so in our appendices, there are various letters of support or endorsement from some of these folks.

Sachdev – But the Board of Pharmacy, as I understand it, is the primary pharmacy regulator, is that correct?

Kamath & McKibbon – Not in Illinois. The Department of Professional Regulations in our state has the statutory responsibility to regulate the pharmacies. The Board of Pharmacy is an advisory group to the director of the Illinois Department of Professional Regulations.

Sachdev – So the Board of Pharmacy would not have a direct role in the program you have designed for importing drugs from Canada?

Kamath – we have not met with the Board, but we have met with a number of members, and the Board given us any official recommendation, whether pro or con, for this situation.

Carmona – Sir, last question. We have heard testimony today and previously from groups that favor importation that it is safe, that there have been no deaths, no deaths or complications because of importation. What is the evidence? How do you keep track of adverse reactions to medications? For example, if we have a patient on heart failure who gets a knock-off drug that's sub-standard, not therapeutic or something, and the heart failure is worsening., the heart patient is probably not going to be looked at as an adverse drug problem, but probably as a patient who's not getting better. Or, a diabetic who all of a sudden become brittle. I mean, how do we actually know the magnitude of the problem, because even if death – which is the worst-case scenario occurs – it may not be attributable to the pharmaceuticals that the patient was taking.

Kamath – Right, I agree, with you sir. In my previous position, I set up a diabetes care clinic and I encountered these diabetic patients coming every day to the clinic who could not afford their medicine. If the medication was taken and it was not effective, the patient will definitely do worse. But, in the first place, if he or she cannot afford the medication that would be even worse. And

those were the situations I was encountered with, my patients coming to the clinic. Those who say "You know, I see their HBNC going up and I asked them what happened?" "You know, I can't afford this drug and I was not taking it." You know, this is what happens; you see them worsening, day by day, losing control, going blind, having an MI. All the sickness.

Carmona – But sir, that wasn't the question. I'm understand the cost issues, I'm trying to do the safety side now. I used those as examples. What system, what metric, what outcome measurement do we have to know? We hear these sweeping statements that say, there have been no deaths, there have been no adverse outcomes. But, you know, just trying to be effective, impartial physician looking at this, where's the evidence? We don't have a system to be able to make those statements. So, I'm wondering how do we, if we consider importation, how do we inject that into a system to ensure that patients are safe and we, in a timely fashion, pick up any adverse outcomes that would lead us to an improper medication.

Kamath -- It would be the same as with the domestic supply. I mean, I do not know of any metrics today to measure what you are asking to be measured. So, in what way, will the Canadian importation supply be different than the domestic supply today? Under both situations, we don't have the metrics to measure what you're asking us to measure.

Carmona – Ok, thank you. Dr. Crawford.

Crawford – We do maintain surveillance programs and reporting systems like (technical) and so on, within the U.S. What the Surgeon General's comment probably referred to is that no government assumes the responsibility for monitoring the products that are so-called "reimported". And that is a concern. We heard testimony earlier today about even the fact that there is more or less an open border to some states -- cannot have escaped the attention of terrorists and counterfeiters. So, you know, we're not trying to make it dramatic or trying to seem draconian, but these are sources of grave concern.

Carmona – Thank you sir, appreciate your remarks. I have a question now, I have some other information on travel. Is Mr. Lothar Dueck, I believe it is, Coalition for Manitoba Pharmacy, is he here? Are you still under a flight restriction this afternoon?

Dueck -- I need to leave by 2 pm.

Carmona -- Why don't we take you next, sir, OK? If there's anybody else in the audience, we don't want you to miss flights or unique travel arrangements you many have. If you could please let one of the staff in front know right now, so we can alter the schedule a little to accommodate you, because we desperately want to hear from all of you. We don't want anyone leaving because we couldn't accommodate you.

Lothar Dueck, Coalition for Manitoba Pharmacy

Good day and thank you for the opportunity to speak today. My name is Lothar Dueck, I'm a community pharmacist in Manitoba, a small rural community a few miles from the border with Minnesota. I also am president of the Coalition for Manitoba Pharmacy, a community pharmacists' organization that opposes the cross-border Internet pharmacy and drug reimportation from Canada to the U.S.

I am here today to explain that importation of drugs to the U.S. is harming Canada's health care system, extremely risky for American citizens, and not a viable policy for the U.S. Let me begin by saying that I am I am astonished by the insensitivity of American politicians who promote schemes to divert Canadian drugs south of the border to meet the needs of Americans. Canadian doctors and pharmacists are extremely sympathetic regarding the need to find a way to make prescription medications more affordable to American patients, particularly those without

comprehensive drug plans and insurance.

But, health professionals in Canada are shocked that many U.S. politicians at all levels of governments are telling Americans to ignore their laws and purchase drugs in Canada. The U.S. has the richest, most productive and innovative economy in the world. Resolving this issue should not be beyond you.

Thoughtlessly appropriating Canada's drug supply and pharmacy care is not the answer to your problems. Those leaders who cheerfully promote reimportation of Canadian medicines should be ashamed of themselves. In 2003, Americans bought approximately \$1 billion in Canadian drugs through Internet pharmacies. This is a drop in the U.S. market, but it is a huge proportion of the Canadian drug supply. In fact, last year, more than 40 percent of the entire supply of the province of Manitoba's drug supply was diverted to U.S. This is causing dangerous shortages in Canada. According to a survey sponsored by the Coalition, more than 80 percent of Manitoba pharmacies reported having a harder time finding sufficient drugs to treat our Canadian patients.

In December 2003, the largest wholesaler in Manitoba ran out of a number of medicines; suddenly it was not possible for pharmacists to order drugs to treat conditions such as depression, influenza, and asthma. Shortages of prescription drugs used to be rare occurrences, as when a manufacturer had a production problem. But, we have never seen such a severe shortage before. In addition, Manitoba is facing a critical shortage of pharmacists who care for patients in our province. Because it is so much more profitable to ship drugs to Americans, rather than to dispense them to Canadians, now more than 20 percent of community pharmacists in Manitoba have become Internet pharmacists rather than devoting themselves to caring for Manitoba patients. This is desperately straining the ability of remaining community pharmacists to offer proper care to their Canadian patients.

Cross-border drug-sellers buy Canadian drugs at Canadian prices, which are controlled by the government federal Patent Control Review Board. On the Internet, sellers buy huge quantities of Canadian drugs at controlled Canadian prices, and then sell them at a large markup to Americans. In short, U.S. demand -- with the help of opportunistic politicians -- has made it more profitable for Canadian pharmacists to sell drugs to Americans than to care for their own patients in their own community.

Today, thanks to the U.S. drug diversion, Canada is experiencing sudden price inflation. Because of the growing cross-border diversion, many drug makers have raised their Canadian drug prices by as much as the price control system will allow. Some of them have increased drug costs for the first time in decades of stable drug prices. Have any American drug importation enthusiasts bothered to ask what impact drug importation is having on Canada? The results have been shortages of medicines and pharmacists, higher drug costs for all Canadians, and new drugs not being available to Canadians because of the reimportation.

That is not fair and it's not right. American reimportation proponents have also dismissed concerns of the FDA with respect to the safety of cross-border drugs. They do so at the peril of American patients. The safety concerns are real, and I will tell you why. Recently, Internet pharmacies in Manitoba were caught promoting the sale of drugs from foreign countries to Americans. These medicines neither have been approved by the FDA or Health Canada. Neither country has any way of verifying the quality of these drugs, or even if they contain any active ingredients at all. Reports from Prudential Financial and the FDA have shown major increases in transshipment of drugs from countries such as Pakistan, Bulgaria, and Argentina. These drugs may enter Canada before being shipped to the U.S., but they entered the Canadian drug verification system. Health Canada does not guarantee their safety.

When I hear U.S. Governors saying "If Canadian drugs are unsafe, where are the dead Canadians?" I respond by saying that Canadians are safe because we don't take foreign, unregulated drugs. Our government won't permit it. If those drugs are not good enough for

Canadians, why should you assume that they are good for Americans?

And a final point I want to make is that politicians who tell the American public that they can simply solve their problems by buying up Canada's drug supply system are misleading you. It may make for popular political sound bites, but it's nothing close to a workable policy. Canada's drug supply policy is starting to break down, while we're supplying less than one-half of one percent of the U.S. drug demand. Any increase in Canada's drug diversion will – or even the continuation in the current rate --- will result in American patients with chronic disease not receiving their prescriptions from Canada. Maybe *through* Canada, but not *from* Canada. Then you can expect to see an increase in adverse events for U.S. patients, this is what happens when patients don't get the drugs they need. Canada is less populous than California alone; we simply can't take the strain of you buying our medicines. Drug makers ship enough medications to meet the needs of Canadians; they do not ship us enough to meet the U.S. needs....

Carmona – Sir, would you sum up now, please?

Dueck – Yup. Drug reimportation supporters are leading you down the garden path. There is no panacea, so solution to be found in poaching from Canada's drug supply. This is not a workable policy. Canadians are sympathetic to America's challenges about prescription drugs, and I'm sure that America can solve this problem. Thanks for allowing me to speak.

Carmona – Thank you sir, any questions? Yes, Dr. Duke.

Duke – Given the extent of the shortages of the drugs and pharmacies, in Canada, is the Canadian government considering putting any restrictions on the Canadian pharmacies filling American prescriptions?

Dueck – Well, this is a political question as well. We have talked to our counterparts at Health Canada and they say they are monitoring the situation. I wish they would come up a little more firmly and say, yes, we need to protect the Canadian health care and our health care system.

Carmona – Thank you sir, oh, I'm sorry, Mr. Azar.

Azar – I was wondering -- even the states and regimes that are involved in importation of drugs from Canada, you heard the representative from Illinois saying that they did not favor transshipment of foreign-made drugs that would just get passed through Canada in an unregulated manner. What is... you're obviously a pharmacist in Manitoba and you consider that the drugs you sell in your pharmacy are safe for Canadians to consume. Is there any more limited regimen of importation into America that could be designed that would really simply take drugs from storefronts like yours and send them into America that would be safe and would be sustainable?

Dueck – I'll tell you what's happening in Canada. Drug manufacturers are putting extreme pressure on the pharmacy and actually limiting amount of medication that's being sent to Canada. Pfizer actually shut down a wholesaler in December, or in the beginning of January, and said that they are not sending any more products to that wholesaler, because they are shipping them to Americans. All major manufacturers have sent letters to the pharmacies saying you shall not knowingly dispense or sell medications to anyone who will export them, or to customers who come up to buy medication. You should not be doing it. So, the drug supply is drying up in Canada and I don't know how we can ensure that the drugs that are coming through Canada are coming from Canada. The Internet pharmacies announced today that they will be having to source drugs from elsewhere in the world, because the Canadian drug supply is drying up.

Reilly – Do you have any view on the comment that Americans are subsidizing the R&D costs of drug manufacturers while the rest of the world – including Canada – benefits from the innovation?

Dueck -- The U.S. and the rest of world have different health care systems. In the rest of the world, the government is the health care system and the payer of all health care costs. In the U.S., it's an open market system, so the drug companies have agreed to do business in the countries, under the terms that they have made for the arrangements, and I guess the countries that are price controlled are kind of, you know, we don't have the first line drugs as soon as you do in America. Right now, we don't even have new drugs that are licensed in Canada, because of the reimportation and the price issue, because we are going to be selling them in Canada. So, yet, Canadian health care is going to be suffering because of our price control system to some degree.

Carmona – Other questions? Anybody? OK, thank you, sir. Our next speaker is Joel Miller, National Alliance for the Mentally Ill.

Joel Miller, National Alliance for the Mentally Ill

Thank you Mr. Chairman and members of the task force. I am Joel Miller, acting director of the policy research institute at the National Alliance for the Mentally Ill, known as NAMI. NAMI is the grassroots advocacy organization representing hundreds thousands of people with serious mental illness, major depression, schizophrenia, bipolar disease, and other major disorders. And we have over 1,000 affiliate organizations across the country.

Late last year, we established a task force to develop policy recommendations on importation. I would like to preface our task force position by making the following points. First, significant progress has been made in discovering new and effective treatments for patients with serious mental illness. Second, these advancements have enabled persons with serious mental illness to improve significantly and to remain in their community and with their families, leading productive, rewarding lives.

But third, having said those things, we are very concerned that, unlike many medications that treat other chronic illnesses, medications that treat serious mental illnesses cannot be used interchangeably. Each psychiatric medication has a very different mechanism of action, and the brain is such a complex organ, and mental illnesses are so complex, that they affect each person's brain differently. So we are extremely concerned that if medications are modified accidentally or inappropriately in any way, or people with serious mental illnesses receive mislabeled medications through reimportation, the side effects will likely be very serious and worsen the patients' condition.

In addition to those specific issues, the task force also has other observations that the task force looked at with respect to psychiatric medication, a couple of other observations guided the task force's discussion. First, an important issue is not safety standards across the U.S.-Canadian border, but a lack of safety standards for products coming into Canada from other countries where there may not be product of origin label requirements.

Second, the importation of medications by wholesalers, as envisioned under various Congressional proposals is different from Americans going to a licensed pharmacist in Canada. It is our understanding that wholesalers would not have to meet either American or Canadian standards for licensure requirements. And third, over the next couple of years, several atypical antipsychotic medications will become available in long-lasting, injectable forms. These new technologies will require special handling and storage in accordance with standards set forth by the FDA and the manufacturers. The FDA must have been given the legal and regulatory authority to ensure that these products meet these safety standards, before reaching U.S. consumers.

Based on those considerations, NAMI's official policy is that – based on safety and quality concerns raised by the FDA – we support the provision in the Medicare Drug Benefit Law, whereby only medications from Canada should be imported and medications must be certified for their safety by HHS. Second, although NAMI supports the safety provision in the Medicare law, we recognize that individuals – especially in the border states to Canada -- will go across the border

to purchase them. Individuals who seek less expensive medications at Canadian pharmacies and return with reasonable quantities of their prescription drugs should not be prosecuted by FDA. And finally, NAMI has grave concerns about importation through Internet-based pharmacies. The importation of medications through these operations compromises the public health and safety. Safety and efficacy must remain the most important concerns, and prescription medications used by consumers with serious mental illness. Thank you.

Carmona -- Thank you, sir. Task force, members, any questions? Thank you very much, sir. Is Jeffrey Axelrad still in the audience? Sir, do you still have a time constraint. I know that we're a bit over. Are you able to wait until after the lunch break; we have one more speaker and then we're going to take that half hour for lunch, but I was told that you might have a problem.

Axelrad -- Yes. I have to teach eventually, but I can wait until after lunch.

Carmona -- Ok, sir, I appreciate that very much. Then we'll go to Panos Kanavos, London School of Economics.

Panos Kanavos, London School of Economics

Mr. Chairman, distinguished members of the panel. Thank you very much for giving me this opportunity to share with you the results of my research on drug reimportation and the economic impact of drug importation in Europe. My name is Panos Kanavos, and I am a professor of international health policy at the London School of Economics, in England.

Let me start by saying that the freedom of the movement of goods within the EU provides the legal justification for parallel trade. And within, of course, that context, what we set out to do was to quantify the economic impact of parallel trade in six major destination countries -- among them Germany and the UK: the third and fifth largest Pharma markets, respectively.

And it is by focusing on six widely used product classes, among them lipid-lowering, and peptic ulcer medicines accounting for approximately 22 percent of the branded retail market. We also sought to apportion the benefits to individual stakeholders, namely health insurance, patients, industry, Pharma distributors, and pharmacy. And you can see the research endpoints on the right hand side.

This slide gives you the justification for parallel trade in the EU, with prices in euros. And you can see, for example, that Fluoxetine sells in Germany for 104 euros, that is branded Fluoxetine (or Prozac), and that the lowest price in the European Union, in Spain, is 65. So, the German price is almost twice the size. In the U.K., Simvastatin (or Zocor) sells for 47 euros, but you can acquire it more cheaply in Greece for merely 18 euros. So, the UK price is nearly three times as high.

Of course, we set out a series of economic hypotheses to test our objective, as you can see here: including price competition, including aggregate welfare effects, including patient benefits, and of course the impact on industry. Let me share with you the direct benefits on health insurance, pharmacy, patients, parallel importers and the industry.

So, of course, the size of price differences suggests that there are significant benefits to be had from parallel trade, so patients and health insurance organizations are going to benefit significantly. But, what I aim to do is to show you that this is not the case, and I have the evidence based for that. It also casts doubt on the arguments put earlier by the Governor of Wisconsin.

Let's look at the allocation of benefits and the impact on patients. First, patients do not benefit from parallel trade in Europe. So, in four of the six countries -- Germany, UK, Sweden and Netherlands -- the benefits are zero. In countries like Norway and Denmark, there are marginal

benefits to be had.

Let me show you the allocation benefits. Looking at patients, zero benefits; looking at pharmacies. Zero benefits in the majority of cases, or 0.3 percent of the market in Norway and 1.2 percent of the market in the Netherlands.

Looking at health insurance organization, the benefits accruing to health insurance organizations are very modest. 0.3 percent of the market in Norway; 0.3 percent of the market in Germany; and slightly higher in the UK: 2.8 percent. And, of course, these are a proportion of the total branded medicines market. If you include generics, the savings are significantly lower as a proportion of the total pharmaceutical market.

The question of course remains: who are the main beneficiaries from parallel trade? We've estimated with accuracy that the main beneficiaries are the parallel distributors with a ratio of 22.7 percent of benefits in Norway, five and a half times more of the benefits in Germany than for the health insurance organizations. In the UK, it's 8.4 times, and the average total impact is 6.5 times more for parallel distributors than for health insurance organizations.

So, we also looked at the indirect effects; that is, the extent to which there is a competition effect within and across countries. And we find no statistical evidence of that over a seven-year period. And, of course, that led us to conclude that, whereas the pecuniary benefits may accrue to patients if they themselves fill their prescriptions in a lower-price country, when distributors are the main actors of reimportation, these financial benefits are eliminated for patients and accrues entirely to distributors. Payers may benefit, but only modestly. And, finally, Mr. Chairman, there is evidence of product shortages in some countries, in the pursuit of profit by parallel distributors in destination countries such as Germany, the Netherlands, the UK and Sweden.

Thank you very much for your kind attention. Any questions, I'll be happy to take.

Carmona – Thank you. Questions, Mr. Sachdev?

Sachdev – This is very interesting; I don't think the task force has seen these numbers defined in this way. Can you give me some more information about why you think it is that the people doing the parallel trade – the parallel trade importers – are the ones seeing the most benefits?

Kanavos -- They realize there are significant price differences between countries, and they are near monopolists. Because they can source from the cheapest, or the second or third cheapest country and sell, and therefore undercut just by a small margin, the locally sourced product in a destination country. So, if you looked at one of the earlier slides, the prices for the branded Floxetine – in other words for Prozac – the parallel imported Prozac is just under the branded locally sourced Prozac produced and distributed in Germany. If you look at the price at which they acquire Prozac in Spain, or Italy or Greece, obviously the price differences are huge. In that sense, they are near monopolists. They have, of course, no incentive – absolutely no incentive -- to lower the cost and offer health insurance organizations significant benefits. The incentive is simply not there. And, the information and evidence base from the national government perspective may be – at times – very limited. Parallel traders may claim they have incurred significant cost, but the question is (and we actually managed to estimate these very crudely) how much does it cost to put a truckload of medicines on the road? We know pretty much what the costs are for filing a drug application for parallel imports. They do not exceed 2000 euros, per drug; if you are looking at European centralized administration (garbled), the fee for the regulatory process is in the region of 3.4 thousand euros per product. So, you're talking about relatively modest costs and, of course, in terms of repackaging and labeling, we have seen products imported from Spain and offered in the UK or Germany in precisely the same packaging and form as they are in Spain. Now, this is partly allowed by European legislation.

Sachdev -- As a follow-up, can you comment on – if you can – on what you think would be the

impact in this country of legislation to legalize importation? And, would you expect that we would see similar types of breakouts.

Kanavos – Let me comment on it from an alternative perspective. There is nothing stopping a British patient (or a German patient) from taking a bus and going across to France and filling a prescription at a significantly lower cost. The potential to realize pecuniary benefits is there. If you legalized importation, you'd have to take into account how wide you want it to be. If it's only Canada, can the supply meet the requirements of the U.S. market? If you allow from third countries, either directly or through pharmacies, I have serious reservations about the impact. We only allow reimport from 15 (going up to 25 with the new members) members of the EU. So, a phenomenon like importation, we can't do it from Fiji, or from Costa Rica, or from Thailand. So long as there is a valid licensing, the license holder has to be located in Europe. With regards to pecuniary effects, you would need to consider the incentive structures for those who actually perform the importation; what are the incentives they face, and whether the governments – as in one of the early slides I showed you – whether governments have incentives in place to allow them to benefit out of this process. In the UK, we have more savings, in Germany we have negative savings; in all other countries, we have zero savings. So, really you would need to consider the incentive structure and really the policies that states, in your case, do have in place to benefit from this process. It is not directly to be shown that the patient and the system will benefit from all this.

Carmona – Thank you. Other questions or comments? Dr. O'Grady.

