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CANADIAN PRESCRIPTION DRUG IMPORTATION: IS THERE A SAFETY ISSUE?

HEARING

BEFORE THE

SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

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CANADIAN PRESCRIPTION DRUG IMPORTATION: IS THERE A SAFETY ISSUE?

THURSDAY, JUNE 12, 2003

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 2:06 p.m., in room 2157, Rayburn House Office Building, Hon. Dan Burton (chairman of the subcommittee) presiding.

Present: Representatives Burton, Sanders, Cannon, Watson, Allen, Maloney, Crowley, Gutknecht, Duncan, Janklow, and Tom Davis of Virginia [ex officio].

Staff present: Mark Walker, staff director; Mindi Walker, professional staff member and clerk; Nick Mutton, press secretary; John Rowe, Brian Fauls, and Liz Birt, professional staff members; Rob Rubenstein, Will Drinkwater, Tiara Wuethrich, and Allison Ket, interns; Tony Haywood, minority counsel; and Jean Gosa, minority clerk.

Mr. BURTON. We have to be on the floor in just a few minutes, so I would like to go ahead and get some of the technical things out of the way so when we leave, we won't have to deal with that when we come back.

I will apologize in advance for the time we are going to have to be away from the people who are going to be testifying today. Please accept our apology but we are going to have votes I don't have much control over.

A quorum being present, the Subcommittee on Human Rights and Wellness will come to order.

I ask unanimous consent that all Members' and witnesses' written and opening statements be included in the record and without objection, so ordered.

I ask unanimous consent that all articles, exhibits and extraneous or tabular material referred to be included in the record and without objection, so ordered.

I ask unanimous consent that the following Congressmen and Congresswomen be allowed to serve as members of the subcommittee for today's hearing because of such interest in it: Congressman Gutknecht of Minnesota, Congressman Duncan of Tennessee, Congressman Janklow of South Dakota, Congressman LaTourette of Ohio, Congressman Allen of Maine, Congressman Tierney of Massachusetts, Congresswoman Kaptur of Ohio, Congresswoman Maloney of New York, Congressman Brown of Ohio and Congressman Miller of Michigan. Without objection, so ordered.

I also want to welcome the gentleman from Virginia who I believe will be here when we get back, Congressman Davis, the chairman of the full committee, to today's hearing and we will thank him for being here.

I will make an opening statement after Congresswoman Watson does when we get back from the vote.

I would like to ask all Members to put their statements in the record, however, Congressman Sanders has been working on this issue for a long time and I will be happy to yield to him briefly if he would like to make a few comments.

Mr. SANDERS. Thank you very much, Mr. Chairman, and I want to thank you for calling this very important hearing to address one simple question. Are prescription drugs from Canada any less safe for American consumers than those they buy here in the United States?

I am sure every Member of Congress shares your desire, Mr. Chairman, to address the safety of the prescription drugs purchased by American consumers and you are to be commended for calling such a timely hearing. I would like to make a very brief comment, if I might. I would like to put the issue of safety in some context.

The pharmaceutical industry provided $30 million to candidates in last year's election cycle, three-quarters of it, as it happens, to Republican candidates. Having spent $500 million on elections and lobbying in the last 6 years and as you mentioned earlier at the previous hearing, planning for its trade group alone to spend approximately $150 million next year, nobody in this room, in this country should be naive about the enormous power of the pharmaceutical industry which the New York Times documented is going to spend $150 million this year trying to make sure the American people pay the highest prices in the world for prescription drugs.

No one should be naive about the fact that the pharmaceutical industry has 600 paid lobbyists trying to influence Congress so that we don't do anything to protect consumers.

Mr. Chairman, I consider safety to be an enormous issue and I know you do also. All of us want to make sure that every medicine the American people take is safe but I will tell you about another safety issue which has to be addressed. That is that there are millions of senior citizens in this country who are suffering and who are dying in some cases because they cannot afford the astronomically high prices the pharmaceutical industry is forcing them to pay. That my friends, is a safety issue. Congress has to lower the cost of prescription drugs for all Americans, pass a strong prescription drug benefit under Medicare, but until that day comes, and I don't think you are going to allow that day to come in the immediate future, we have to make sure Americans have the right to purchase safe and affordable medicine abroad.