O'Grady – In terms of the applicability of your research to the American situation, two things came to mind based on your comments. One was, you know you have quite a bit of a lack of competition with the existence of wholesalers in European markets, which I don't think holds. We do have a fair amount of competition and therefore the idea that one particular provide could retain all profits without other people entering into that market and whittling it down is somewhere unlikely. The other thing is -- and correct me if I'm wrong, my experience in European markets is not total -- when you talk about the insurer, you're almost always talking about the government. And, when we talk about cost sharing policies, and again correct me where my interpretations are I'm wrong, the prices are quite a bit lower. I mean, there's a price sensitivity that you've heard testimony about that you see among American consumers (especially the elderly and uninsured) that you wouldn't (or at least I have the impression that you wouldn't) see among European consumers. So, when you say, there's really no reason ... the notion of going from Buffalo to Toronto, you can't go from London to Calais and load up... at that same point when you brought up about incentives. If the Europeans are already paying so low a price, for them, it's probably not even worth the bus fare, for someone in America, might be worth a fair amount.

Kanavos – For the European consumer, I think you're right. I was primarily referring – to try to make it analogous to U.S. situation – to the private market. So, if you're not – and the drug is not covered by health insurance (and there are, increasingly, several cases where that sort of thing occurs), then it makes it worthwhile for the patient to go across the border. In fact, we've seen these phenomena, particularly in the near-border areas. Now, with regards to who benefits, and whether there is competition, we also need to see the extent to which there is competition and the prices are significantly or vastly different between nations. And, in fact, what we know, because of price regulation and other regulatory practices, is that prices in the European Union are vastly different among member states. But despite this, we do not have competition. To give you an idea, we know who the wholesalers are, the parallel distributors, and the largest German wholesaler has approximately 63 percent of the German market. Across borders, there are approximately between 20-25 parallel distributors, so really you would have to consider the pricing structure, and also the availability of product. So, if it is not very available in Portugal, can you get something similar from Greece, from Finland, or Spain, or so on and so forth? And that does not necessarily require huge costs, but the greatest difficulty that wholesalers would have in this particular process is laying their hands on inventory. There's also another case, and might be interesting, when you translate it into the U.S. environment, is really the extent to which drug manufacturers can exercise some kind of vertical control over supply and the distribution system.

We had a benchmark legal case in the European Court of Justice, which is the equivalent of the Supreme Court, effectively, in the European Union, suggesting that, if done with caution, manufacturers are allowed to control – smartly -- the supply. I've showed you data for 2002, and I suspect that parallel trade for individual products is significantly lower for some in 2003, compared to 2002. So, lots of different issues. And reverse incentives, because we've seen parallel importers not necessarily distributing themselves, but using legal wholesalers and the legal channels – so to speak – to distribute products in any of the six countries we examined. It's a tricky market.

Carmona -- Thank you sir, any other questions? No. I thank you very much for your comments; I really appreciate it. We will adjourn now for lunch and I've just been told that the cafeteria there is open until 2:30 so we're running tight. I'd ask for task force members to please be back in 30 minutes so we can begin. Thank you very much.

(Lunch break)

Ladies and gentlemen, we're going to go ahead and get started. Thank you so much for working with us on the schedule. As I said, I know we ran over but we want to keep this as open and transparent as possible, to make sure we get to all of the issues before us. Our first speaker this afternoon will be Mr. Jeffrey Axelrad, who is a consultant. Sir, thank you for accommodating us.

Jeffrey Axelrad, Consultant

I appreciate the opportunity you are providing to discuss the serious monetary, liability issues that would attend non-manufacturers importation of drugs into the United States.

My experience may be helpful to the task force's consideration of liability issues. For more than three decades, I was an attorney at the US Department of Justice. For more than 25 years, I was the torts branch director responsible for most federal tort claims act litigation, including medical and medicine litigation. Currently, I am an adjunct professor at George Washington University law school and I am also a consultant to PhARMA. My views, however, are entirely my own.

Very substantial liability concerns would exist for any entity in the U.S. pharmaceutical distribution system that facilitated importation, specifically, those entities would subject themselves to the full panoply of state law remedies associated with the sale of drugs.

An importing party may not be able to prove a defect was the responsibility of the manufacturers. Importation may well bar an importing entity from establishing a direct causal link between the manufacturer of a drug by a US manufacturer and the drugs subsequent alleged cause of an injury to an individual. The importing party, consequently, may well be solely responsible for any damages suffered as a result of importation. At a minimum, the importing entity would likely be embroiled in litigation claiming that it is liable to pay a share of the damages. This conclusion follows from established tort law principles.

The black letter law is that one engaged in the business of selling or otherwise distributing a product, who sells or distributes a defective product, is subject to liability for harm to persons or property caused by the defect. Product sellers have same legal responsibility as manufacturers, under strict liability. Any seller or distributor of a drug falls within these principles.

The principles applied establish a theory of liability if a seller causes a stale, counterfeit or mislabeled prescription drug to reach a customer and the customer is harmed. Objectively, the FDA would consider whether it is feasible to guard against harm to our citizen from importation of stale, counterfeit and/or mislabeled prescription drugs.

My point is somewhat different. It is that the persons selling or distributing imported drugs not only need to exercise care to ensure that they are not part of any chain that distributes any imported stale, counterfeit or mislabeled drugs. But, also that they could be strictly liable if they sold or distributed such a defective product. Even one bad outcome can result amount to millions of dollars of liability, as I learned all too frequently in my years at the Justice Department career. Liability of a seller or distributor of a stale, counterfeit or misbranded drug is straightforward. That species of liabilities would not be sole source of litigation that would arise from drug importation for non-manufacturers for sales and distribution.

Sellers and distributors might also be liable for the consequences of *good* drugs that have rare or harmful effects on a handful of users. A plaintiff's lawyer would want to sue all potential partners, if the lawyer is pursuing a product liability claim. A drug manufacture would presumably deny knowledge of distribution starting in another country over which it lacked either sufficient knowledge or control.

Moreover, it might be difficult to ensure jurisdiction over the foreign participants in the distribution chain in a suit filed in our country's judicial system. A prudent plaintiff's lawyer representing an injured individual, is likely to target the seller or distributor as a defendant or defendants. Joint and several liabilities add to the US seller or distributors liability. Although the law pertaining to joint and several liability varies form state to state, in many states, one liable entity may be required to pay all of a plaintiff's damages, even if other defendants or absent foreign parties are primarily responsible for a plaintiff's injuries.

In a worst case scenario, a seller who is one percent responsible for an injury can be held legally liable to pay 100 percent of the damages. If a defective imported drug is sold, the defendant may have to bear the burden of defending and potentially paying judgments in suits claiming a drug is defective because it included inadequate warning or labeling defects do due to application of joint of several liability. Responsible distributors and manufacturers may reasonably shy away from this substantial and potentially huge liability. As a consequence, it is very possible that major sellers and distributors of imported medicines might be the least responsible product sellers.

Irresponsible sellers may not make a careful effort to provide adequate product information or guard against potentially stale or counterfeit drugs. Moreover, some sellers might be judgment-proof parties. All this could create a substantial domino effect, creating tort liability against the only available and viable distributor or product seller defendant within the jurisdiction of the court. For each of these reasons, liability concerns do exist. Clearly, the concerns are real and very significant.

A notice for this public meeting also asks, if liability concerns do exist, what liability protection should be implemented? Federal legislation immunizing sellers and distributors from suit when they sell imported prescription drugs would be the surest way to protect from liability. Presumably, to avoid any such legislation from being entirely irrational, all prescription drug sales – not just imported drug sales – would need to be immunized from suit. I want to be clear. I do *not* advocate the legislative proposal that I have just outlined. The approach I have just outlined would eliminate and all effective tort remedies for injured persons. I am merely addressing the question the notice for this public meeting asks. I would be happy to answer any questions.

Carmona – Thank you. Task force member, questions? Mr. Azar.

Azar – Professor Axelrad, thank you very much for your analysis. I don't know if you got to hear, earlier this morning when we were discussing with Governor Doyle the disclaimers that he has put on his website with access to Canadian portals and pharmacies selling drugs here in America, but could you give some perspective on the efficacy of such a disclaimer? Would this be sufficient to immunize a seller or distributor of imported drugs from this sort of liability you were just describing?

Axelrad – Yes, I'd be happy to. My glib initial answer is that it would have the same effect as any waiver by any seller or distributor. The Governor, if I heard him correctly, explained that the website merely facilitates the citizens' use of the site to connect with a Canadian pharmacy. If that raises an issue as to whether the facilitation that the Governor spoke to, puts the state in the same position as a seller or distributor. A jury would decide if they are sufficiently in the chain, to be treated like a seller-distributor. But, to the best of my knowledge, no state -- and I can't say that I'm an expert in Wisconsin law -- says that merely because someone hangs a sign up saying "Hey, we don't want to be liable, please don't sue us", it doesn't have a legal effect of eliminating tort liability.

Azar – Another issue I wanted to get into is the duty to warn claims. In, I think, our last hearing, which discussed counterfeit, we heard testimony from people ordering drugs from Canada through the Internet, and they arrived with Russian labeling. But that would be a most extreme case. Others have spoken about labeling that's not quite what the FDA requires for the labeling of food and drugs sold here in America. What would be the liability impact for a seller or distributor for a product that does not conform to the FDA's labeling requirements for distribution here in America? Would this also subject them to strict liability under that theory of failure to warn? Does strict liability apply in that type of context?

Axelrad -- Absolutely. A seller can be held completely responsible. Unlike the typical situation where the drug manufacturer could be brought in to answer for the bulk (if not all) of the damages, that remedy for the seller to share the responsibility would not be available. So, the seller would be betting the business, so to speak, that no one has a viable product liability claim on sales of the prescription medicine.

Azar – And then, if I might, in one last area. When individuals buy a drug over the Internet, or even from the neighborhood pharmacy, they don't often keep the labeling after the fact, or even one of the tablets as proof of exactly what they look at the chemical composition of it. If you have large-scale importation with, as we've heard, substantial risk of transshipment through Canada, counterfeit, knock-off products that are labeled to pretend to be the real product -- could you discuss a little bit about the risk impact for drug manufacturers and insurability of this risk? I guess my concern there would be that it seems like the person would be under the belief that they took X product. And they would sue the manufacturers of that product if there were an adverse event, and the manufacturer would be in the position of having no ability to prove or disprove that their product was the one that was, in fact, taken. They would only have a prescription and an order for something that purports to be their product. Is that something that's such an indefinite, an unknowable risk that it could actually affect the insurability and -- hence -- fundamentally go to the stability and viability of the pharmaceutical research and development industry?

Axelrad – Well, manufacturers as a practical matter, sometimes, want to keep themselves from being liable by saying that it wasn't their drug, and that's certainly a viable defense. Market share liability for a few products had its hey-day, but that hay day has passed. So, the individual responsibility premise of our tort law says that they are only responsible for a product that *it* manufactures. If there is a different chain, such as the one you describe, and the manufacturer can show that it didn't have control -- that the chain was broken -- then the ordinary rules of tort law would place the burden on the plaintiff to show it was the manufacturer's product. While you're saying it would be an increased liability for the manufacturer, I tend to think that the manufacturer could established through evidence that the drug came from another country, it would reduce the manufacturer's liability and that would mean there wouldn't be the ordinary tort remedy against them if there's a defective product, as there would be under a closed system.

Azar -- Thank you, that's very helpful.

Carmona – More questions?

Harden – Mr. Axelrad, you mentioned that the surest way to protect from these liability concerns is to provide blanket protections for importers involved in the importation scheme. Is there a more limited method by which we could address these concerns that would be more palatable?

Axelrad – I can't think of one that would do the job. If you're talking about protecting the sellers who are bringing in drugs. If the chain from the manufacturer is broken, they are going to be absorbing a large amount of potential liability, they are going to be the target defendants in a lot of cases in which the sellers are not the focus of litigation today. The kinds of claims that would come from good drugs would be targeting them -- as well as the claims from stale, counterfeit and misbranded drugs. I think that these kinds of claims would be the kinds of claims that would drive the most responsible drugs out of the market. But, if it didn't, it would increase their costs, so by the time that we're talking about the savings, the savings might well disappear in the long run. Now, the first day a drug is imported, hypothetically a high blood pressure medication. And the person takes the drugs, whether it is a defective original drug or a counterfeit, the person who takes the drugs isn't going to know. The effect won't be seen for some time. And when they are seen, it takes more time for the lawyers involved; and then it take still more time for the lawsuits to be seen. So there is a delay here, and the persons who are originating the idea of having an importation program such as I just outlined might be gone from the scene, and other people might have to bear the burden of all the consequences. My suggestion is that, based on established tort law principles, these consequences would likely follow from the kinds of beginnings that what we're talking about.

Harden – On a separate issue, in response to Mr. Azar's question, you at least had implied that states such as Wisconsin might be taking on some liability despite the disclaimers that they place on the website. I guess my question is, would the U.S. under the FTCA, be assuming similarly liability if it, through the FDA, blesses some sort of importation regimen?

Axelrad -- Probably not. The U.S. has a protection that states don't have. Under federal law, not merely discretionary functions but also misrepresentations are protected against liability. Most states don't protect their governments against tort liability based on misrepresentation. So, the outcome might well be different there. Buy, if the U.S. is in the business of distributing – or even approving the distribution of medications -- the liability of the U.S. in certain circumstances has been established by the courts and applied by the courts.

Carmona -- Other questions, task force members? Thank you very much, sir. We are going to take a couple of people out of orders because of the time constraints and some people have travel constraints. So, the next two will be out of order and then we will go back to the schedule. Jack Sharry, Group Benefits Strategies, please.

Jack Sharry, Group Benefits Strategies

First of all, thank you for taking me out of order. I do have a plane that I'm going to try to catch a little bit later. I think I have to be honest, I'm a little bit shaky, because after that last presentation, with what I'm about to say, I'm bound to be indicted, or sued. Certainly, I'll go broke, because my professional liability insurance policy does not cover what I'm going to say. So, I'm going to be a great target for any attorneys who are listening out there.

As I said, I am very impressed with the caliber of those who have come up to speak, particularly with the credentials they have. As I said to the Admiral, during the break, it took me 12 years to graduate from college and then, when I looked at my badge here, they typed the name "Jackie Sharry." The only person who calls me that is my 88-year-old mother, but after that last speaker, I'm glad she isn't.

Well, let's get down to what I'm about to say. I would like to first of all tell you that I am president of the largest municipal benefits consulting firm in New England, Group Benefits Strategies, of New Auburn, Massachusetts. I'm here today to provide information on whether and

under what circumstances drug importation could be conducted safely and what its likely consequences would be on health, medical costs as well as the development of new medicines for American patients – as requested by this task force.

My friends, the American consumer is poised and ready for creative and innovative changes to our health care system. Years of complacency of medical care and costs have drawn to a close. The high costs of medical care and prescription drug coverage are now serious pocketbook issues. To date, consumers have shouldered the burdens of three-tiered programs, co-pays, deductibles and other cost-shifting strategies. Today they have come to the realization that they – the consumer – are ready to become actively involved in health care plan changes.

I'd like to take a couple of minutes to describe a new voluntary prescription drug program designed to give health plan members access to choices through a safe, cost effective drug alternative, which happens to include a Canadian purchasing option. I'm presenting today proactively, focusing on the positives rather than the negative bias that has been directed either sometimes at the FDA or the pharmaceutical industry. We accomplish nothing by negativity. We've invested a significant amount of research and development into this program that is cost efficient and assures patient safety.

Effective this very week, this past Monday, a 6,000 health plan member client has hired Prescription benefit strategies to administer a program that includes the Abacus Group of Cranston, Rhode Island. Abacus provides an education platform; this is the first time since I've been sitting here, midmorning, that I've heard the words "educational platform". Designed to improve the safety of consumer medication use and to promote cost effective purchasing practices. Ironically, Abacus, under a federal grant from a sister agency if NIH, the AHCRQ, has created a program called "my medication". This program has served other employers in the US, however, this is the first time that this program has collaborated with a Canadian prescription program through CanUSA.

In simplest form, the My Medication program is a consumer educational tool accessed via the Internet or over a telephone. A member can access website or call for personal attention, if preferred, to review their prescription drug needs, their habits, possible alternative medications, and to register for financial incentives as a reward for utilizing the site on a voluntary basis. Through participation, the member's copay will be waived. My Medication Advisor incorporates valuable educational features into the process: the ability to access and communication with a pharmacist; consumer education on drug safety, consumer medication records (which is a mandatory element for the consumer to access the program); and, very importantly, incident reporting by members, which is a vital tool to measure and ensure program quality. And, as I said, the incentive programs to motivate and rewards participants.

My Medication Advisory has been designed to address important safety concerns of the American consumers and the federal government. Once a member has provide the vital medical data, My Medication Advisory will then guide them to the most cost effective maintenance drugs available. The information will contains pricing for the existing PBM (in this case, express scripts), and alternative U.S. PBM, intermediary pharmaceutical inc. The idea is to provide access first and foremost to a U.S. PMB for drugs. It's common knowledge that up to five percent of hospitalizations are caused by improper use of medication, either from the physician, the pharmacist, the subscriber. That equates to nearly \$2 million in unnecessary hospital changes nationwide. And statistics show that 65 percent of all prescription drug patients improperly use their medications. 65 percent. My medication advisory, working with the IPS, will encourage them to check the accuracy of the prescriptions, even if it requires calling the attending physician.

Moving along, we did go to CanUSA, because we felt that their safety mechanisms that they have in place are second to none, of those we had investigated. Price is not primarily, safety is. Other drug companies will have their products at much less cost than Canada, but – again -- safety costs money and that's the idea of this program.

There are several of my protocols that are in my presentation that I'll skip over, but most importantly, and I'll end up this way: the shelf life of Canadian prescription importation will be short, but the impact will be long. I think that what the Canadian debate does is that it raises the height of discussion on prescription drugs, which is at a level we've never seen before in this country. It's that educational model – to teach people how to properly purchase medications, that will save not only the consumer but will also reduce hospital costs and, in my opinion, with the limited production that this CanUSA has, should have no negative impact on pharmaceutical R&D. I think the pharmaceutical companies will rise to the occasion and do what they always do well. So, this program that we've launched – we're not hiding it – it's small, much smaller than a state program. It has tools in there to measure it. We would invite and hope that the FDA could be a partner with us to see how this program works on a voluntary basis in Massachusetts.

Carmona -- Thank you, sir. Do we have any questions from the task force members? Thank you, sir, for your presentation. The next speaker will be Bernard Kerik, from Giuliani-Kerik, LLC. Mr. Commissioner, thank you for being with us.

Bernard Kerik, Kerik-Kerik, LLC

First, I would like to thank the task force for the invitation and the opportunity to make these brief remarks. The purpose of me being here today is to advise the task force that the former Mayor of the City of New York, Rudolph Giuliani and Partners has been retained to conduct an independent review of the safety issues related to the wholesale importation of medicines from outside the U.S.

As many of you know, I am the former Police Commissioner for the City of New York and as of recently was a senior advisor for the Minister of Interior for Iraq and a senior advisory to Ambassador Bremmer on the reconstitution of Iraq's interior ministry. Today, I'm the CEO of Kerik-Kerik, and we'll be working with the Mayor on this review.

The review includes documentation, site reviews, and we are making every effort to speak to people and groups on both sides of the issue, including those who support it as well as those who oppose the importation. Although the review will be on-going over the next few months, we anticipate having some preliminary findings this month, and we would be anxious to share them with the task force, as well as others. We are quite concerned about the growing support for wholesale importation of drugs or the purchase of medicines over the Internet when there are clearly so many unanswered questions regarding the safety of such practices. There are many risks to the health and safety of Americans with respect to the importation of drugs from outside this country.

Together with Senator Norm Coleman, the Mayor and I made a recent visit to the U.S. mail facility in Queens, and it was very disturbing. We were amazed at what we observed; thousands and thousands of parcels containing prescriptions, including controlled substances being shipped through the US mail service. Many of the packages were such countries as India, Pakistan, Brazil, and the Netherlands. Many of the drugs were not FDA-approved, some expired, others did not have any dosage information or were improperly packaged. Some that required refrigeration were clearly not refrigerated and some were injectable. There was even one highly sensitive cancer drug that requires very close doctors' supervision, being shipped through the mail directly to a patient. It was obvious that, contrary to popular opinion, medicines being purchased over the Internet are not just coming from Canada and – based on visual inspection -- not FDA-approved.

It is not clear to us that we can have any confidence in where the drugs are coming from and what's in them when they are purchased from these sites. Based on what we are learning and what we have seen over the last several weeks, I am very concerned that, if such wholesale importation were to be permitted, it would make this country's medical supply extremely vulnerable to terrorist interaction. It appears that it would be very hard to ensure the quality of medicines that would be coming from outside the U.S. As a result, some terrorist organizations could easily contaminate a portion of the medical supply. It might not take a lot to do this and,

based on my experience, I can see this being a real threat. Do we really want to take that risk with our own health and safety or the health and safety of our parents or our children?

There is also some evidence that some of the profits are being made by drug counterfeiters have been used to fund terrorist activities, or facilitate their activities. I have heard those in support of importation say that the FDA and customs should be doing more to address this problem. I can tell you that what I saw at JFK, and based on our review, they are doing the best they can but the volume is great.

I think that the same people who are encouraging people to operate outside the current law are contributing to this burden, in a very irresponsible way. If the borders are opened further, I'm not persuaded that a safe system can be designed that would again ensure the safety and quality of the medicines being imported. Although we still have a lot to learn from the safety perspective, it does not clear appear that the existing law can be changed. Unless we can ensure that it is done safely and in a cost-effective and efficient manner, the law should stay as it is.

The Mayor and I look forward to the opportunity to sharing our findings with you on the task force we our review continue; thank you for the opportunity to appear here today.

Carmona -- Thank you sir. Task force members, any questions? Thank you sir, we appreciate your being with us. We look forward to your report also, when it's done. Our next speaker, which I think will be our last out of order, due to time constraints, will be Mr. Lew Kontnik, Consultant.

Lew Kontnik, Consultant

Thank you, Mr. Chairman. My name is Lew Kontnik. I have dealt with the counterfeiting issue for about 15 years. I am the author of Counterfeiting Exposed, a book that deals with counterfeiting in its many aspects. Last year, I published other documents that addressed counterfeit pharmaceuticals and other aspects of counterfeiting. And, I'm now serving as an anti-counterfeiting advisor to a public information nonprofit organization, called the Partnership for Safe Medicines. The website being www.SafeMedicines.Org. That organization really is intended to go ahead and give consumers, patients, some insights into the risks that we're talking about today.

What I really want to propose to the task force, to the panelists, is that we're really talking about the wrong issue. And, I understand that this is the only HHS task force on importation. But, to be honest, having thought about it and written about it for some time, I don't think that the issue is importation. The issue is price and accessibility. And, I think there's another, very important issue -- which is safety and counterfeiting.

So, what do I mean my that? Let's just go to a mass balance analysis of the drug importation issue. The Canadian population is some 10 percent of the US population; their demand for medicine is less than 10 times ours, so the numbers don't work. There's no way to get there from here -- we clean their shelves in 23 days.

Plus, if we put in force some kind of management system, we're adding expense and complications. Are there risks with importation, or is it a red herring? We know that there are criminal attacks on our closed system. We heard Ron Roberts describe that in personal detail this morning. With the Procrit, Serostim, Zyprexa. But, we're talking now about opening the system -- with an open system, we're open to attack by all. And we've seen it happen already. Lipitor: millions of tablets were recalled last year. Evra, you can put the birth control patch here or here or here, if you watch as much TV as I do. And we know that some of these imports -- well, the Lipitor, Evra, Viagra -- are coming from overseas already. And, now, let's think about that -- where are the bodies? Where are the bodies? I don't mean to be crass, or hostile, but we may see bodies in the form of new births in Evra context. Placebo patches coming from Pakistan, although I don't endorse the idea that we should be having to look for those bodies.

Is counterfeiting real? You've probably seen some of these slides before. These are all some of the class of 2000, that have been counterfeiting. But, counterfeiting is not unique to pharmaceuticals. Every product, including White Out and Glad trash bags, in my experience, in the counterfeiting arena, has been counterfeited. Brake pads, auto parts. So, as we begin to think about importing products from overseas, as these industries are already fighting again, we *will* be importing the counterfeiting problems.

But there are security systems, aren't there? There are holograms, there are watermarks, and so on and so forth. After all, the Bureau of Engraving does this with money, right. We should be able to defend against that. I think they're useful but they're not conclusive in terms of this situation.

We have a closed system. Let's compare the money with pharmaceuticals. With the money -- how many manufacturers do we have? One, the BEP. They control everything with absolutely high security. With pharmaceuticals, how many pharmaceuticals do we have? Hundreds. How many packagers? Thousands. In the money situation, we know that there are counterfeits, despite the money going through the Bureau's scanning systems every day. Who is going to check with pharmaceuticals?

The real issue is affordable access. The importation destroys the system's integrity, increases its complexity -- and we heard another thing today that I think is critically important and I didn't understand it until last night. And that is, it won't accomplish the stated objective in any kind of massive way. What's that stated objective? Decreased price, but we heard that the distribution system will get the benefits of the arbitrage without the patients. Why is that? I can go, in the micro sense today, and save money on the Internet or to Canada, but when you bundle it into a business system you've gone to the macro level where you have interposed financial institutions between the savings and the beneficiaries. So, it doesn't accomplish its purpose at all.

So, what I ask is, respectfully, that the task force say importation cannot be done safely but we do need to address the issues of price and access, safety and counterfeits. Thank you very much.

Carmona -- Thank you very much. Task force members, any questions? Thank you very much. Our next speaker, we'll go back on the schedule. The next speaker will be Durhane Wong-Reiger, Consumer Advocare Network.

Durhane Wong-Reiger, Consumer Advocare Network

Thank you very much, and we really appreciate the FDA is holding these open hearings and especially appreciate that the FDA is allowing Canadian consumers to come up and speak about our concerns about cross-border Internet pharmacies have for Canadian patients.

I recognize that your mandate is to ensure, for consumers, that the drugs that are imported are indeed safe. I guess, as a patient, I would say to you the only way that you are going to convince patients that the drugs are safe is to *insure* that they are indeed safe. And, I think we all know the systems that are critical to ensuring that. The whole system of clinical trials systems; millions of dollars spent by the pharmaceutical companies to do so.

We know the reviews by the FDA in this country and by Health Canada in our country. We know all of the systems that are in place to ensure that drugs are dispensed properly; the system of recalls and for reporting of adverse reactions. I think as we've heard today -- and for those of us in Canada -- all of those will be bypassed if we open up for cross-border Internet pharmacies. I think that overall, of course, the concern that we have is, in fact, boiled down to safety. I think we've heard several times now that the gap between what Canadians have -- in terms of drugs that are manufactured, sold to the Canadian pharmacies and wholesalers -- can not begin to up what the American demand is or will be.

I think what we've heard over and over is that that gap is going to be made up from importers; some of those, quite obviously, importers that we have agreements with. Some of them, of more concern, importers that we *don't* have agreements with. Our concern, of course, is that at the end of the day Canada will become nothing more than a drug broker. And I will say that that is a thought that sends great chills through me.

I was the head of the Canadian hemophilia society for many years. I was the president of the society during the time of the blood inquiry, when we set up the commission to investigate how so many Canadians got infected through tainted blood. One of the things that was very chilling for us to learn was that, during that period of time, was that there were blood brokers. Blood brokers who existed in the state and, unfortunately, in Canada, who were allowed – legally – to purchase blood from establishments which at that time could not sell directly to the blood product manufacturers because they were considered to be not safe. Brokers can, in fact, buy that blood and can resell it without having to reveal the origin of that blood.

By the time the problem became apparent, and I, in fact, have to bow to what the speaker before me said, there were thousands of people who were infected. In fact, there were tens of thousands of people who were infected. When you talk about cost savings, I was one of the people that helped to negotiate the class settlement, \$1.3 billion class action settlement for people who were infected through tainted blood. This is something that, from a cost point of view is huge, but from a patient point of view, we're going to be living with those costs for many years to come.

So, I think the message is not to take a short sighted approach. Do not look for bodies, the adverse events. I really appreciate very much the Surgeon General's comments, can you tell if they are safe? Because one of the things we learned from tainted blood is that we don't need to see proof of harm. If we know that there's a risk there, there's a potential for harm, then we must – just as the speaker said to us -- assume that there is potential for harm and we must act accordingly.

I think the proof – unfortunately -- is very strong here. So, we are hoping to be able to work cooperatively, as Canada and the US, to take some real actions. I do agree that the issues are access and price. From my point of view, I think it's a myth that Canadian patients have access to drugs because they are lower priced. I think that most Canadians would be astonished to hear that drugs are cheap. We're told over and over again, we can't have access because the drugs are expensive. And, quite frankly, if you can't afford \$2000 for a medication, you can't afford it for \$1,600. So, trying to buy it "a little cheaper" isn't going to solve the problem for a patient with an expensive drug plan.

The problem for most Canadians is that, the way we get access to drugs is, like most Americans, by having access to an affordable drug plan. The nice thing is that, in Canada, we do, in fact, have provincial drug plans that cover mostly seniors, those who are low-income. The rest of us, of course, have private drug plans. Because our overall costs of the health care plan are so much cheaper, the drugs have to be looked at in the same perspective. We often say, if you really want to lower the costs of health care in the US, you should send all of your patients to Canadian hospitals. They're half of the costs. Want really cheap health services? Send us all of your patients – our physicians are wonderful, at 1/3 the cost. And, I'll give you a real bargain, the cost of administering the program is 1/8 of the cost that it is in the US.

Unfortunately, we know patients don't do that, in part because of access issues. You have to be on a waiting list; I mean, I had an MRI that was recommended, it took me 8 months to get the MRI. Most American patients would not stand for that. I think there is a trade off here.

The other thing I just want to wind up with here is in terms of access. I think what most Americans don't know is that you do reap the benefits of R&D in this country. On average, it takes a drug two years longer to get licensed and approved in Canada, because we do have a slower system – of course – but also because drug companies wait to launch a drug in Canada. They've

told us point-blank, they don't recoup the costs as fast; they will often wait until a drug is well established. I was at a meeting just recently where a major pharmaceutical company stood up and said "We have had internal discussions to say we won't launch new drugs in Canada unless we can get price parity with the U.S. because the last thing that we want to have happen is to put a major drug into Canada and watch it come back in the U.S."

So, we pay the price for that. We used to say to patients, "Before you get on that bus and cross the border to purchase the drug, you better see if it's even available." Because it takes our drugs a lot longer. And, we also don't get the R&D.

Canada is 1/10th the size of the US, and we get 1/25 or maybe 1/100 of the investment in R&D of the U.S. That's why our best scientists are coming South, that's why our best clinicians and physicians are coming South. We lose them to their system too. So, I supposed if we're going to be paying higher prices, we'd like to have a share of the R&D, too. I guess there's no easy solution - our system kind of works for us the way it does, because those of those are the values we believe in. The American system has some bumps and hiccups too, but I think that -- if we work together -- we can recognize the integrity of each country, we can solve those problems and make sure what I hear you folks are worried about, and what I'm concerned about - and that is that patients have access to the best medicines.

Carmona -- Thank you ma'am. Task force members, questions? Thank you very much.

Our next speaker is Louise Binder from the Canadian Treatment Action Council. I guess it's *Louise*.

Louise Binder, Canadian Treatment Action Council

Thank you very much for the opportunity to present,

Carmona - Thank you - my apologies for the introduction; the E was dropped off your name on my list.

Binder - Well, I was smiling when one of your earlier speakers was concerned because he was turned into a Jackie; imagine my surprise when I found out I'd had a sex change operation.

But I really do sincerely thank you for inviting my organization to present to you today. I'm the chair of the Canadian Treatment Action Council. And, our organization provides systemic advocacy for access to treatment for people with AIDS in Canada. And, it's from that perspective - the Canadian patient perspective - that I wanted to ensure (and our organization wanted to ensure) that you understand the implications from our side of cross-border Internet pharmacy. Particularly, I wanted to make a few comments on the realities of the availability of drugs from Canada to the U.S., about the realities regarding the safety of Canadian drugs from our experience, and also some of the social and economic context as it impacts the pricing policies and regulations that we have in Canada. I trust that these data will be of some help to you in your deliberations here today. I wish, actually, in Canada, that we would have such open hearings on these kinds of issues.

So, first, let's talk about availability. And, this was referenced earlier. As you can see from this chart, Canadian sales -- relative to Canadian production -- make it very clearly that Canada can't meet its own supply needs. So, imagine how impossible it would be to meet the needs of the much, much larger U.S. pharmaceutical sales market. In fact, the drugs that we are already supplying you - and they are already meager compared to your needs -- are already creating profound drug shortages for some people. These are just two examples that have been given to me, of shortages that people have provided.

I'd like to provide you with something that is more recent, which is a list of 132 drugs that can no longer be supplied to Atlantic Canada – I'm happy to leave this list with you of drugs that can no longer be supplied to Canadians in the Atlantic Provinces. And many are related to the fact that (these are for serious illnesses) and some of them are related to the whole issue of the Internet pharmacies. In fact, we would suggest to you that many of them are. So, any suggestion that there are not drug shortages as a result of this practice, I think, are simply not true. So, you are very welcome to this if it will be of assistance to you.

As Ms. Wong-Reiger has told you in some detail, there are definitely some implications for the safety of Americans resulting from these drugs reaching the U.S. But, I'd like to make another point about sagely that's true and it's related to professional ethics. When an American doctor writes a prescription, he or she does so based on the basis of a number of factors – their knowledge of that patient. They also do so based on their knowledge of the formulation of that drug in the US. Now, when a patient decides to buy that drug through the cross-border Internet pharmacies, that prescription is sent up to Canada, and a Canadian physician (shamefully, in my opinion) who has never seen the patient co-signs the prescription. And the drug is sent to the patient.

And the question is, what is that patient receiving? And the answer is, not -- even if this is not a counterfeit drug -- it is not necessarily the same formulation that the American physician prescribed. And I would simply say to you that that is creating a profound risk for American patients, because even if the medical ingredients are the same, the binders in the formulation are often different. And therefore, that impacts how the drug is absorbed in the body. And the implications of that are that the American patient may experience a very different reaction to that drug, and it may really lead to serious toxicities and adverse events. I happen to have HIV, and I can tell you that that's a very complex disease to manage even face to face with the doctors – because of the number of drugs I have to take to manage not only that virus but also opportunistic infections that I have. There are many drug interactions also just because of the way, personally, that I react to drugs. I would be frightened to death to be managing this disease through Internet pharmacies. And I would I suggest to you that Americans with HIV would be frightened to death also, and people with any other kind of complex diseases.

We mustn't forget that, the drugs that are being transshipped are not being sold and distributed in Canada, they are except from Canadian safety and quality inspections and that's a very, very serious safety risk. And, if you don't believe me, perhaps you will believe Health Canada, which has been telling Canadians since 1998 that personal use importation is risky business, and it really is.

The last point I'd like to make to you is about the economic and social context in which our pricing systems has been created. As you are well aware, we have very different systems – Canada has a publicly funded system that – in most provinces -- includes some reimbursement for some drug costs. We Canadian wait must longer for access to drugs, including breakthrough drugs. I can remember buying a three month supply of an AIDS drug out of my own pocket; because they were not yet available in Canada, and taking them across the border. In the bad old days. And, we have very different advertising and liability laws. And cross border Internet pharmacies cherry pick one aspect of the Canadian system out of context.

I wish that they would take the rest of our system too, including our long waiting lines for surgeries, such as hip replacement surgeries. And I wish they'd take our high taxes, and I wish they'd take our lower Canadian dollar, not just our drug prices. Of course, as you well know, Canada has a drug pricing system that not only limits the costs that manufacturers can charge, but also has a direct impact on the amount of R&D that's done in Canada. Which in turn limits job creation in this and related fields; perhaps you'd like that as well.

I'd like to say, in conclusion, I trust I have given some valuable information about the reality, which is that cross-border importation via Internet pharmacy is not a long-term viable, safe solution to the issue of ensuring access the pharmacies. It is clear to us that Canada can neither

ensure a sustainable supply for all Americans requiring drugs, nor we ensure that those drugs meet the U.S. safety standards. And we, as Canadian patients, commit to continue to pressure our government to ban the practice cross-border of shopping on the Internet for drugs. I trust that you will do so as well. Thank you very much.

Carmona -- Thank you very much. Task force members, any questions? Dr. O'Grady.

O'Grady -- This list of drugs that manufacturers cannot supply and are in shortage; there's not a lot of flexibility in some of these. I mean some of these, I mean there are couple of insulins here. What happens when a Canadian patient shows up at a Canadian pharmacy and they're told there isn't any insulin? It's not... they don't have a lot of options.

Binder -- Well, exactly. And a friend of mine who's quoted here, Patty Stewart, had this exact thing happen to her. She showed up at her pharmacy in New Brunswick, and she needed her insulin for her diabetes. And she was told, "We sold the last six vials to an American." And, she was terrified, and her pharmacist starting phoning around, and literally had to phone around not only within her own province but other provinces to find somewhere to get her a vial of insulin and have it Federal Expressed to her. She lived in a fairly isolated area. It's not an isolated problem. I mean, this is no joke; these are people who may certainly die because of drug shortages. And, you know, why would we want to wait for that? Why would we want to wait for that from a Canadian perspective and why would we want to send through to you drugs that may not be appropriate for your citizens either?

O'Grady -- Do you know of any instances where folks --- just for availability concerns -- are coming through to the U.S. to get it at a higher price?

Binder -- Well, of course, I did that once, as I mentioned to you earlier. But that would be the only instance I could give you right now.

Carmona -- Other questions. Thank you very much. Our next speaker is Gary Stein, American Society of Health Systems Pharmacists

Gary Stein, American Society of Health Systems Pharmacists

Thank you. My name is Gary Stein, and I'm the Director of Regulatory Affairs for the American Society of Health Systems Pharmacists. ASHP is the 30,000-member professional association representing pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care agencies and other components of health care systems. I'm pleased to provide you with ASHP's views on the importation of prescription drugs into the US.

ASHP has a long history of advocacy Congress and federal agencies on the importance of maintaining the integrity of the US drug distribution system. For more than 50 years, the U.S. could boast the safest and tightly regulated system for approving and regulating prescription drugs.

Today, there are challenges facing that system. A growing illegal drug trade, including counterfeit and rogue Internet sites, and efforts to US markets to drugs from abroad, have all raised questions as to the FDA's ability to respond to those challenges. In particular, the issue of the safety of the drug supply is being obscured by the issue of allowing individual citizens to purchase prescription drugs from overseas pharmacies.

You might wonder how pharmacists who work in hospitals might have to confront this issue. But, I receive calls from members say, "My hospital administrator wants me to start buying drugs from Canada, how can I show them that it's illegal to do so?" So, I send off regulations and copies of

laws, but I still get these phone calls.

The scope and volume of unapproved drugs entering the US has raised the concerns of our members. That's why our House of Delegates will vote this June to reaffirm the following policy: "to oppose importation of foreign pharmaceuticals, except in cases in which the FDA determines that it would be necessary for the health and welfare of US citizens."

There's another factor to the importation issues that has not been addressed adequately, and it relates to terrorism and our nation's counterterrorism activities. The integrity of the drug supply and the health of consumers are at significant risk if terrorists use more lenient new importation rules to introduce harmful agents into the country. Only two people previously have address this today. Is this issue not being considered a priority because it hasn't happened yet – do we have to wait?

The FDA's regulatory system has been the world's gold standard. To ensure the safety of imported products, the FDA will need significantly more resources to examine those products for quality, purity, safety, and effectiveness. Since a significant amount of imported drugs are imported via the Internet, the agency should ensure the adequate regulation of Internet pharmacy sites. In addition, the FDA must have the authority to ensure the same level of quality for imported as consumers expect from drugs purchased at a state-licensed pharmacy. There could be no added level of risk that ASHP's members would consider acceptable.

In terms of financial impact, the FDA must thoroughly study the financial impact of importation to determine if it would actually lower costs for American consumers. Regulations put into place to implement Section 1121 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 must not be burdensome to pharmacists or wholesalers. If pharmacists are required to conduct extensive testing and authentication of imported drugs, the majority of membership would not be able to meet these requirements and still have cost savings to pass along to American consumers.

ASHP appreciates the opportunity to comment to the HHS task force on this significant issue, and we are ready to assist the Department in dealing with the issue at any time.

Carmona – Thank you, sir. Task force members; Dr. Raub.

Raub – Do hospital system pharmacists now currently make any significant use of Internet pharmacies?

Stein – I know in addition to being plagued with advertisements for Canadian drugs, they are also plagued with faxes daily for ordering supplies through Internet pharmacies. In particular, drugs that might be in short supply

Raub – What I was trying to get a feeling for is that, given that they are under some obligation to seek lower costs, is that modality under significant use right now?

Stein -- No, we haven't seen that.

Carmona – Any other questions? Thank you sir. Our next speaker will be Charles Hardin of RetireSafe.com.

Charles Hardin, RetireSafe.com; Council for Government Reform

Thank you, Mr. Chairman, for the opportunity to testify on behalf of the non-profit, non-partisan Council for Government Reform, Retiresafe.org, and our more than 280,000 senior and near-

senior supporters nationwide. Founded in 1991, the Council for Government Reform and its grassroots project (retiresafe.org), are dedicated to protecting the retirement security of Americans of all ages. I am also pleased to speak on behalf of our colleagues at the 60 Plus Association.

Prescription drug is an issue of concern to all Americans, and I would first commend the FDA for its efforts to protect all Americans from the many dangers of imported prescription drugs. The prospect of an unregulated and potentially unsafe influx of drugs from abroad is frightening. We all remember the Tylenol scare of the 1980s, when seven people lost their lives because unscrupulous people tainted the nation's supply of the popular drug.

The World Health Organization estimates that roughly six to eight percent of the world drug supply is counterfeit. We've heard just a few minutes ago, another organization that addressed that issue. We know that neither the FDA nor the Canadian authorities have been able to certify that drugs imported or reimported from Canada are safe for use. On the grounds of safety alone, we strongly oppose any attempt to import or reimport foreign drugs into the United States. It's like playing Russian roulette with the health of Americans – and that risky course is not even necessary.

The best solutions are often found at home. Our Rx Challenge survey last year showed that Americans can save hundreds, even thousands of dollars a year by simply being good consumers and simply shopping around their own home town for their prescriptions. The Rx Challenge proved that the retail prices of commonly prescribed prescription drugs varied by hundreds of percents from pharmacy to pharmacy in the same city. With no more effort than just making a few calls, the study found that consumers in Virginia, for example, could save as much as 53 percent on brand name drugs. Certain generic drugs varied up to 559 percent. The Rx Challenge proved that prescription drug purchasers do not have to cross the border for discounts; in most cases, they only have to go across town. Further information on this survey – and I think it includes about a dozen states -- can be found on our website at www.retiresafe.com.

There are also many other ways for consumers to save in their own hometowns, including drugs assistance programs and samples from their doctors. Virtually every major pharmaceutical company has a discount drug or assistance programs. Insurance will often pay all or most of the costs, and doctors will certainly try to help, if asked. Finally, there's a great new prescription drug benefit option for Medicare beneficiaries that the President signed into law in December. For the first time, tens of thousands of seniors will have the option of drug coverage. Beginning in June, seniors will have the option to enroll in a privately provided discount program designed to save them as much as 25 percent off the cost of their individual prescriptions. This new coverage is a better deal for America's seniors, providing the most innovative, cost effective and safe prescription drugs developed, manufactured, sold and distributed in America.

On behalf of the Council for Government Reform, Retiresafe.org and our many supporters around the country, I thank you for your opposition to the importation or reimportation of potentially unsafe prescription drugs. Thank you, Mr. Chairman.

Carmona -- Any questions? Thank you very much for your testimony, sir.

Our next speaker is Lynda Mitchell, Parents of Food Allergic Kids.

Lynda Mitchell, Parents of Food Allergic Kids

Good afternoon, and thank you for having me. I'm Lynda Mitchell, I'm the facilitator of our organization's 2300-member support group for parents of food-allergic kids. I have to say, I'm a reluctant participant for having to need to be here regarding the this issue. Although I'm presenting my concerns from the perspective of the parents of young children rather than Medicare beneficiaries, the concerns I raise can apply to Medicare beneficiaries in obtaining

allergen-free beta-2 agonist inhalers.

I want to start by just telling you how I got involved in this issue. Like I said, I got involved as a reluctant participant in the Canadian importation issue. About a year ago, I went to my local CVS pharmacy to pick up a prescription Serevent inhaler for my son, who is severely allergic to milk, and found that it's no longer available in the U.S. When I found out what the alternative is, it's a new type of inhaler that's called a diskuss inhaler that can contain lactose and trace-milk protein.

So, therefore, here I am faced with a child with severe persistent asthma, and no choice for a lactose-free, long-lasting beta-2 agonist inhaler. The current situation is that cow's milk allergy affects more than 4.6 million Americans. And, for some of these Americans – half of them are children, incidentally -- milk allergy can be severe and life threatening. The smallest exposure to trace milk protein can evoke a severe and life threatening allergic reaction: we're talking about 10 parts per million for some severely allergic individuals, which is an exquisitely small amount.

In addition, asthma as we know is a nation's epidemic in this country; it affects over 20 million people in the U.S., over half of them as well are children. Once again, poorly controlled asthma can be severe and life threatening as well. Now, the NIH has guidelines -- NAEPP – National Asthma Education and Prevention Program guidelines that include best-practice treatments for asthma maintenance. And, one of the medications that recommended for optimal treatments for asthma classifications is a type of drug called a "long acting beta-2 agonist inhaler". And that's used in conjunction with an inhaled corticoid steroid.

The current situation is that, due to the Montreal protocol, which is being examined by the FDA (this is the CFC issue) whereby medications that use chlorofluorocarbon as a propellant are being replaced by CFC-free devices. Because of this whole issue, there are no longer any long-acting beta-2 agonist inhalers in the U.S. The only ones that are available are diskuss inhalers, like I mentioned earlier, that can contain lactose which is a milk protein, and trace milk protein. If you look at the product insert for the product, the manufacturer will say, "This contains trace milk protein."

A recent letter to the editor in an allergy journal, just in April, has shown that when an analysis was done of these inhalers, that it did contain enough protein in some batched to involve allergic reactions, including life-threatening anaphylactic reactions in some individuals.

However, the same manufacturers that have stopped producing them in the US because of the Montréal protocol still produce them in Canada for the Canadian market. And so, right now, as the parent of a child with an anaphylactic milk allergy, I am faced with two options. He's also severely asthmatic. I can either choose a sub-optimal product for maintenance for him, because of the lack of a long-lasting product that is a lactose-free, long-acting, beta-2 agonist inhaler. Or, by going to Canada and purchasing the same product – out of pocket – the same product made by the same manufacturer that used to produce them here, but no longer does so.

I just want to bring this to the attention of the panel. There are safety and efficacy issues that imply poor health outcomes for importation of Canadian prescriptions. But, this is an example of reverse, where the lack of available medicine in the US may produce poor health outcomes. I just want to point out that there could be exceptions and hardship cases that should be taken into consideration when you are putting together a revised policy on importation.

Carmona -- Thank you ma' am. Task force members, any comments? Thanks for your comments. Our next speaker is Jim Rittenburg, Authentix.

Jim Rittenburg, Authentix

I'd like to thank the Surgeon General and task force for allowing me to speak today. My name is

Jim Rittenburg; I'm with Authentix. Our company provides authentication technologies to the pharmaceutical companies. We've been involved in inserting technologies for several of the pharmaceutical companies in response to some of the recent high-profile counterfeiting situations that have occurred.

Drug counterfeiting is recognized as a global problem. I think anyone who is familiar with what's going on in this situation can't argue with that. The World Health Organization has published studies, as well as have a number of other independent sources, on the level of counterfeiting around the world. We know that there are some countries where well in excess of 50 percent of what's on the shelf are counterfeit.

The incidence of fake drugs in the U.S. has been very low, and that's because of the FDA. I think that people just take for granted what the FDA actually does for our drug supply and the oversight that they provide. Even with the oversight that is provided by the FDA, in the last several years, there has been a significant increase in the cases of counterfeit product that has shown up in the US. And that is what we know about. What we don't know is how much other counterfeit product might be out there out there, because many of the counterfeit cases surface because of adverse reactions that have shown up.

If drug reimportation is allowed, it'll essentially bypass the oversight that is provided by the FDA. And it will reduce the safety of the drug supply in the country. The true origin of the drug supply will become questionable; we may think they are coming from Canada, or some other country that has a well-established regulatory system, but we won't know. They could very well be coming in from some other country elsewhere in the world. The storage and handling conditions those drugs have been exposed to are unknowns. Within this country we have a well-regulated system; once it is opened up to outside of the country, anything could be happening to those.

The Internet already represents a loosely controlled border and FDA, Customs, a number of the regulatory authorities in this country have repeatedly said that they do not have the resource or ability to control what's coming into the country through the mail system. And we know that millions of parcels are coming into the country through the mail services. Surveys that have been done on those show that many do not comply with the U.S. regulations for pharmaceuticals. So, we do not believe that allowing drug importation is in the best interests of the U.S. population, and this will increase the risks to the drug supply.

I think where we need to focus, even in the US, is: more vigilance is required. There are proven technologies that can be inserted today, into pharmaceuticals, that can help protect the supplies. There are low impact that can be put into the pharmaceuticals, that can readily be integrated into the manufacturing processes, and that are relatively low cost. For the cost of running a couple of advertisements during Super Bowl, would pay for putting authentication features into an entire company's portfolio of products. So, the costs are not high, relative to what we are talking about.

The recent FDA report that was published on combating counterfeit pharmaceuticals highlights the issues in this country, and sets out recommendations that we should be looking at to improve the security and ensure the safety of products for this country. And, I think that's where we need to start -- before we even contemplate opening our borders. There are variety of technologies, both overt and covert, that allow inspection to be done all the way from the consumer or patient level, back to the government regulatory agencies or the company's themselves. So we believe that, as part of good manufacturing practices, all drug products should incorporate some type of technology that allows their simple and authentication.

Our currency is protected that way. You can imagine, if that was counterfeited, if it were completely and in such a way that was undetectable, would completely undermine the security of the country. Pharmaceuticals can take a similar approach to putting overt and covert authentications throughout the chain, all the way down to the patient.

RFID technology is in development and we believe there are some promising new technologies coming along there, but realistically that technology is years away before unit-level marking will be possible and before a real net can be put around the drug supply. So, we do have technology that can work. I believe that, once this technology is incorporated into products, an ongoing, low-level inspection process can be put into place that can flag counterfeit drug supplies before they get to the patients and before that gets to the point where it's discovered.

Just examples of what companies are starting to do now. They are starting to put authentication features into both the products, the dosage forms, as well as the packaging to protect them. There's a whole range of different products, from different companies, that are available today that can go into these products – from overt technologies that can be seen in the field, to covert technologies that inspectors can use to quickly assess whether a product is authentic or not. And even, down to the dosage form where there are companies now that are building authentication features into the dosage, so that once it's separated from the packaging, it can be quickly revealed if it's authentic. I'd like to thank the panel for the opportunity to speak, and would address any questions you might have.

Carmona – Thank you sir. Task force members, any questions? I would like to ask one, then. As far as authentication goes, certainly it's an issue we've heard some testimony on prior, and we've done a lot of reading. What is your opinion – and you've mentioned already that the state-of-the-art is maybe a couple of years away -- do we have technology that could allow us to be able to guarantee the safety of imported drugs today? Or in the near future, for that matter.

Rittenburg – I don't think we have that today and I question whether we will have that in the future as well. Because I think once you move beyond the point where there's direct oversight on what's happening with those products -- how they are being handled, how they are being moved through the supply chain. What we currently have in this country through the FDA. Once you move beyond that, and extend the supply chain, you then open up the possibility for other things to happen. Whether it's the quality of the product, because of the way it's been handled, or whether there are actual counterfeits that have been inserted into the product that's coming through the chain. So, I think it's pretty difficult. Even with new technology that's coming on the RFID, the technology that's being developed, I think we are many, many years from where that will be implemented at the unit level to protect product.

Carmona – Even at the unit level, as I learned about the technology out there -- and, certainly at the unit level -- we were very concerned. Because, as you looked from the larger batch level to a bottle and then to an individual dose, to have that type of technology would be important. But the concerns that come up are the ones that the Bureau of Printing and Engraving has faced for years. That is, as advanced as they are, as technologically proficient, your adversaries are always trying to stay a step ahead you and develop countermeasures to your countermeasures. In other areas that we deal with, across the board, as it relates to homeland security and our counter-terrorism efforts, the concern is always that the adversaries' goal is to be able to identify the measure that we've put in for authentication and then counter it somehow. Do you anticipate that this will be an ongoing issue, in your area of expertise?

Rittenburg – Absolutely. That has been addressed. The counterfeiters are extremely clever and they are finding ways to compromise each technology as it is developed and put out there. So, there has to be a migration path of technologies; there has to be a multiplicity that's used. I think, to really get at the issue, you can't just put technology into the product. You need to couple that with a field program, where there is some low-level of testing going on throughout the supply chain. And the manufacturers right now that we're talking to are all considering implementing those types of audit programs themselves, so they can get an early warning signal if something breaches the supply chain – and hit it before it gets to the patient. We mark a lot of fuels in this country. All of the oil companies routinely send samples of their fuel for analysis for EPA purposes to show that they have the right octane boosters and things in there. The pharmaceutical industry could do a similar thing to show that the population of drugs that's on the market is safe and that there are not counterfeits that are not breaching the supply chain.

Carmona – I have an additional concern; this will be my last question. It's that, even with best case scenario for authentication and, as you said, it would have to be coupled with some low-level of surveillance as well, keeping in mind the dynamism of this whole process with the adversaries trying to keep one step ahead of us. You know, the concern I have is that, if we were dealing with clothes or tires and there's a defect—you pick it up and take it off the market. But, there's no acceptable casualty rate with this. I mean, it really has to be 100 percent certainty that the public is safe. So, the bar is raised to the highest of anything that I've been involved in, certainly. I'd like your comments – I'll ask you to be a visionary being that this is your area of expertise – can we ever get to that point? I don't want to sound complacent, but that we are satisfied that we can bring that degree of protection to the American public?

Rittenburg – I think we can get close to that level, we can get very close to that point where we have a very high level of confidence that what's out there is safe. I think to say that 100 percent is going to be very difficult to do.

Carmona – Thank you. Any other questions?

Sachdev – Yes, just very quickly on the field test kits. What's the reliability of those? False positives would probably be more important than false negatives,

Rittenburg – Yes; the field test kits have 100 percent accuracy. The way they are developed, I mean there are several types of field test kits – you're talking about the packaging and then with the product. Authentication features that are put within a product, the field test kits for those will detect the markers that are in the product with 100 percent accuracy.

Sachdev – One hundred percent; but product-specific?

Rittenburg – Yes.

Sachdev – Yes one follow up question to that. On your slide you list several types of technology – overt, covert, forensic technologies including the laser marker and the authentication. And, you've identified the technology you'd need, including field instruments, lab analysis, in order to actually deploy and assess the validity of that technology. One of the questions we've been tasked with is to provide an estimate of the costs of this. Without, obviously, having you provide any information that is specific to your products, do you have, or are you aware of, or could you submit to us, general cost information associated with these specific types of technologies? That would be helpful to us in answering the questions that were posed to us.

Rittenburg – Yes. The costs of the technologies are not a highly significant cost. To try to put it into terms you might understand for the products; you are talking tenths of a cent, or a handful of cents per unit to put technology in.

Sachdev – To put technology in. But, what about the costs to actually validating the field-testing, the lab results? Have you estimated what those costs would be when you add them to the costs of the, say, hologram or reversible ink, or things that aren't just visual inspections.

Rittenburg – We'd put that at similar costs as the technology itself to put in there. We're talking a similar cost. Like I said, the cost of running advertisements during the Super Bowl, I mean, you're talking several million dollars to advertise. Those sorts of costs will go a long way to covering a company's portfolio of products.

Carmona – It's an interesting point you bring up, because as we go from the larger unit-packaging authentication, down to unit dose, and then we get into billions of doses over time... certainly, those tenths of a cent add up when you get down to the specific unit dose. I know that's a tough

question to answer, but it's something we'll have to grapple with as well in weighing a cost benefits analysis of any programs that we might consider or recommend in our report. So, if you do have any information that you work with, or know of in your work, we'd certainly appreciate it.

Rittenburg – It's certainly a substantial cost, but if you look at this as a GNP process, and look at the things that are already happening out there, there are things already happening out there in terms of logistics. There are inspectors already in the field looking at product quality and looking at expiration dates. They can also, at the same time, be looking at the authentication features that are in those products to quickly authenticate those. The fellow from the pharmacies talked about getting product back and they don't know if it's real or not, and it might go out again. If features are in there, there will be the ability to qualify that for redistribution. So if you integrate it into the systems that are already in place, the costs aren't going to be as awesome as they might appear if you look at it on a stand alone basis.

Carmona – Thank you, sir, very much; any other questions? Thank you, we appreciate it. The next speaker is James Love from the Consumer Project on Technology.

Our next speaker, James Love, from the Consumer Project on Technology.

James Love, Consumer Project on Technology

I have hard copies here for people if you want to get a copy. I work for a small organization, that is a small association. We're mostly about intellectual property rights; the major part of our focus is on medicines. A lot of my work is done outside the U.S., I spend a lot of time in developing countries, I do a fair amount of work with the European Commission, international commissions. I'm going to give a bit of an international flavor to my discussion here.

The first point I wanted to make is that, if you think that about what's taking place here about people in America thinking it's unfair to pay more than people in other high-income countries, parallel trade is a particular trade to address this problem. I think people have focused on some of the particularly problems of bringing medicines across borders; I'm not going to get into that. I'll get to the quality issue in a bit, but if the US wants to have European prices, if it wants to have prices similar to other countries, you could do something simple.

Like, you could issue a compulsory license on any patents that, for drugs where the price is higher in the US than in other countries. In fact, (garbled) Brown actually proposed that legislation a few years ago. You wouldn't have to worry about taking drugs from one country to the other. You'd just basically make it a very strong incentives for companies not to charge higher prices in America than they do elsewhere. That's something you can do.

Now, people may feel that they may not want to do that. They may not want to have official price controls and what they want to do is go the more free trade route. Now, I think that's a legitimate route to go, that's what Europe does. I mean, Europe is trying to build an efficient market in Europe, so they have a system of parallel trade. It is not, as has been portrayed by some, some rocket science impossible thing. It's been going on for a really long time. IMS had a report in October 30, 2002, where they talk about the drug companies always try to scare people about parallel imports, but it's a well regulated industry in Europe and supply significant parts of some countries' markets, particularly in Northern Europe.

I'll just quote from this report, they say that the "products are high quality, well-distributed and cannot be criticized for their inferior quality compared to brand name products, and the market is growing." Now, IMS is, as you all know, not some sort of Marxist outfit. I mean, these are guys that are a consulting firm for big Pharma. And big Pharma is concerned about parallel trade because they like to price discriminate from country to country. The European Commission wants to have a more efficient domestic market, so they allow this, it's a strong measure of public

policy.

That's sort of the first point, that if you want cheaper prices, there's lots of ways to get it in the U.S. Number two, if you want to do parallel trade, it's not impossible. Just pick up, get a passport, and like, look around. It's harder there, because they actually do a lot of translating of the packages. They allow people to rip off the blisters, translates the package inserts, all sorts of stuff.

Now, getting back to.. a couple of legal things here. We think that, if you do parallel trade between other countries, it needs to be limited to countries defined by the World Bank as "high income". Some of the earlier proposals on parallel trade included South Africa, for example, because South Africa has a good regulatory system. But it's wrong to permit parallel trade at this point in history between middle and low income and high-income countries. A single trade is not good for the low-income countries, and it's not good for the high-income countries. So, to the degree, and I think that most of the proposals are talking about high-income countries. But, I just want to say at the outset, everyone who works on these issues, I think, is opposed - or should be -- to parallel trade between developed countries and developing countries.

The WTO framework for dealing with... there's an issue I think I heard talked about this morning, that it should be addressed more clearly and that is that there's is a patent issue that you have to deal with. IN the Jazz-Camera decision in 2001, the circuit court just threw in as an aside, that hadn't been included in the brief by either of the parties, that they didn't accept international exhaustion of patent rights. They didn't accept the first sales of international exhaustion of patent rights. It was really a new change in the US law; didn't get much attention, but it should have. If you want to permit parallel trade, you have to fix patent law because of the Jazz-Camera decision. If you don't, you'll change all of the regulatory things and they'll just hold them up in the border on the patent issue. There's a lot of people who know more about this than I do, my training's in economics, not law, but I know a fair amount about this decision.

Secondly, just as an aside, the TRIPS agreements allows countries to go with exhaustion of rights, for exhaustion of rights, but there is just a technical problem in the TRIPS. It says that exhaustion has to be the same in every country, they don't allow you to pick rich countries versus countries as two separate classes.

Now, we have complained about this for years, and we've asked the US Trade Representative in the European Commission to change the TRIPS so that countries that permit parallel trade can discriminate between poor countries and rich countries. you should be able to discriminate between rich and small countries. So they can say, fine for rich countries, not fine for poor countries. I mean this is actually helping big Pharma out; they actually have an interest in market segmentation between rich countries and poor countries. And we agree with them on this, that's a legitimate interest. This is something that should be fixed. It was something that was proposed in the DOHA agreements last year, but it was rejected because there was this sort of other tactical things that people were doing; but it should be fixed.

Now. there's, more recently, a big problem with these bilateral agreements. The US is in the Australia agreement, the Morocco agreement, the Singapore agreements, they have these provisions that are designed to prevent -- and make it illegal to do -- parallel trade in patented goods. These things have to do principally in areas where there are patents involved. What these agreements say is that the provisions, if there is a contract that says you can't do parallel trade, it has to be stopped at the border. And, the USTR guys, they know what the heck they're doing; we know what they're doing. We talked to them about this. The last guy that was working on this is now working for Abbott Labs. Because he left the USTR, like most of these guys do, and went to work for the industry. What we're saying is that you can't have this discussion here and have the USTR running around plastering the universe with 25 bilateral agreements saying you can't do parallel trade. I mean, that's illegal. You have to pick up the phone and call the USTR and say, "Hold your horses; we're having a public policy debate, don't do those agreements until we sort it out at home."

Next, there's an international treaty on something called the Hague Convention. Now, the Hague Convention, on limitations on foreign judgments, has been reduced now to a contract convention. We have asked the State Department -- which is heading up the US delegation -- and the European Commission and other delegations, pulling from the Hague Convention these issues of parallel trade doctrine generally, and I think the decision is still out, but these are issues that will address this thing.

Carmona -- Sir, could you sum up please?

Love -- Yes, sir. In the *New York Times* today they had a long story about Guenevir, generic name of Conovir, which is sold by Abbot Laboratories. Now the price here is ten times higher than it is in Canada. It only used to be twice as high, but Abbott Laboratories decided on a five-fold increase last December. Now, that drug and other drugs like (garbled) was invented on government grants. The government has rights in those patents, and it could be as a matter of policy just declared, by Tommy Thompson, that any drug developed on a government grant should not be priced more expensive in the U.S. than it is charged in foreign countries. Because the argument that you need the higher prices to pay for R&D is just absurd in this case, where you are talking about government-funded drugs. Now, Tommy Thompson will have to make a decision and he's been asked to send a strong signal.

Now, on the R&D issue, and this is the last part of my presentation, it is true that, if you do things to lower the prices in U.S., that will reduce the profits of big Pharma. And to the degree that investments are driven by profits, that will have a negative impact on R&D and innovation. Now, one possibility is just to throw up your hands and say, we can't do any protection of consumers, the drug companies can do what ever they want to, so. A lot of people have said that today and a lot of people would say that. A different way is to decide that you need a new policy to compensate when a consumer protection thing reduces the profits of a company, to ensure that R&D stays the same.

We have proposed, to parallel traders, that they have to contribute 15 percent of the difference between what they buy drugs for from foreign companies and what they sell them for here. Then you have a mechanism to ensure that -- as the profits fall -- the R&D is held constant. That would do it. Now, more generally what we've been trying to do is to get the European Commission and the US generally to start thinking about this from a trade framework. We've been influenced a lot by what Commissioner McClellan's been working on at the FDA, where he's actually, I think, on the right track in focusing attention that the inequality between what we pay for R&D and what the public sector and the private sectors pay for and what the rest of the world does. It's so far out whack that it's not really sustainable. Plus, you run into all sorts of things like border controls, patents laws, the prices of drugs here, versus the prices of drugs in Africa. There's a whole series of issues related to the crazy way we fund drugs' R&D.

Carmona -- We need you to sum up right now, OK.

Love -- I will, I will conclude right now. In the longer run, what you have to do is to find different ways to fund R&D and getting money to developers and entrepreneurs rather than creating 20 year marketing monopolies that lead to the kind of predictable problems that you have in this country right now with the cross-border trade in drugs, and the kind ethical problems that you have in Africa right now. You have to fund our R&D more than we currently have -- to a greater extent than we do now. We have invited the representatives of the European Commission and the US governments and other governments to participate in discussions on this in the fall of this year ... and I can't explain it right now. Thank you very much.

Carmona -- We need you to sum up right now.

Love -- OK, I am summing up.

Carmona – Thank you. Task force members, any questions? Thank you sir, I appreciate your presentation. The next speaker is Mr. Raymond Keating, Small Business Survival Committee.

Raymond Keating, Small Business Survival Committee

Good afternoon, I want to thank you for the opportunity to speak today regarding the potential impact of prescription drug importation or reimportation. I serve as the chief economist for the Small Business Survival Committee, we have 70,000 members across the country; we are a nonprofit, nonpartisan group that works on a wide range of policy issues that affect the entrepreneurial sector of our economy.

The idea of allowing for the reimportation of prescription drugs from nations that impose price controls is another unfortunate example whereby some politicians choose to ignore political reality in order to score a few short-term political points. Allowing reimportation from countries in which the government sets the price of prescription drugs would be quite dangerous.

We've heard about the safety issues and the dangers on that front, and that is clearly a major and very real concern for all of us. But I would like to talk a little bit about the economic dangers involved with reimportation, from a basic economics perspective. Unfortunately, as is the case whenever the government inserts itself into market, price controls come with a mighty and -- in this case -- potentially deadly cost. Small businesses, specifically small pharmacies, would pay a big price. Make no mistake, we certainly believe competition is a good thing for consumers and the economy. And it small pharmacies are challenged in the marketplace by more efficient and innovative competitors, so be it. That's the free market process.

However, allowing for importing drugs from countries with price controls is not real competition. It's government regulation that would have the effect of severely hurting local pharmacies and maybe driving many of them out of business.

Then there is the entrepreneur. It's easy to imagine the doctor or scientist with the love of research and a passion for improving and saving people's lives. Perhaps that person has the talent, knowledge and vision to pursue a cure for some kind of cancer or another illness, and is on track for a potential breakthrough. However, undertaking such research is a high-risk endeavor. Capital must be raised from investors in order to proceed.

Consider the example of biotech. Venture capitalist John Clarke was quoted recently in the *Palm Beach Post*, noting, and I quote: "For the past two decades, it has been the premise that the smaller biotech companies would be the true engines that fuel the biopharmaceutical industry." Biotech ventures are entrepreneurial, they are high risk, they need capital to discover, develop and commercialize new medicines. As the article reported, and again I quote, "These early-stage biotech companies need enormous amounts of money to sustain them."

But how many entrepreneurs and investors will be willing to take such risks if, in the end, even if they beat the very long odds and end up succeeding -- the government is going to set prices and limit their returns? For anyone with a basic understanding of economics, the answer to this important question is clear: Few, if any, would make such investments.

Of course, the same goes for the established pharmaceutical firms. Researching and developing new medicines is risky and costly for these firms as well. The pharmaceutical research and manufacturers of America have noted the costs and risks involved, and I'll just quote them very quickly. On average, it costs \$802 million to develop new drug, up from \$138 million in 1978. It takes 10-15 years to bring a drug from the laboratory to FDA approval. The risks are formidable, one in every 5,000 compounds screened is approved, and so on.

It's also worth noting that investment in research and development has accelerated twice as fast

in the U.S. than in Europe over the last decade. And eight of the top 10 drugs in terms of sales, originated in the U.S., and only two in Europe. Again, Europe has price controls; we don't.

Innovation gets hit hard when price controls are put into place. There have been many reports and I know that some folks have talked about this today. One recent report from Bean and Company -- which was presented to the governments of the world at an economic forum in January -- they noted that pharmaceutical profits have shifted away from Europe and toward the U.S.; rates of return on R&D are much higher in the U.S. than they are in Europe. They also noted that this is not a free ride for Europeans: they have their costs too. They have lost investments to America, lost jobs, have fewer value-added drugs, and fewer drug launches. Obviously, all of this hurts patients. Also remember what Ms. Wong-Reiger said about the lack of R&D in Canada and the waiting period involved in new drugs.

Price controls, including the reimportation of prescription drugs might sound good to some, but the economic reality is quite grim. It is instructive to note that in all but five years from 1979-2003, pharmaceutical companies boosts their R&D spending by double digits per year. The years when they didn't were 1994 and 1995, the years when the Clinton health plan debate which threatened to impose price controls. It also happened in 2002 and 2003, and it's no coincidence, I don't think, that we were having the reimportation debate heating up at the time. We also had an attack on patent protections during that time.

One other study that I think is worth nothing. University of Connecticut professor John Vernon projects that 50 years of price controls would reduce the number of new medicines by 60 to 73 percent. And if the US had price controls from 1980 to 2001, there would be between 330 and 365 fewer new medicines today. I don't think that a centralized, politicized fund, in terms of what we heard earlier, where money would be pooled and somehow distributed is not going to provide the innovations that consumers expect and need. Price controls through reimportation of prescription drugs will hurt small businesses, entrepreneurs, investment, innovation, and therefore, ultimately, patients. Thank you.

Carmona -- Thank you sir. Task force members? Dr. Raub.

Raub -- If we were to eschew price controls, as your analysis clearly suggestions, what are we supposed to do? Should we just tread water with the current system? Or is there some other direction that you would recommend?

Keating -- Well, I think we have some systems already in place today. Obviously, you have government programs that help lower income individuals to buy prescription drugs. We have the expansion of Medicare going forward. We have other solutions, actually, like health savings accounts, which we are big fans of at the Small Business Survival Committee. And, those are wonderful because you put the patient in control of the dollars so you have your own money in your own account. I know I heard a speaker talking about people being willing to shop around, and that's critical in the market process and it so often doesn't happen when a third party payer is involved. When someone else is picking up the tab, what do you care what the price is? But if it's your money in your account, and you deposit it along with the employer -- or some combination -- that would help the process as well. I have to say, the whole political debate is interesting because we seem to be having a lot of attacks essentially going on the pharmaceutical companies. Which is quite striking to me. It's not like these companies are providing a service that *hurts* people -- quite the opposite. I guess I'm just making a political comment, that we're having this discussion on an industry that, basically, saves lives.

Raub -- The witness who preceded you made reference to instances where the federal government has had a substantial investment, and suggesting that the government might have a different view in that arena. Is that practical, from your experience?

Keating -- I think when you look at the numbers, especially in terms of recent years, I've seen the

numbers of what the NIH invests and what the industry invests, and the industry investment is bigger than the entire government investment. I've heard a lot of talk that it's really the government funding that's behind our new drugs. I don't see much evidence of this, but I hear it bandied about a lot. When you look at the numbers, I don't think it holds up very well.

Azar – Just on that point, under the Bayh-Dole Act, where the government funds some initial research... and the Bayh-Dole act was intended, as I understand it, to promote the commercialization of research so it wouldn't just sit on shelves in government research libraries or be made public domain information where nobody would have a commercial incentive to actually turn primary research into commercialized products that, as you said, could save lives. As I understand it, the Clinton Administration and NIH actually decided that to try to use any authority to price- regulate costs that might be generated from research funded by the Bayh-Dole Act, would actually impair the willingness of entities to invest the hundreds of millions of dollars that are actually needed -- in addition to the primary research -- in order to save lives. Do you have a perspective on that? Do you agree with the Clinton's government's approach there?

Keating -- In terms of not imposing price controls? Yes I would agree wholeheartedly with that. The Clinton Administration problems came in 1993, really in 1994-95, when the push was on for national health care. In that effort, the big morass, there was discussion and debate and the emphasis about price controls coming into the equation -- and we saw the effect. You know, we saw the drop-off in research and development spending. So, on that case, I would agree with them; on the other case, I would not.

Carmona -- Other questions? Thank you, appreciate it.

Jamie Martinez, Latinos Unidos Health Access Alliance

Good afternoon, my name is Jamie Martinez. I am the chairperson of Latinos Unidos Health Access Alliance, which is made up of Latino activists from around the country. It is a great honor to be here today, to be part of this presentation, and to bring you some awareness of our concerns in the Latino community.

As the Latinos that are involved with health and safety in our communities, our primary mission is to advocate for access to quality health care services and treatments for the Latino community to reduce health disparities. I have spent 35 years of my life working with the Latino community as a worker. I come here talking to you today as a worker who has spent 35 years in the grassroots. It reminds me of the days of working with Cesar Chavez, the 60's and the 70's, when pesticides – dangerous chemicals – were being dumped on the poorest of the poor, the forgotten poor, the farm workers. And I learned from him at a very early age that safety plays a very important role in the lives of workers.

And as I sat here all day today listening to the experts, I believe that what we do here today will determine the future of the next generation. I remember children being born without hands, without legs, deformed because of those chemicals. And it took years of research to find out about the poisonous chemicals that caused cancers, about the toxins. And we started talking to the consumers about the problems that we faced when we have unsafe working conditions.

It is a sad state of affairs that here in America today we have almost 45 million people uninsured, underinsured. Two-thirds of them are working poor, who make 200 percent of the federal poverty level. And one-third are Latinos, one-third are workers. Disproportionately many of those without health insurance are the Latino working families. I see it in the communities where I live and work everyday. And increasing access to affordable medicines is important, but I believe, not at the expense of safety.

Mr. Carmona and the members of the Board here, I thank you for the opportunity to be here to present our views. The public should be aware that prescription drug importation is unsafe, and

hurts patients' health. Maybe no one else notices or cares whether importing medicines is good or bad for Americans until someone we love is harmed by medicines that contaminated, adulterated or counterfeited. Medicines that come from all over the world, using Canada as a post office.

In order to remember to understand more these safety concerns, I remember working in the factory back in 1966. I was a member of a safety committee. And I will highlight some of the important issues for us as workers in America. As members of the working class, we were always fighting for the safety of the workers and protecting the laws that we have on the books right now. We passed laws that protected the health and safety of our communities. There were long struggles for workers that lobbied for these laws. Laws such as the 1970 Occupational Health and Safety Act, the 1969 Coal Mining Health Act. The establishment of these laws protected the health and safety working people in America.

Whether in the work-place or in the prescription drug importation industry, the safety protections should be one of the most important issues here before us today. What we decide and what we do with this committee will determine the safety and welfare of our young generations and our consumers.

Congress has debated the issue of drug importation many times, despite the fact that the Senate has approved this legislation three times for these safe, cost effective measures. There are some members on the Hill right now that are trying to do away with safety laws that protect workers and safety. For example, there are some lawmakers that would try to eliminate 16 health and safety protections from federal law. Existing law already allows drug importation under certain condition where the health and safety of Americans can be assured.

Even the law I heard being talked about today, that the Wisconsin Governor talked about that he went to Canada, they found some prescription companies that they want to do business with and they are encouraging citizens to do business with. But at the same time, I do not understand that they have this ... you can cross the border but beware and sign these waivers. They cannot verify that these drugs are safe that imported to Canada from other countries -- Third World countries -- from Indonesia, from China, from India and from Pakistan and other countries.

Even though we have safety laws on our books, we cannot turn back the clock and reverse the safety laws that we have as protection. One thing I know for sure; there is no way for us to ensure that imported medicines will be safe and effective. Many people think, if they import drugs from Canada, they are actually medicines drugs from Canada – same medicines the Canadians are getting from their pharmacies. But, the truth is that we have no way of knowing where these imported medications came from, or how they were manufactured, or the quality of the medicines. The reason is that the FDA, Health Canada, the US drug importation agency or US customs agencies have said that they how safe they cannot monitor every package sent through their mail systems, nor can they determine the safety of any drugs being mailed through their ports.

In March, 2004 the Pharmacy Alliance for Canadians released a report, showing that Canada cannot sustain the U.S. demand for pharmaceuticals through its regulation systems, citing that nearly half of their medicines for chronic conditions are actually being shipped to the U.S.

This gap between the supply and demand for prescription drugs in Canada is already being filled by drugs through the black market and by people who wish to take advantage of American's belief that medicines they import are will actually be from coming from Canada. They have already noted increases in drug imports from other countries including Singapore, up 30 percent, Ecuador, up 198 percent, China, up 43, Iran, up 2075, Thailand, up 52 percent. The majority have documented counterfeit problems; none have agreements with Canada. Since these drugs cannot be sold to Canadian citizens, it is likely that they are bound for the U.S. and will end up in the corner drug store. No one with any sense will approve this program Thank you very much for your time. On behalf of the Latino community, we will continue to educate.

Carmona – Senor Martinez, I have a question. You know, today we have heard a lot of about the importation issues with Canada. I know you are from Texas; and we also have a Southern border, where people from the South go across to Mexico to get cheaper drugs. This is an issue for the Latino population there. We are looking at this issue more globally, to consider the risk for the entire U.S., so I'd be I'm interested in your perspectives on the Southern border also and problem we have there.

Martinez – I live 150 miles from the border. I see elderly people getting g up early in the morning, 6 am, they are elderly, retired, grandmothers, poor families, and apparently they get on the buses go to the border. Because of the security, they and spend hours crossing the border and then buy at discount prices. Our concern right now is to educate them on patient assistance programs so and how they can tap in to these programs so they don't they don't have to travel that far and be at risk. We can't tell if the drugs are counterfeit, fake or contaminated -- the risk is there. The FDA has documented this the risk, there are tens of hundreds of documentations of that. We try to educate people who are low income to help them learn how they can get access to cheaper drugs.

Azar – You spoke at great length about the safety concerns about imported drugs. I was wondering if you have a concern about a disproportionate impact on the Latino community from a two-tiered safety system? One that would be the FDA gold standards of drugs, and the other would be another system of dugs that seem like they are almost safe, almost the FDA system.

Martinez -- There is a two-tiered system. People that are on welfare, that are incarcerated – they will be subjected to diluted drugs that are not of quality. We need to have affordable quality drugs for all human beings in our society. The aspect of approving unsafe drugs, and reversing laws that we have to protect the safety and welfare that we have now, it's not the answer. We need to come up with solutions that will work for all Americans. If someone gets a hold of a contaminated drug, it doesn't matter if you are rich or poor, doesn't matter.

Carmona – Other comments? Thank you. Our next speaker is Frances Smith, Consumer Alert. Is Frances Smith here from Consumer Alert? No, not here anymore. Then, I think that our agenda, as listed, is complete. We have one person who signed up later, Nancy Martin, Pharm-D. Is Nancy Martin here?

Nancy Martin

Good afternoon; my name is Nancy Martin. I trained here in the US, and I practice currently as a community pharmacist in the state of New Jersey. I thought it would be worthwhile making a point that I think is germane, but which hasn't been addressed before. I think that prescribers are fundamentally not aware of their habits -- I think that this is really overlooked in this issue. Dr Crawford asked about this several times, in terms of, what is the root cause of the issue, in terms of access to affordable medicine in the U.S.?

Prescribers are not aware of the cost implications of their habits. There is a lack of awareness of whether they have the right drug, at the right dose, for the right patient, at the right time, and for the right reasons. To achieve this basic understanding, we have to understand what the alternatives are for an individual. I don't think that everyone who leaves surgery needs a \$4 anti-inflammatory, as opposed to the one that they can get over-the-counter for some few cents. Providers are not fundamentally aware of this when they give a patient a sample of a product that they have just received.

This is really important because it gets right to the crux of the matter. The crux isn't about importing product that are available at a lower cost. The issue is, are we on the appropriate medications that we need? This is not being addressed and it is within the scope of this panel, because it is about access to affordable care. It is not appropriate for us to be on the wrong agents. It may be that we need for controls to be put in place to ensure accountability for

prescribers, for them to understand the cost implications of their prescribing habits.

Carmona – A quick comment. The issue you raised is one that we raised in our first hearing. More globally, I'm thinking about health literacy. We usually mean this with respect to the public -- not understating the drugs and the regimens. But, there is also a component of health literacy that I think you're alluding to, and that is that is the prescriber, and understanding cost effectiveness, understanding the use of generics and so on. So, I think that your points are very well taken and, in a comprehensive review, we need to look at all of the aspects as you have pointed out. So, I thank you for your remarks. Task force members? Yes, Dr. O'Grady?

O'Brien – Yes, it seems to me that you have two points that you are making there. One has to do with quality and, at the same time, it seems to me that you also wove in there a lack of price sensitivity on the part of the prescribing physicians involved. And, I think we have seen that; it is one of the areas that we have seen in some of the research that I have done, that our office has done, when you look at managed care versus fee-for-service. Part of that is within a managed care organization. When you are not only writing the prescriptions, but also paying for them, there is that sort internal communication that goes back to the providers saying "Are you aware that what you wrote is 25 times more expensive than the alternative?" And I think that although they have been criticized for being overly cost sensitive, it's is one area, when you look at growth trends in terms of drug pricing. It's also an area in terms of two types of care; your ability to, sort of, manage both in terms of maintaining, and dispensing quality but also being price-sensitive at the same time. From my work, I agree with notion that there is not a high level of price sensitivity among most prescribing physicians. I had always hoped that, because my side was the more economic, that there was high attention to quality, but both of your points are well taken.

Martin -- It not only extends to the prescriber -- which is beyond the physician, because there are allied health care providers who also prescribe -- but throughout the whole health care system and the consumer. I don't think that people are aware of the costs of the health care system. And that really is the crux of the issue, because you would demand to understand all of your alternatives, just as you would for any other product you procure, if you understood your options.

Raub – Just an observation – you could also add the sensitivity to litigation; the \$4 pill is sometimes seen as a bigger shield than the 20 cent one. That too also is contributing to the root cause.

Carmona – Other questions, comments? All right, I think those are all extremely good points. I know that, having been in academic medicine for some years, it was always a challenge to get our residents and medical students not to order the latest drugs because that was the last rep they spoke to and they had it fresh on their mind – but to remind them to think about what actually provides the greatest remedy at the lowest cost. This is a matter of challenging them and injecting this into the educational system, whether that's on rounds or when pharmacist is doing the prescription.

All right, are there any more members of the public who would like to say something? Anyone who came in late or signed in that I am not aware of who would like to say something? I want to thank the public who has come today and spent their time with us. This is essential for us in our deliberations, to provide recommendations to the Secretary and Congress. I would like to thank the task force for their commitment to this kind of boot camp approach; we made it through the day. I'd also like to thank the media for hanging with us, and helping us to get this story to the American public. After all, we understand the huge responsibility that we have in making these recommendations for the American public and without you we can't get the story out. We want to make sure the American public understand what the issues are, and that we are working to get the best practices on their behalf. Thank you all very much.

Last revised: June 21, 2004

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ATTACHMENT D

RECEIVED BY CALIF.
BOARD OF PHARMACY
2004 JUN -3 AM 10: 53

Carmen Catizone, MS, RPh, DPh
Executive Director/Secretary
NABP Foundation
700 Busse Highway
Park Ridge, IL 60068

June 1, 2004

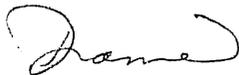
Dear Carmen;

Enclosed please find our report for the Medication Error Analysis Proposal which was funded by the Foundation. As stated in the report and several emails, our original goals were not able to be realized because of some restrictions to data, but we still feel there is value in the effort and results.

We are seriously considering presenting the data at a national meeting in the Fall. Should you want the data presented at a NABP meeting, let me know.

Thank you again for your support of this project.

Sincerely,



Dianne Tobias, Pharm.D., CGP
Mark Sey, Pharm., CGP

CC: Patricia Harris

An Evaluation of the Implementation of a State-Mandated Medication Error Quality Assurance Program

Dianne E. Tobias, Pharm.D., CGP

Mark Sey, Pharm, CGP

Introduction

With impetus from the landmark 1999 Institute of Medicine Report, "To Err is Human", the State Board of Pharmacy of California (the Board) promulgated regulations (California Code of Regulations, Title 16, Division 17, Section 1711) mandating a medication error quality assurance program in all licensed California pharmacies, including hospitals, "closed door" pharmacies (that generally serve long-term care facilities) and community pharmacies. This regulation became effective January 14, 2002, however was not actively assessed and cited by the Board until June of that year. This hiatus allowed for pharmacy education and implementation. Prior to enacting this regulation, only the State of Florida had a requirement pertaining to pharmacy medication errors, although at that time, Florida's program was not mandatory.

Broadly, this California regulation requires a pharmacy to establish or participate in a quality assurance (QA) program, which documents and assesses medication errors to determine cause and an appropriate response in an effort to improve the quality of pharmacy service and prevent future errors. While definitions and scope of medication errors vary, this regulation defines a medication error as "...any variation from a prescription or drug order not authorized by the prescriber". However, this definition does not include any variation that is corrected prior to furnishing the drug. That is, any variation from the prescription identified and corrected prior to furnishing the drug, often referred to as "near misses", are not considered medication errors and not subject to internal review under this regulation. Additionally, prescribing errors, such as

inappropriate medication, excessive dose, duration or errors, are not considered errors under this regulation. Other important components of the regulation include:

- Written policies and procedures must be maintained in the pharmacy in a readily retrievable form.
- All medication errors that are discovered are subject to a quality assurance review.
- The QA review analyzes circumstances surrounding the error and provides recommendations regarding pharmacy systems and workflow processes in an effort to prevent future medication errors.
- Patient and physician notification of an error, and steps required to avoid injury or mitigate the error.
- Recordkeeping and record retention components.

While not discussed in the regulation, it is important to note the primary principle of quality assurance (QA) is the measurement of performance usually through an audit or inspection process, which identifies and assists in the correction of errors. QA is generally considered only the first step in providing quality and meeting customer expectations, and should not be confused with the principles of quality improvement (QI), which is an ongoing, proactive, system-wide method which uses QA data in order to analyze and improve processes to prevent errors and better meet customer expectations.

The objectives of this evaluation were to chart the profession's implementation of this new regulation through the Board's enforcement efforts. The original intent was to prospectively assess, through a Board inspector questionnaire, which components of the QA requirements were most difficult for pharmacy to implement, over time. However after this evaluation was initiated, additional limitations were imposed causing re-evaluation of the original objectives to the following:

- Identify and compile correction order (deficiency) data and citation/fine data for the new QA regulation;

- Identification of Board inspector subjective interpretation of pharmacy's compliance with various aspects of the regulation, and
- Identify and compile data on types of medication errors through a review of Board citation/fine data.

Methods

Prior to enforcement implementation in March 2002, the authors provided Board inspector training on quality assurance/quality improvement concepts and medication error education. This training was provided at the Board of Pharmacy's request.

In December 2003, all citation/fine reports from public records for both the QA regulation (Section 1711) and medication errors (Section 1716-variation from prescription) from 1999 to November 2003 were provided to the authors. In addition, correction order data for pharmacies found to be deficient with the QA regulation for the period April 2002 to November 2003 was obtained. All data obtained relating to licensed pharmacists were separated and deleted from that of licensed pharmacies. Pharmacy data was reviewed and compiled.

Additionally, the authors attended a public hearing which included a discussion of the implementation of the QA regulation and interviewed the inspectors informally regarding their perceptions of the profession's implementation of the regulation.

Findings

Table 1 shows data for the period of the QA regulation implementation and enforcement, April 2002 to November 2003. Correction orders reflect 'deficiencies' some of which may lead to citations/fines. Table 2 lists the correction orders by type of inspection visit. These were most commonly issued during routine Board inspections followed by inspections secondary to a complaint investigation. Interestingly, the fourth most frequent type of visit leading to QA correction orders were new pharmacy inspections.

Types of medication errors are listed in Table 3. These error types were categorized from citations/fine data for variation from prescription based on information in the citation report. There were a total of 193 citation/fine reports for the period 1999 to November 2003. Interestingly, the most common type of medication error appears to be consistent with that reported within the medical/health literature, errors pertaining to wrong drug and wrong strength.

Numerous look-alike and sound-alike medications were identified within the medication error citations. Examples include:

Common Look-alike / Sound-alike Errors	
Seroquel 200mg	Serzone 200mg
Aciphex	Aricept
Hydroxyzine	Hydralazine
Zyprexa 10mg	Zyrtec 10mg
Quinine 324mg	Quinidine 324mg
Prinivil 5mg	Proscar 5mg
Celebrex 200mg	Celexa 20mg
Trazodone 50mg	Tramadol 50mg
Elavil 10mg	Enalapril 10mg

Discussion

Perhaps as expected with the implementation of a new requirement, the greatest number of deficiencies (correction orders) and citations were issued within the first three months post inspector training and with the implementation of enforcement in June 2002. Thereafter, the data appears to reflect a significant decline in the numbers of correction orders and citations issued over subsequent quarters. However, this data must be considered in light of Board procedures, timelines, staff availability and prolonged investigations. It is very possible that procedural issues would delay

completion and delay the public reporting of these investigations and therefore not reported within the study timeframes and should be considered a limitation of this study. Therefore, it is highly possible that the numbers of correction orders and citations for the last six to 12 months of the study evaluation period is significantly under-reported.

Graph 1 shows the relative breakdown of QA and medication error citation/fine data by type of pharmacy. It is interesting to note that a disproportionate (high) share of correction orders and citations for the QA Program were issued to independent pharmacies, however medication error citations appear to be proportionate to classification of pharmacy type within the state. Further evaluation of this data over time would be required to draw conclusions as to the correlation between the identification of QA program deficiencies and cited medication errors.

The identification of the majority of QA program deficiencies during routine Board inspections appears to indicate that the inspectors have quickly and readily included the review of the pharmacy's QA program into their inspection process. Subjectively, upon interview the Board inspectors acknowledged the importance and significant potential of this regulation in providing consumer protection.

A detailed review of the citation data pertaining to medication errors was interesting yet unfortunately limited, given the detail available in the reports. While error categorization was possible, it was not possible to identify error attributes/contributors, e.g., transcription, computer input, verification, etc. However, we were able to identify a significant number of common look-alike, and sound-alike medication errors as well as similarities in the strength of the prescribed and inaccurately dispensed drug, e.g., 10mg or 20mg. The identified look-alike and sound-alike errors are also reported by the Institute for Safe Medication Practices (ISMP) as frequent medication errors. Prevention of these error types is an effort strongly supported by ISMP who provides

error type notifications and recommendations for pharmacy system modifications. Their error prevention recommendations should be strongly considered by all pharmacies.

In the informal discussion with the state inspectors, the consensus was that the initial requirements of the QA regulation, e.g., presence of a policy and error forms had been accomplished by most pharmacies over time, but not surprising, the more critical QA review, the tracking of errors for cause and analysis of processes contributing to errors was more difficult.

QA programs are recognized as an integral initial step to enhance quality and foster customer satisfaction. Within mature quality-oriented businesses and organizations, the initial concepts of QA programs have grown into QI, continuous assessment of internal systems in an ongoing effort to prevent errors and achieve optimal customer satisfaction. While not required by this regulation, it is important to recognize pharmacies which have undertaken this greater step in systematically reviewing their performance processes and not only relying on the analysis of 'after the fact' errors. The California State Board of Pharmacy should be applauded for their foresight and efforts to protect the consumers of the State in taking this first step to realize the broader goal of quality improvement.

Conclusions

This evaluation has attempted to provide a retrospective analysis of the implementation of a state mandated pharmacy medication error quality assurance program.

Unfortunately due to concerns expressed by officials within the State of California, the authors were not able to access important data elements necessary to achieve the original objectives. This caused re-evaluation and negotiation of accessible information and re-alignment of objectives. Those revised objectives included an analysis of regulation implementation via analysis of trends of correction order (deficiency) data and citation/fine data over time; Board inspector subjective interpretation of pharmacy compliance; and a report of common medication errors by

type. To summarize, the California State Board of Pharmacy and its inspectors have fully embraced the concepts of quality assurance in an effort to protect consumers through analysis of medication errors. This is supported subjectively through the interview process and objectively through the number and frequency of correction orders (deficiencies) and citations/fines issued by the Board during this review period. Further, this evaluation has compiled a list of medication errors by type in an effort to further medication error prevention. These error types are similar to those reported by national patient safety programs. Further analysis will be necessary to determine if the implementation of quality assurance requirements actually impacts medication errors encountered by consumers.

**Tobias and Sey: An Evaluation of the Implementation of a State-Mandated Medication
Error Quality Assurance Program**

Table 1

QA Correction Orders and Citations During Regulation Implementation

	4/02- 6/02	7/02- 9/02	10/02- 12/02	1/03- 3/03	4/03- 6/03	7/03- 9/03	10/03- 11/03
QA Correction Orders	173	90	110	76	54	53	45
QA Citation/Fines	5	12	34	12	data incomplete (time delay between deficiency and report)		

Table 2

QA Program Correction Orders April 2002 to November 2003 by Type

Type of Inspection	Number
Routine	408
Complaint	103
Probation	52
New Pharmacy	15
Diversion or Fraud	11
Call Back	6
Change of Ownership	3
Other	3
Total	601

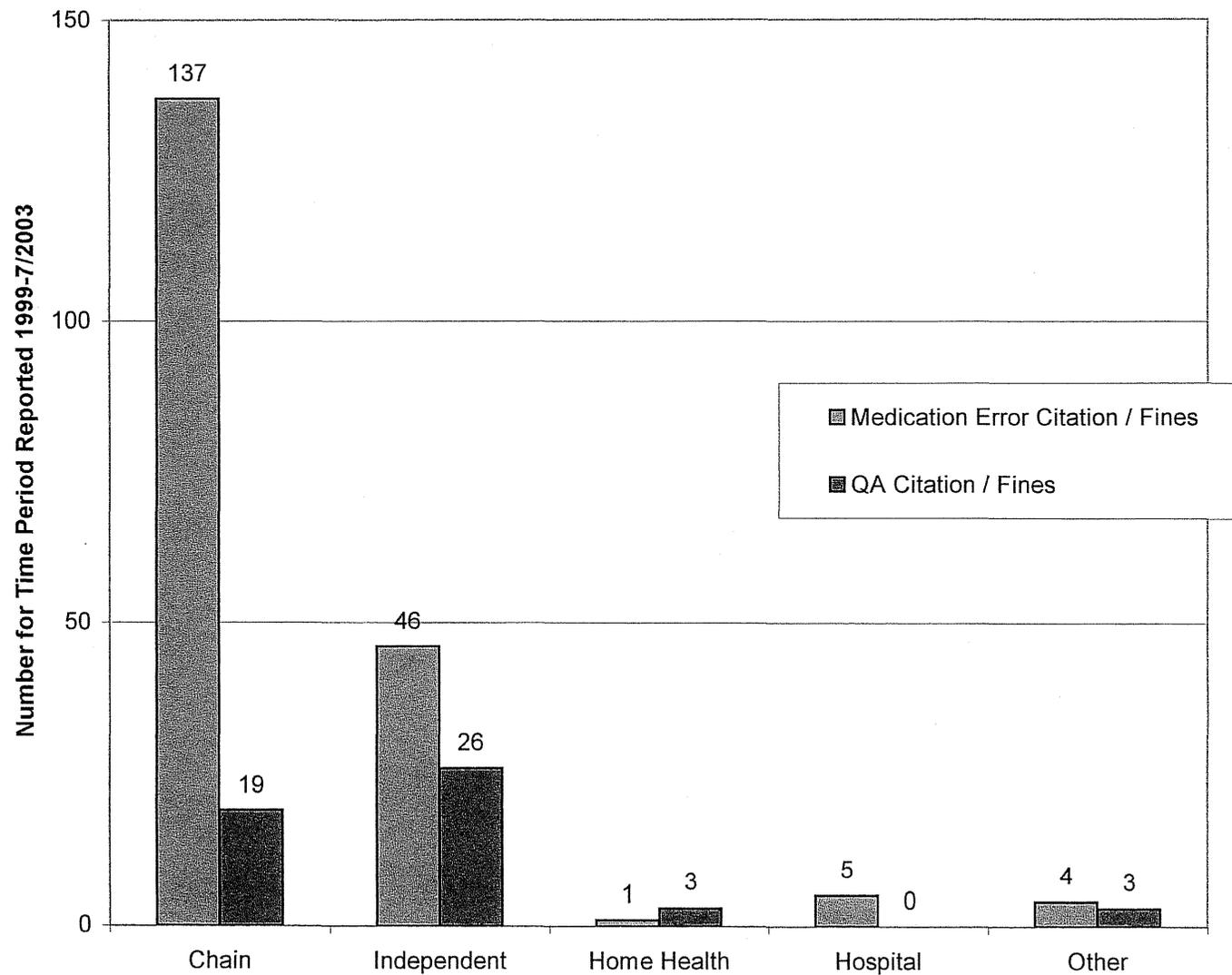
Tobias and Sey: An Evaluation of the Implementation of a State-Mandated Medication Error Quality Assurance Program

Table 3

Medication Errors from Citation / Fine Data Reports 1999-November 2003

Medication Error Category	Number	Percent of Total Citations
Wrong Drug	88	45.6%
Wrong Strength	44	22.8%
Wrong Instructions	21	10.9%
Wrong Patient	12	6.2%
Wrong Medication Quantity	8	4.1%
Other Labeling Error	10	5.2%
Compounding/Preparation Error	7	3.6%
Refill Errors (frequency, timeliness)	5	2.5%
Other (not listed)	10	5.2%
Total # Citations for errors (may have more than one category listed)	193	

Citation / Fines by Pharmacy Type



ATTACHMENT E

FAX

To: Patricia Harris
Pharmacy Board

Fax: (916) 327-6308

From: Linda Morris
Manager, Licensing Operations Section
Medical Board of California

Attached please find a copy of the letter mailed February 9, 2004 to all retired physicians notifying them of the change to retired status and voluntary status and the options that are available to them. This is the result of SP 1077 and the implementation date is 7/1/04 for the retired status and 1/1/04 for the voluntary status.

The letter dated 6/2/04 was mailed to the Medical Societies in California and all hospitals to make them aware of these changes.

This is to notify you of these changes. We feel that the pharmacists should be notified to assure retired doctors do not write prescriptions on or after 7/1/04 since they will no longer be able to practice medicine.



MEDICAL BOARD OF CALIFORNIA
LICENSING PROGRAM
1428 Howe Avenue, Suite 56
Sacramento, CA 95825-3236
Telephone: (916) 263-2417 Fax: (916) 263-2567
Website: www.caldocinfo.ca.gov



June 2, 2004

To Whom it May Concern:

RE: Notice of Changes to Retired Status as a result of SB 1077

This is to advise that on and after July 1, 2004, a physician who is in retired status will no longer be eligible to practice medicine. Senate Bill 1077 (Chapter 607, Statutes of 2003) states that physicians and surgeons who hold a retired license will still be exempt from payment of the renewal fee and the continuing medical education (CME) requirements, however, the holder of a retired license may not engage in the practice of medicine.

Additionally, this law removes some of the restrictions that affect physicians who are in voluntary service status. Effective January 1, 2004, a physician whose license is in voluntary service status is no longer limited by the requirement to practice solely in a not-for-profit agency in an underserved area of this state.

This is to notify you that physicians and surgeons who are currently in retired status and wish to receive compensation for practicing medicine or continue to write prescriptions, will need to request that their license be restored to full active status. If physicians are providing voluntary, unpaid service, they must apply for a voluntary service license. In order to continue practicing without interruption physicians must notify the Medical Board of any desired change prior to July 1, 2004.

I hope this information is helpful in explaining the recent changes to the retired and voluntary status'. If you have any questions regarding the above information, do not hesitate to contact the Medical Board's Consumer Information Unit at (916) 263-2382.

Sincerely,

Joyce E. Hadnot
Acting Chief, Licensing Program

**MEDICAL BOARD OF CALIFORNIA****EXECUTIVE OFFICE**1430 Howe Avenue, Suite 92
Sacramento, CA 95825-3236

Telephone: (916) 263-2389 Fax: (916) 263-2387

Website: www.medbd.ca.gov



February 9, 2004

Re: Notice of Changes to Retired Status as a result of SB 1077

Dear Doctor:

This is to advise you that on and after July 1, 2004, a physician who is in retired status will no longer be eligible to practice medicine. Senate Bill 1077 (Chapter 607, Statutes of 2003) states that physicians and surgeons who hold a retired license will still be exempt from payment of the renewal fee and the continuing medical education (CME) requirements, however, the holder of a retired license may not engage in the practice of medicine.

Additionally, this law removes some of the restrictions that affect physicians who are in voluntary service status. Effective January 1, 2004, a physician whose license is in voluntary service status is no longer limited by the requirement to practice solely in a not-for-profit agency in an underserved area of this state.

This is to notify you that if you are currently in retired status and wish to receive compensation for practicing medicine or continue to write prescriptions, you will need to request a change to your license status. Should you wish to remain in retired status no action is required. In order to continue your practice eligibility without interruption, you will need to notify us of any desired change to your licensure status no later than June 1, 2004. Listed below are the status options for your consideration. For your convenience we have enclosed the applications required for the various options listed below.

- **Voluntary Service Status.** This status allows the renewal fee to be waived when the license is renewed for the sole purpose of providing voluntary, unpaid service. Compliance with CME will still be required unless a CME waiver is separately granted. To request this status please complete the attached application for "Voluntary Service", the "Financial Interest and CME Statement" and return them with your current retired wallet license. A new wallet license will be issued to you that identifies the new license status.
- **Active License Status.** This status allows full and unrestricted practice. Compliance with CME will be required. To restore your license to active status, the biennial license renewal fee of \$600.00 will be required along with the application to "Restore to Active Status", certification of CME, and the "Financial Interest Statement". Please return them with the \$600.00 biennial renewal fee and your current wallet license. A new wallet license will be issued to you that identifies the new license status.

February 9, 2004
Page 2

- **New Retired Status.** The holder of this license may no longer engage in the practice of medicine. A licensee who holds a retired license will still be exempt from payment of the renewal fee and from the continuing medical education requirements. A physician who wishes to remain in retired status will not be required to take any action at this time. On July 1, 2004, all physicians who remain in retired status will be issued a new wallet license by the Board which will reflect "Retired - No Practice Allowed".
- **Voluntary Surrender.** The license may be canceled at the licensee's request. That license will not be eligible to be renewed or restored. If you later decide to become licensed, you will be required to apply for a new license and will be subject to the requirements in effect at that time.

After choosing one of the above options please submit the required forms and fees (if required) for that option to the Medical Board of California, Licensing Operations Section, 1428 Howe Avenue, Suite 54, Sacramento, CA, 95825. Please check each required form to be sure it has been completed correctly and you have signed in all boxes requiring signature, attached any required fees, and you have included your current wallet license. Applications must be received by the Medical Board no later than June 1, 2004 in order to be processed before July 1, 2004. Please be aware the renewal cycle in which your license expires is based upon your date of birth. Those persons choosing to change to active or voluntary service status, depending upon date of birth, may have a renewal period of less than 24 months.

I hope the above information is helpful in explaining the recent changes to the retired status as well as options that are currently available to you. If you have any questions regarding the above information, or about your eligibility in a license status, do not hesitate to contact the Medical Board's Consumer Information Unit at (916) 263-2382.

Sincerely,


Ron Joseph
Executive Director

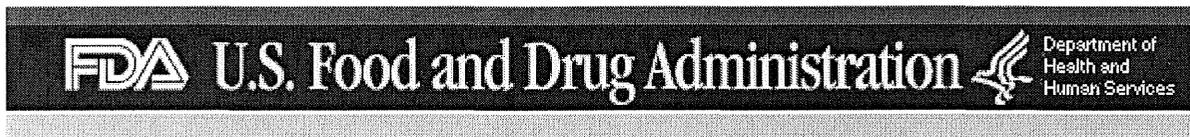
Enclosures

ATTACHMENT F

Implementation of SB 151 – Changes to the Prescribing and Dispensing of Controlled Substances

This document is still under legal review.

ATTACHMENT G



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FDA Statement

FOR IMMEDIATE RELEASE
Statement
June 30, 2004

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-FDA

FDA is Alerting the Public to Counterfeit Viagra Found in Two California Pharmacies

FDA is alerting pharmacies and the public of a small number of confirmed reports involving counterfeit Viagra (sildenafil citrate) sold in two California pharmacies. Both FDA and Pfizer, Inc. of Groton, CT, the manufacturer of the legitimate drug Viagra, are analyzing the counterfeit product to determine its true composition and whether it poses any health risks.

To date no injuries have been reported in connection with this problem and the counterfeit products have only been found in pharmacies in Glendale and Fresno, California.

It is important to note that the concern over these counterfeit drugs in no way applies to real Viagra tablets which are formulated and manufactured in strict compliance with FDA's standards.

Pfizer and FDA are providing pharmacists and the public with information on how to identify counterfeit Viagra packaging and tablets. The counterfeit drugs bear the lot number 3023803 with an expiration date of 1 MAR 06 (this lot number and date were used on legitimate Viagra product distributed between July 1 and July 18, 2003) and resemble real Viagra tablets in terms of their general size, shape, color and debossing (imprints). Yet several significant deviations are evident between the counterfeit and real drugs - these differences can be seen in comparative photos included with Pfizer's Dear Pharmacist letter, posted on the company's Website at http://www.pfizer.com/subsites/counterfeit_importation/mn_pharmacist_viagra.html. These differences include a different debossing font, more pronounced tablet edges, and the lighter blue film-coat.

Consumers who have Viagra at home and may have questions about its legitimacy can reference the above websites or contact the dispensing pharmacist. Pharmacists and consumers who have counterfeit Viagra should contact their local FDA office.

FDA's Office of Criminal Investigations is actively investigating this case and the agency will aggressively prosecute those found responsible for any counterfeiting operation.

####

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Counterfeit and Importation

Counterfeit and Importation

► For Pharmacists

- Pfizer Authorized Wholesalers
- Greenstone Authorized Wholesalers

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For Pharmacists

Description and Identification of Counterfeit Viagra

[Counterfeit and Importation Home](#) > [For Pharmacists](#) > [Description and Identification of Counterfeit](#)

June 30, 2004

Dear Pharmacist:

Pfizer Inc has been made aware of a counterfeit Viagra product that has been distributed least one, and likely two, retail pharmacies in California. This communication is intended you with a notice on this situation and instructions on how to identify this counterfeit product working closely with the Food and Drug Administration (FDA), who is actively investigating

Viagra® (sildenafil citrate) manufactured by Pfizer and distributed in original Pfizer packaging stringent standards of quality, safety, and efficacy as regulated by the FDA.

Pfizer has received 2 complaints regarding suspect product from California. One of these involving 4 bottles of 100-mg x 30 count Viagra purchased from a pharmacy in Glendale, been confirmed to be counterfeit Viagra found in counterfeit packaging that appears similar packaging. The second report, from a pharmacist in Fresno, CA, is currently being investigated. **reports involve product with lot number 3023803 and expiration date 1 MAR 06** (this date was used on legitimate Pfizer product distributed between July 1 and July 18, 2004)

To date, there has been no indication of a safety concern or adverse events related to the product. However, only genuine Viagra is approved by the FDA and can be considered to be effective.

This counterfeit product is identifiable in two ways:

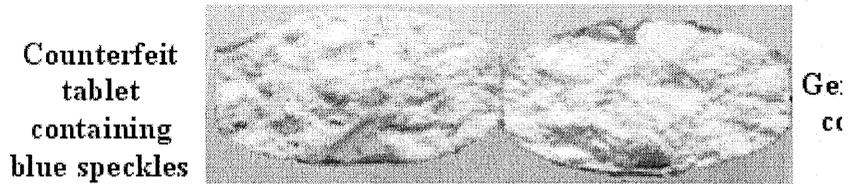
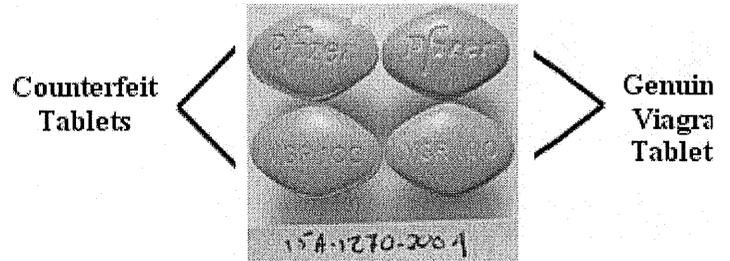
1. Packaging

- Black ink print on counterfeit label is excessively bolded
- Pill shaped border around strength field on counterfeit label is pointed & "1" touches the border
- Pfizer logos on counterfeit label and foil seal are poorly rendered
- Counterfeit foil seal contains less gloss and appears thinner than authentic



2. Tablets

- Thinner debossing font than genuine tablets
- More pronounced tablet edges than genuine tablets
- Lighter blue film-coat than genuine tablets
- When cut, small blue particles can be seen in the normally pure white core tablet



Anyone who discovers suspect product that fits this description is encouraged to contact FDA office or call the central FDA number at 1-888-INFO-FDA (1-888-463-6332).

As detailed in a previous communication, Pfizer is currently introducing new security packaging for Viagra. The new bottles, which will arrive in pharmacies between July and the end of 2004, will feature a color-shift Pfizer logo in the lower left-hand corner of the label's center panel. The Pfizer logo will change from purple to blue when examined from various angles. The new bottles also contain square turn closures.¹



New genuine Viagra packaging with color-shift logo

As it will take some time to deplete older inventory already in distribution, there will be a limited amount of Viagra available without the new packaging. Purchasing Viagra without the Pfizer color-shift logo may mean it is counterfeit, though it is important to purchase Viagra from an authorized wholesaler.

If patients have any questions concerning the authenticity of the product, Pfizer is urging them to speak to their pharmacist.

Pfizer is committed to supporting patients and healthcare professionals who rely on our Viagra product information, communications regarding this topic, and updates on the site available at www.pfizer.com/counterfeit. For further questions, please contact your local representative or call the central FDA number at 1-888-INFO-FDA (1-888-463-6332). Additionally, you may contact Pfizer Medical Information at 1-800-438-1985.

Pfizer supports vigorous enforcement of the law to protect patient safety and continues to work with the FDA and other regulatory authorities to help prevent the trade of counterfeit medicines.

Sincerely,

/s/ Gary Palmer

Gary Palmer, MD MBA
Vice President
U.S. Medical

¹ Please note one exception: the introduction of the squeeze-and-turn feature for the 100-mg x 100-count bottles occur in 2004. However, these bottles will have the color-shift logo feature.

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The product information provided in this site is intended only for residents of the United States. The product information discussed herein may have different product labeling in different countries.

ATTACHMENT H

Citation and Fine Statistics for July 1, 2003 – June 30, 2004

21 Office conferences were held this year

Contested Citations Office Conference

Requested	Scheduled	Appeared	Affirmed	Modified	Dismissed	Withdrawn
399*	302	197	43	72	82	23

*97 of these cases are scheduled for OC in June of 2004; their dispositions are not included

Average number of days from request to meeting date 21 days

- Total amount of fines issued FY 03/04 \$939,259.00

Citation Breakdown by license type

Total Citations issued	RPH with fine	RPH no fine	PHY with fine	PHY no fine	PIC with fine	PIC no fine	TCH with fine	TCH no fine
1410*	303	21	345	273	285	41	52	4

* miscellaneous citations issued: 35 wholesalers, 18 exemptee's in charge, 3 vet distributors and drug rooms, 2 interns.

- Average number of days from date case opened until date citation is issued is 293. The current average is 142 days.

Top Ten Violations by license type

Pharmacists	%	Pharmacies	%	Pharmacists in charge	%
1716 - Variation from prescription	42	1716 - Variation from prescription	21	1716 - Variation from prescription	11
4051(a) - Conduct limited to a pharmacist; conduct authorized by pharmacist (unlicensed activity by a revoked pharmacist)	8	1714(b) - Operational standards and security; pharmacy responsible for pharmacy security	9	4125/1711 - Quality assurance program	11
1716/1761 - Variation from Rx / Erroneous Rx	7	4125/1711 - Quality assurance program	7	1714(b) - Operational standards and security; pharmacist responsible for pharmacy security	9
1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission...	5	1716/1761 - Variation from Rx / Erroneous Rx	4	1715 - Self-assessment of a pharmacy by PIC	5
4125/1711 - Quality assurance program	4	1715 - Self-assessment of a pharmacy by PIC	3	1716.2 - Record requirements - compounding for future furnishing	4
4301(q) - Engaging in any conduct that subverts or attempts to subvert an investigation of the board.	3	4076 - Prescription container requirements for labeling	3	4342/USP 25th edition page 10 - Actions by board to prevent sales of preparations or drugs lacking quality or strength	3
4063 - Refill of prescription for dangerous drug or device; Prescriber authorization.	3	4328 - Misdemeanor permitting compounding, dispensing, or furnishing by non-pharmacist	2	4115(e) - Pharmacy technician license required	3
4231/1732.5 - Requirements for renewal of pharmacist license/ Accreditation agencies	2	4116/1716(b) - Security of dangerous drugs & devices/Operational standards and security; pharmacy responsible for pharmacy security	2	1793.7(e) - Requirements for pharmacies employing pharmacy technician - Job description and written policies and procedures required	3
1707.2 - Duty to consult	2	1716.2 - Record requirements - compounding for future furnishing	2	1716/1761 - Variation from Rx / Erroneous Rx	3
1715 - Self-assessment of a pharmacy by the pharmacist in charge	2	4113(a)(c)/1709.1 - Pharmacist in charge notification to board and responsibilities /Designation of a pharmacist in charge	2	4116/1716(d) - Security of dangerous drugs & devices/Operational standards and security; pharmacist responsible for pharmacy security	2

Fines Assessed Statistic Comparison

Statistic Category	02/03	03/04
Total number of citations issued	908	1410
Average days from case open to citation	228	142
Total amount of fines assessed	\$407,775.00	\$939,259.00
Total amount of fines collected to date	\$361,975.00	\$840,682.00
Number of office conferences requested	124	399
Total number of conferences held	20	21
Average number of days from request to office conference	31	21
Total number of appearances	97	197
Number of citations dismissed	20	82
Number of citations modified	17	72
Number of citations affirmed	60	43

ATTACHMENT I



California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

ENFORCEMENT COMMITTEE MEETING

Meeting Summary June 23, 2004

Department of Consumer Affairs
Board of Pharmacy
400 R Street, Suite 4070
Sacramento, CA 95814

Present: John Jones, Chair
Stan Goldenberg, Board President and Member
Bill Powers, Public Board Member
Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Dennis Ming, Supervising Inspector
Joan Coyne, Supervising Inspector
Board of Pharmacy Inspectors
Joshua Room Deputy Attorney General

Call to Order

Enforcement Committee Chair John Jones called the meeting to order at 9:30 a.m.

Reimportation of Prescription Drugs from Canada

The Enforcement Committee was provided background information on activities in this area since the last board meeting. It was noted that the National Association of Boards of Pharmacy (NABP) held an Importation Enforcement Workshop and Task Force meeting on June 22-23, 2004, to address the issue of importation and the prosecution of entities involved in this activity. Also provided was the NABP's updated report on the most recent action by state boards of pharmacy against storefronts, pharmacies, and other groups and individuals who facilitate or assist in the illegal importation of unapproved prescription medication from Canada. Other documents were: the Interim Findings from the Guiliani Partners LLC report on the examination and assessment of prescription drug importation from foreign sources to the United States and a letter from McKesson Corporation to the Task Force on Importation.

There was general discussion of the legality of this practice and the various legislative proposals that have been introduced at the federal and state level that would allow for the safe importation of prescription drugs from Canada. It was requested that the committee recommend to the Board

of Pharmacy that it write a letter to Governor Schwarzenegger advising him on the legality of such a practice. The committee noted that both the Governor and the Legislature have their own counsel to advise them on legal issues. Also, opponents to the legislation could advise the Governor about federal requirements regarding importation.

Board President Stan Goldenberg committed that the issue of importation of prescription drugs will continue to be an agenda item for this committee and the board. It is a sensitive and controversial issue. The board has been tasked with balancing consumer access to affordable prescriptions against the safety and effectiveness of drugs obtained from foreign sources. The board has heard from many interested parties on this issue during its committee meetings and at its quarterly board meetings and will continue to provide this forum. Finally, both Congress and the California legislature are considering legislation concerning importation and it is proper for the board to wait until the legislative process has concluded.

Disclosure of Citation and Fines to the Public

At its last meeting, the Board of Pharmacy revised its disclosure policy. During the discussion, licensees expressed concern regarding the disclosure of administrative citations. Administrative citations are not considered discipline of a license. However, they do represent the resolution of an investigation or complaint that has been substantiated and is disclosed to the public.

To address the concerns of licensees, the following language has been added to the citations to advise the licensee: "If a hearing is not requested to contest the citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure (Bus. & Prof. Code §§ 125.9, 4314; Cal. Code Regs., tit. 16, § 1775)."

For cases where no fine has been issued the following will be provided:

"No fine has been assessed with this citation and no proof of abatement has been ordered. If no hearing is requested to contest the citation, the right to contest the citation has been waived. If the citation is not contested, the citation shall be represented as a satisfactory resolution of the matter in any public disclosure (Bus. & Prof. Code §§ 125.9, 4314; Cal. Code Regs., tit. 16, § 1775)."

For disclosure to the public, the following language will be provided:

The issuance of a letter of admonishment and/or a citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The final administrative action including payment of a fine does not constitute an admission of the violation(s) charged and is considered satisfactory resolution of the matter. (Bus. & Prof. Code §§ 125.9, 4314; Cal. Code Regs., tit. 16, § 1775)."

Request from Rite Aide Corporation to Accept Biometric Fingerprint Recognition Technology as a Substitution to a Pharmacist Signature on the Prescription Label

Rite Aid Corporation requested a waiver of CCR, title 16, sections 1793.3 and 1793.7 to accept Rite Aid's biometric fingerprint recognition technology as a means of complying with the requirement that a pharmacist must sign the prescription label as a means of verifying a prescription that a pharmacy technician has prepared.

Rite Aid plans to fully use a biometric fingerprint authentication system in its approximately 3,400 pharmacies nationwide with implementation in California by November 2004. The purpose of the biometric system is to provide pharmacy associates with secure access and authorization necessary to create, edit and delete prescriptions during the dispensing process. The biometric function includes the ability to register one or more of the user's fingers, and to use the biometric scan of the fingerprint(s) for secure authorization. It was explained that signing in with the biometric scan then permits Rite Aid to identify the pharmacy associate responsible for various phases of the dispensing process. This technology allows for a more secure authorization of a pending prescription order, including an order prepared by a pharmacy technician.

The committee discussed that the use of biometric fingerprint technology is a viable alternative to the pharmacist's signature on the prescription label; however, a legislative change would be required. The requirement to sign the prescription label is found in Business and Professions Code section 4115(f). The board's inspectors were supportive of such a legislative change to use this technology since it appears to be more reliable and legible than an initial on the label often written in haste.

The Enforcement Committee agreed to recommend to the Board of Pharmacy that it support a statutory change to Business and Professions Code section 4115(f) that would allow another verification process other than a signature as approved by board regulation.

Since there was significant support for this proposal, it was suggested that the amendment be placed in the board's omnibus bill this year if possible.

Evaluation of Implementation of the Quality Assurance Program

The National Association of Boards of Pharmacy (NABP) Foundation funded a study on medication errors in California. The purpose of the study was to chart the profession's implementation of the Board of Pharmacy's new regulation on quality assurance. The original intent of the study was to prospectively assess, through a board inspector questionnaire, which components of the quality assurance (QA) program were the most difficult for pharmacy to implement, over time. However after the evaluation was implemented, additional limitations were imposed that caused a re-evaluation of the original objectives. The objectives were changed to the following: identify and compile deficiency data and citation/fine data for the new QA regulation, identify the board inspectors' subjective interpretation of pharmacy's compliance with various aspects of

the regulation and identify and compile data on types of medication errors through a review of the board's citation and fine data.

The conclusion of the evaluation found that the Board of Pharmacy and its inspectors have fully embraced the concept of quality assurance in an effort to protect consumers through analysis of medication errors. This was supported subjectively through the interview process and objectively through the number and frequency of correction orders (deficiencies) and citations/fines issued by the board during the review period.

The evaluation also compiled a list of medication errors by type in an effort to further medication error prevention. These error types are similar to those reported by national patient safety programs. It was noted that further analysis will be necessary to determine if the implementation of quality assurance requirements actually impacts medication errors encountered by consumers.

It was suggested to share the information regarding the medication errors from the citation/fine data reports with licensees in the next newsletter.

Retired Status of a Physician License

Medical Board of California advised that starting July 1, 2004, a physician who is in retired status will not longer be eligible to practice medicine. While the physician will be exempt from paying a renewal fee and continuing education requirements, they will no longer be allowed to engage in the practice of medicine. The practice of medicine, of course, includes prescribing.

This information will be provided in the board's next newsletter.

Implementation of SB 151 – Changes to the Prescribing and Dispensing of Controlled Substances

Committee Chair John Jones explained that the implementation of this new law will continue to be a standing agenda topic for this committee and the Board of Pharmacy over the next year. The triplicate requirement has been in place for over 60 years and the transitional changes to implement the new law can be confusing. The board has had many questions and has been working diligently with its limited resources to educate prescribers and pharmacists. He added that the educational process will not be an easy feat and acknowledged and thanked those board members and staff who have contributed to this herculean effort.

The Enforcement Committee was provided a list of question and answers that will be placed on the board's Web site after legal review and approval. Clarification was sought on some of the questions and the answers will be revised accordingly.

Update on SB 1307 Regarding Wholesalers

The Board of Pharmacy is sponsoring SB 1307 to strengthen the regulation of wholesalers by enacting comprehensive changes in the wholesale distribution system for prescription drugs. The Enforcement Committee recommended to the board that it sponsor this legislation after discussing the issue for at least two years. The language was carefully developed to directly address issues found during its investigations of wholesale violations in California and the recommendation for the changes came from this committee. The bill contains the following major elements:

- Requires the development of a “pedigree” that tracks each drug through the distribution system beginning January 1, 2007, and the board may extend the implementation date for wholesalers to 2008 and pharmacies until 2009.
- Requires all out of state wholesalers shipping drugs into California to become licensed (This provision was placed in AB 2862).
- Increases the board’s ability to fine for more serious violations related to wholesaling.
- Requires wholesalers to post a \$100,000 bond to secure administrative fines and penalties.
- Restricts wholesale transactions by pharmacies.
- Requires that drugs be purchased only from licensed entities.
- Authorizes the board to embargo drugs when the board suspects or finds drugs that are adulterated or counterfeit.

As the bill has moved through the Legislature, the board through its President has continued to work with all interested parties to resolve issues related to some of the provisions and in those areas where the issues have been resolved, the bill has been amended accordingly.

Report on the Citation and Fine Program

Committee Chair John Jones reported that the citation and fine program has been in place for approximately two years. The first year, a board committee issued the citation and fines and now that function has been delegated to the executive officer. Data from the program was provided. It was noted that staff worked extraordinary hard over the last two months to eliminate a backlog of over 700 citations.

Adjournment

Committee Chair John Jones adjourned the meeting at 12:30 p.m.

ATTACHMENT J



California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, Governor

**Enforcement Team Meeting
June 23, 2004**

2:00 p.m. – 4:00 p.m.

Present: Committee Chair and Board Member John Jones
Board Member Stan Goldenberg
Executive Staff
Supervising Inspectors
Inspectors

Announcements/Introductions

Committee Chair John Jones called the meeting to order at 2:00 p.m.

Quality Improvement Efforts

Supervising Inspector Dennis Ming reported that 1,961 routine inspections have been performed since July 1, 2004, which resulted in 26 investigations. (This is 1.3 percent.) Since the program's inception in July 2001, the board has completed 6,737 routine inspections. The board also has performed 409 diversion inspections, which resulted in 7 investigations. The PRP/Probation team performed 497 inspections this year, which resulted in 1 case. Also, 50 sterile compounding inspections were done and 165 inspections were completed as part of a complaint investigation. So for this fiscal year, a total of 3,082 inspections were done.

The supervising inspectors reported on the many significant inspector accomplishments since the last meeting. Supervising Inspector Robert Ratcliff reported on the status of completed cases. He presented the workload for each team and their significant progress. There are 679 pending complaints/investigations; however, only 336 are under active investigation. Supervising Inspector Ratcliff acknowledged efforts to complete cases that were over the targeted time frames for closure and reiterated that inspectors need to focus on closing the older cases first.

Discussion of Enforcement Committee Meeting

The Enforcement Team discussed the agenda items from the Enforcement Committee meeting.

Adjournment

Committee Chair John Jones adjourned the meeting at 4:00 p.m.

ATTACHMENT K

Board of Pharmacy Enforcement Statistics

Fiscal Year 2003/2004

Workload Statistics July-Sept Oct-Dec Jan-Mar Apr-June Total 03/04

Complaints/Investigations

Initiated	372	337	419	363	1491
Closed	430	469	511	866	276
Pending (at the end of quarter)	935	867	1049	683	683

Cases Assigned & Pending (by Team)

Compliance Team	89	82	59	49	49
Drug Diversion/Fraud	67	69	73	61	61
Mediation Team	71	78	137	125	125
Probation/PRP	45	28	20	40	40
Enforcement	194	164	98	61	61

Application Investigations

Initiated	82	21	25	12	140
Closed					
Approved	122	42	22	11	197
Denied	5	2	1	2	10
Total*	139	57	24	13	233
Pending (at the end of quarter)	73	33	35	35	35

Citation & Fine

Issued	359	281	303	646	1589
Abated	231	73	392	434	1130
Total Fines Collected	\$93,425.00	\$377,200.00	\$149,636.00	\$259,971.00	\$880,232.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Board of Pharmacy Enforcement Statistics

Fiscal Year 2003/2004

Workload Statistics **July-Sept** **Oct-Dec** **Jan-Mar** **Apr-June** **Total 03/04**

Administrative Cases (by effective date of decision)

Referred to AG's Office*	50	42	23	21	136
Pleadings Filed	24	26	38	18	106
Pending					
Pre-accusation	85	97	65	60	60
Post Accusation	67	76	87	75	75
Total	153	179	159	140	140
Closed**	26	22	41	34	34
Revocation					
Pharmacist	3	6	3	8	
Pharmacy	2	2		1	
Other	4	3	3	10	
Revocation, stayed; suspension/probation					
Pharmacist	1		2	1	
Pharmacy					
Other					
Revocation, stayed; probation					
Pharmacist	4	3	1	5	
Pharmacy			1	1	
Other	1	2		1	
Suspension, stayed; probation					
Pharmacist					
Pharmacy					
Other					
Surrender/Voluntary Surrender					
Pharmacist	2	2	2	3	
Pharmacy			3	1	
Other	2	1	4	1	
Public Reproval/Reprimand					
Pharmacist		3	2		
Pharmacy			1		
Other					
Cost Recovery Requested	\$42,992.25	\$68,512.50	\$84,155.00	\$67,502.00	\$263,161.75
Cost Recovery Collected	\$36,714.86	\$47,847.87	\$41,556.37	\$45,575.22	\$171,694.32

* This figure includes Citation Appeals

** This figure includes cases withdrawn

Board of Pharmacy Enforcement Statistics

Fiscal Year 2003/2004

Workload Statistics

July-Sept Oct-Dec Jan-Mar Apr-June Total 03/04

Probation Statistics

Licenses on Probation

Pharmacist	129	122	113	113	
Pharmacy	21	21	19	22	
Other	22	23	22	22	
Probation Office Conferences	8	5	11	7	
Probation Site Inspections	35	17	33	42	
Probationers Referred to AG for non-compliance	1	7	0	1	8

As part of probation monitoring, the board requires licensees to appear before the lead inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

Pharmacists Recovery Program (as of June 30, 2003)

Program Statistics

In lieu of discipline	0	1	0	0	1
In addition to probation	1	3	1	5	10
Closed, successful	3	0	3	3	9
Closed, non-compliant	2	3	5	4	10
Closed, other	0	0	1	0	1
Total Board mandated Participants	50	50	49	50	50
Total Self-Referred Participants*	15	15	15	15	15
PRP Site Inspections**	29	1	6	8	44
Treatment Contracts Reviewed	31	37	26	23	26

Monthly the board meets with the clinical case manager to review treatment contracts for scheduled board mandated participants. During these monthly meetings, treatment contracts and participant compliance is reviewed by the PRP case manager, enforcement coordinator and lead inspector and appropriate changes are made at that time and approved by the executive officer. Additionally, non-compliance is also addressed on a needed basis e.g., all positive urines screens are reported to the board immediately and appropriate action is taken.

* By law, no other data is reported to the board other than the fact that the pharmacists and interns are enrolled in the program.

**Some PRP Participant Inspections are included in the Probation Site Inspections total.

As of June 30, 2004.

ATTACHMENT L

**Board of Pharmacy
First Quarterly Report
April - June 2004**

Enforcement Committee

Goal 1:	Exercise oversight on all pharmacy activities.
Outcome:	Improve consumer protection.

Objective 1.1:	To achieve 100 percent closure or referral on all cases within 6 months by June 30, 2005:																										
Measure:	Percentage of cases closed or referred within 6 months <i>(Based on 270 mediations/investigations sent to SI for review)</i>																										
Tasks:	<p>1. Mediate all consumer complaints within 90 days.</p> <table style="margin-left: 40px;"> <tr><td>0-90 Days</td><td>30 (50%)</td></tr> <tr><td>91-180 Days</td><td>24 (40%)</td></tr> <tr><td>181-365 Days</td><td>6 (10%)</td></tr> <tr><td>366-730 Days</td><td>0 (0%)</td></tr> </table> <p>2. Investigate all other cases within 120 days.</p> <table style="margin-left: 40px;"> <tr><td>0-90 Days</td><td>82 (39%)</td></tr> <tr><td>91-180 Days</td><td>57 (27%)</td></tr> <tr><td>181-365 Days</td><td>44 (21%)</td></tr> <tr><td>366-730 Days</td><td>27 (13%)</td></tr> </table> <p><i>(Based on 866 closed investigations/mediations)</i></p> <p>3. Close (e.g. issue citation and fine, refer to the AG's Office) all board investigations and mediations within 180 days.</p> <table style="margin-left: 40px;"> <tr><td>0-90 Days</td><td>145 (16.7%)</td></tr> <tr><td>91-180 Days</td><td>230 (26.6%)</td></tr> <tr><td>181-365 Days</td><td>422 (48.7%)</td></tr> <tr><td>366-730 Days</td><td>65 (7.5%)</td></tr> <tr><td>731+ 1 (0%)</td><td>4 (0.5%)</td></tr> </table> <p>4. Seek legislation to grant authority to the executive officer to issue a 30-day Cease and Decease Order to any board-licensed facility when the operations of the facility poses an immediate threat to the public.</p>	0-90 Days	30 (50%)	91-180 Days	24 (40%)	181-365 Days	6 (10%)	366-730 Days	0 (0%)	0-90 Days	82 (39%)	91-180 Days	57 (27%)	181-365 Days	44 (21%)	366-730 Days	27 (13%)	0-90 Days	145 (16.7%)	91-180 Days	230 (26.6%)	181-365 Days	422 (48.7%)	366-730 Days	65 (7.5%)	731+ 1 (0%)	4 (0.5%)
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366-730 Days	65 (7.5%)																										
731+ 1 (0%)	4 (0.5%)																										

<p>Objective 1.1, cont'd</p> <p>Tasks</p>	<p>5. Integrate data obtained from computerized reports into drug diversion prevention programs and investigations (CURES, 1782 reports, DEA 106 loss reports).</p> <p>CURES</p> <ul style="list-style-type: none"> ♦ <i>The board received a sample of data that pharmacies transmitted without identification from Atlantic Associates. Board staff reviewed this data and was able to identify the originating pharmacies on the majority of the data. During this process, one of the major pharmaceutical software companies was identified as the cause for a vast majority of this unidentified data. Board staff uncovered a glitch in the pharmaceutical software that erased the pharmacy license number every time the software was upgraded.</i> ♦ <i>The Board has requested the addition of several critical date fields to the CURES system to ensure meaningful and accurate reports: 1) the date CURES was last updated by DOJ; 2) the date data was received at AAI from the pharmacy; and 3) the date data was transmitted from AAI to BNE. The date CURES was last updated is now available. Do to limitations in the current programming and since we are currently in the process of moving to a web based system, BNE has placed the other two date requests on hold until early 2005.</i> <p>36 CURES reports were provided to supervising inspectors and/or inspectors this quarter to aid in an investigation or inspection.</p> <p>CURES data were used in 19 complaint investigations.</p> <p>CURES compliance issues were found in 23 inspections.</p> <p>21 CURES reports were provided to staff this quarter for investigations involving theft or loss.</p> <ul style="list-style-type: none"> ♦ <i>1782 Wholesaler Database - no change this quarter.</i> ♦ <i>DEA 106 Theft/Loss Report- no changes this quarter.</i> <p>6. Re-establish the CURES workgroup that includes other regulatory and law enforcement agencies to identify potential controlled substance violations and coordinate investigations.</p> <ul style="list-style-type: none"> ♦ <i>The CURES Users Group began meeting the third Tuesday of every month. Meetings were held on March 23, April 13, May</i>
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**Objective
1.1, cont'd**

Tasks

18 and June 25th to work on pharmacy non-compliance and data error issues as well as improving database functionality.

- ◆ *BNE hired a consultant, Octet, to assist them in building a new web-based CURES database. The new database will be accessible to users through a secure Internet connection with the look of a browser. BNE hopes to provide board users with faster, easier access and query capabilities. Standard reports will be made available that can be downloaded on command or set to automatically email to the user on a regular basis. Adhoc reporting capabilities will still be available as well. The CURES Users Group dedicated its May 2004 meeting to meet with the consultants for Phase 1 of the project. The user boards had the opportunity to voice their needs and issues with the current system. The users also provided a wish list of standard reports. The next meeting has not yet been set.*

CURES Users Group Meetings: Upcoming Meetings are schedule for July 20, August 17, September 21, October 26, and November 30th. No meeting is scheduled for December due to the holidays.

- ◆ *Inspector and supervising inspector continue to participate on the monthly diversion task force meetings regarding the importation of dangerous drugs, repackaging and distribution in the U.S.; monthly Oxycontin task force meetings in Ventura; FBI task force meetings; and diversion task force meetings in San Diego.*

7. Secure sufficient staffing for a complaint mediation team and to support an 800 number for the public.

8. Improve public service of the Consumer Inquiry and Complaint Unit.

- *In May Board staff participated in 3 Senior Health Fairs - 2 in Sacramento and 1 in Yreka.*

9. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities.

- *A request to provide the board the capability to download its entire CAS enforcement database into an Access database has been submitted to the department's Office of Information Systems. This modification will enhance the board's reporting capabilities.*

- ♦ *Revisions made to the automated inspection system this quarter include:*
 - *The following enhancements were made to the inspector data program to force correct data entry, improve overall functionality, and provide additional data elements and reporting capability:*
 - *Exhibit Label printing program - now capable of printing unlimited number of exhibits and unlimited number of pages per exhibit.*
 - *Assignment Program – Various adjustments made to improved reports and user interface.*
 - *Inspector Data - added features - COPY function - allows inspector to copy previous inspection. Primary use will be for Probation team. Probation team visits the same sites quarterly and saves them retyping the information every time.*
 - *Added ability to designate legal references between Inspection Report and Written Notification form.*

Installed on Inspector laptops June 2004

- *Developed and implemented a behind-the-scenes weekly email delivery of an assigned versus completed inspection report to the supervising inspector. This is a weekly status report that shows inspections assignments completed and inspections assignments yet to be completed for each inspector. No changes this quarter.*

Inspection assignment status reports are sent weekly to supervising inspectors.

- ♦ *Each month staff extracts license data in various forms from one large chunk of data to meet the needs of several different internal and external requestors. Board staff completed the development of a data scrub program to automate this function.*
 - *Automated evidence database – No changes this quarter.*
 - *Automated sterile compounding database - No changes this quarter*

	<ul style="list-style-type: none"> ♦ <i>Implemented New Security Printer database –SB151 (Burton) requires the board to approve security printers in advance of producing controlled substance prescription forms beginning July 1, 2004. Staff began development of a database in December 2003 that will track the security printer applications through to “approval”. No changes this quarter.</i>
<p>Objective 1.2:</p> <p>Measure:</p>	<p>To achieve 100 percent closure on all administrative cases within one year by June 30, 2005.</p> <p>Percentage closure on administrative cases within 1 year</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Pursue permanent funding to increase Attorney General expenditures for the prosecution of board administrative cases. <ul style="list-style-type: none"> ▪ <i>April 1st DAG costs increased from \$112-\$120 per hour to \$132 per hour and Legal Assistants hourly costs increased from \$53 to \$91. Before this increase in fees, the board projected a deficit of \$35,000. For 2003/04 the board will have to absorb the increased costs. For 2004/05 the board redirected \$70,000 to the AG budget line item rather than pursuing an augment by a BCP.</i> ▪ <i>July 1 DAG costs increase to \$139 per hour. Board receives supplemental funding of \$135 thousand to purchase the same level of AG services at a higher hourly rate.</i> 2. Aggressively manage cases, draft accusations and stipulations and monitor AG billings and case costs. <ul style="list-style-type: none"> ▪ <i>Case management and review of pending cases is a continuous process. Status memos sent this quarter: 8.</i> ▪ <i>Disciplinary cases closed this quarter:</i> 0-365 days 16 (47%) 366+ days 18 (53%) ▪ <i>Disciplinary cases reviewed this quarter:</i> Accusations reviewed: 21 Accusations needing revision: 3 Accusations filed: 18 Stipulations/proposed decisions reviewed: 22 Cases reviewed for costs: 15

<p>Objective 1.2 cont'd.</p>	<ol style="list-style-type: none"> 3. Establish a disciplinary cause of action for fraud convictions similar to current cash compromise provisions related to controlled substances. 4. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. <ul style="list-style-type: none"> ▪ <i>Administrative Case Management Database Program</i> - no changes from last quarter. 5. Review and update disciplinary guidelines. <ul style="list-style-type: none"> ▪ <i>No changes from last quarter.</i>
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<p>Objective 1.3:</p> <p>Measure:</p>	<p>Inspect 100 percent of all licensed facilities once every 3 years by June 30, 2004.</p> <p>Percentage of licensed facilities inspected once every 3 years</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. <ul style="list-style-type: none"> ▪ <i>See response to Objective 1.1, Task #9.</i> 2. Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public. <p><i>For this quarter:</i></p> <p><i>Total number of inspections identified was approximately 8,133; total number of inspections completed 6,391; total number of inspections to be completed by July 2005 are 1,742.</i></p> <p><i><u>Total number of inspections completed this quarter: 804</u></i> <i>(This is all inspections combined i.e., routine, diversion, probation/PRP, sterile compounding, status 3 (delinquent), CURES, inspections as a result of a complaint investigation, etc)</i></p> <p><i>Of those inspections, there were:</i></p> <p><i>Total Sterile Compounding Inspections: 50</i></p>

	<p><i>Total Status 3 (delinquent) inspections: 3</i> <i>Total routine inspections resulting in a complaint investigation: 36</i></p> <p>3. Seek legislation to mandate that periodic inspections be done on all board-licensed facilities.</p>
<p>Objective 1.4:</p> <p>Measure:</p>	<p>Develop 4 communication venues in addition to the inspection program to educate board licensees by June 30, 2005.</p> <p>Number of communication venues (excluding inspection program)</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Develop the board's website as the primary board-to- licensee source of information. <ul style="list-style-type: none"> ▪ <i>Public disclosure of disciplinary history on licensees is in the <u>final</u> stages of development and test. Projected production date: April 19, 2004.</i> ▪ <i>During this quarter website revisions included:</i> <ul style="list-style-type: none"> ✓ Regulations updates. ✓ Updated public disclosure. ✓ Revised Key Facts About Emergency Contraception. ✓ PowerPoint presentation for SB 151 ✓ Protocol for Pharmacists Furnishing Emergency Contraception ✓ Listed 8 approved security printers and their distributors 2. Prepare two annual <i>The Scripts</i> to advise licensee of pharmacy law and interpretations. <ul style="list-style-type: none"> ▪ <i>October 2003 Script published</i> ▪ <i>March 2004 Script published</i>

**Objective
1.4, cont'd.**

3. Update pharmacy self-assessment annually.
 - *June 2004 - Inspector review*

4. Develop board-sponsored continuing education programs for pharmacists in the area of pharmacy law and the expectations of the pharmacist-in-charge and coordinate presentations at local and annual professional association meetings throughout California.
 - *C/E presentations given this quarter:*
 - ✓ **April 13, April 20, April 22, April 28, May 19, May 21, May 28, June 8th** - presentation by board staff on prescribing and dispensing controlled substances under the new California requirements to a teleconference of pain management experts, to the Academy of Long Term Care and to attendees at a DHS Public Health Grand Rounds meeting, to 25 RPhs in Sacramento, to San Luis Obispo County Narcotic Task Force, to HMO pharmacy managers and physicians in Los Angeles and to 150 physicians and others at Memorial Care Hospital in Anaheim
 - ✓ **May 13th** - presentation by board members and staff re: the board's CE program at a meeting of the San Diego Pharmacists Association.
 - ✓ **April 29, May 11, May 13, May 20th** - presentation by board members and staff on the new examination process to students at the Western School of Pharmacy, Loma Linda students, USC students and UOP students (with board's Power Point presentation),
 - ✓ **June 1-** board staff presented a segment on pharmacy issues to staff of the DOHS.
 - ✓ **June 19** - board member and staff did a presentation to the Korean Pharmacists Association.
 - ✓ **June 24** - board member presented the board's Power Point presentation top RPhs at a UST Pharmacy Alumni Association meeting.
 - ✓ **June 30** - board staff did a presentation to DHS' Audit and Investigation Staff.
 - ✓ Board member attended a discussion session hosted by the Pharmacy Foundation of California on importation.
 - ✓ PowerPoint presentation on SB 151 to RPhs at a Sacramento pharmacists association meeting.

<p>Objective 1.5:</p> <p>Measure:</p>	<p>To monitor alternative enforcement programs for 100 percent compliance with program requirements by June 30, 2005.</p> <p>Percentage compliance with program requirements</p>
<p>Tasks:</p> <p>Objective 1.5, cont'd.</p>	<ol style="list-style-type: none"> 1. Administer effective alternative enforcement programs to ensure public protection (Pharmacists Recovery Program, probation monitoring program, citation and fine program). <ul style="list-style-type: none"> ▪ <i>Pharmacists Recovery Program: As of June 2004, there were 66 participants in the PRP. During this quarter the board referred 4 pharmacists to the program. Statistics for closures are not yet available.</i> ▪ <i>Probation Monitoring Program: As of this quarter there are 113 pharmacists, 22 pharmacies and 22 other individual licensees (technicians, interns, exemptees) on probation with the board. 10 new probationers were added during this quarter.</i> ▪ <i>Citation and Fine Program:</i> <ul style="list-style-type: none"> ✓ April thru June: 674 citations issued. ✓ Total fines: \$259, 971.00 ▪ In December, reviewed compliance provisions of SB 361 for implementation – order of correction, letter of admonishment and revisions to the citation and fine program. 2. Automate processes to ensure better operations and integrate technology into the board's investigative and inspection activities. <ul style="list-style-type: none"> ▪ <i>Citation and Fine Database Program –No changes this quarter. The database is scheduled for modification.</i>

<p>Objective 1.6:</p> <p>Measure:</p>	<p>Respond to 95 percent of all public information requests within 10 days by June 30, 2005.</p> <p>Percentage response to public information requests within 10 days</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Activate public inquiry screens to expand public information. Establish web look-up for disciplinary and administrative (citation) actions. <ul style="list-style-type: none"> ▪ <i>Teale Public Disclosure Screen – Completed disciplinary actions are entered into the database on a going-basis.</i>

<p>Objective 1.6, cont'd.</p>	<ul style="list-style-type: none"> ▪ <i>Web Enforcement Look-Up – In production on or about May 1, 2004.</i> <p>2. Establish on-line address of record information on all board licensees.</p> <ul style="list-style-type: none"> ▪ <i>Licensee address of record information became available on-line to the public in December.</i> <p>3. Respond to specialized information requests from other agencies about board programs, licensees (e.g. subpoenas) and Public Record Act requests.</p> <ul style="list-style-type: none"> ▪ <i>In the last quarter the board responded to:</i> 37 public records requests 73% within 10 days; 27% over 10 days. 15 requests from licensees – 73% within 10 days; 27% over 10 days. 20 requests from other agencies – 75% within 10-day response time; 25% over 10 days. 254 written license verifications – 70% within a 10 days; 30% over 10 days. 3 subpoenas – 100% responded to within 5 days.
<p>Objective 1.7</p>	<p>Initiate policy review of 25 emerging enforcement issues by June 30, 2005.</p>
<p>Measure:</p>	<p>The number of issues</p>
<p>Tasks (Issues):</p>	<ol style="list-style-type: none"> 1. Reimportation of drugs from Canada. 2. Modification to the Quality Assurance Regulation regarding patient notification. 3. Proposals regarding wholesale transactions. 4. Clarification regarding prescription records by authorized officers of the law. 5. Review of Pharmacy Law regarding the delivery of medications after the pharmacy is closed and a pharmacist is not present. 6. Off-site order entry of hospital medication orders (Bus. & Prof. Code Section 4071.1). 7. Prescriber dispensing. 8. Implementation of federal HIPAA requirements. 9. Prohibition of pharmacy-related signage. 10. Implementation of enforcement provisions from SB 361. 11. Implementation of SB 151 (elimination of the Triplicate). 12. Dispensing non-dangerous drugs/devices pursuant to a prescriber's order for Medi-Cal reimbursement.

**Objective 1.7,
continued**

13. Authorized activities in a pharmacy.
14. Review of Quality Assurance Program.
15. Limited distribution and shortage of medications.
16. Conversion of paper invoices to electronic billing.
17. Automated dispensing by pharmacies.
18. Public disclosure and record retention of substantiated complaints.
19. Evaluation of QA regulation
20. Biometric technology