Mr. Chairman, I am very happy to release to the public today a research memo prepared at my request by the Congressional Research Service. This study analyzes in detail the Canadian regulatory system for prescription drugs and puts to light to industry and FDA attempts to paint the Canadian prescription drug market as some kind of provincial backwater. CRS has convinced me and

I think will convince you that nothing can be further from the truth.

Mr. Chairman, thank you again for calling this important hearing. It is time that Congress and the American people stood up to the juggernaut of the most powerful lobby in this country and that is the pharmaceutical industry. I think we are going to make some progress today.

Thank you very much for calling this hearing.

[The information referred to follows:]

Memorandum May 28, 2003

SUBJECT: Questions Concerning the U.S. and Canadian Regulatory Systems for Approving and Distributing Prescription Drugs

This memorandum responds to your various questions regarding the U.S. and Canadian regulatory systems for approving and distributing prescription drugs. In keeping with your time frame, the answers to the questions are fairly general and do not address all of the detailed regulatory differences in the way pharmaceuticals are approved in the two countries. The information about Canada's drug distribution system came mostly from discussions with representatives of Canadian trade associations, pharmacy regulatory authorities, and officials of Health Canada, the nation's leading health protection agency. We used this information and compared it with our knowledge and understanding of the U.S. drug approval and distribution systems.

Background

The statutory requirements for approving and marketing pharmaceutical products in the United States and Canada are in general quite similar. In the United States, the approval and marketing of prescription drugs is governed under the **Federal Food, Drug, and Cosmetic Act (FFDCA)**. The Act is enforced by the Food and Drug Administration (FDA), an agency of the U.S. Department of Health and Human Services.

In Canada, the marketing of pharmaceuticals is regulated under the **Food and Drugs Act**. Prescription drugs are approved and regulated by the Therapeutic Products Directorate (TPD), the arm of Health Canada responsible for assuring the safety and quality of all medicines sold in that country. These statutes in the two countries are similar in that they both require drugs to be proven safe and effective through clinical studies – and then be manufactured to strict quality standards – before they are approved and distributed for use in general medicine. Recently, in a move to improve drug safety, the Canadian health agency issued a guidance document on Commercial Importation and Exportation of Drugs in Dosage Form under the Food and Drugs Act, clarifying the requirement that drugs imported into or

fabricated in Canada for commercial use must be safe and effective and comply with all Good Manufacturing Practices (GMPs) and Establishment License (EL) requirements.[1]

The United States and Canada have analogous requirements for the licensing of retail pharmacies and pharmacists. In Canada, pharmacies and pharmacists are licensed under provincial or territorial law; similarly, in the United States these entities are licensed at the state level. Drug wholesalers, however, are licensed differently in the two countries. In Canada, drug wholesalers are federally licensed and regulated by Health Canada, in particular its Health Products and Food Branch Inspectorate, Establishment Licensing Unit. In the United States, drug wholesalers, like pharmacies and pharmacists, are licensed and regulated by the states.

The United States and Canada have had formal regulatory systems in place to ensure the quality of pharmaceuticals for decades. Through long-established GMPs, both countries mandate strict quality controls, testing standards, and thorough inspections to ensure the safety and efficacy of prescription drugs. In 1973, the FDA and the Canadian Department of National Health and Welfare's Health Protection Branch (now Health Canada) signed a mutual cooperation agreement allowing the agencies to exchange drug plant inspection information. In the agreement's preamble, the FDA Commissioner "noted that the two agencies for a number of years have cooperated and coordinated efforts in many ways with respect to the manufacture and distribution of pharmaceutical products." He also stated that "it is in no small measure because of this cooperation that drugs marketed in Canada and the United States are as safe and efficacious as modern science and technology will permit."[2] According to a former FDA official, the information that was exchanged throughout the 1970s, 1980s, and early 1990s was quite extensive.[3] Although this agreement remains in effect, little information has been exchanged in the last few years, in part because FDA appears to have concluded that it could not afford the money or time needed to ensure that Canada's system of inspections was equivalent to that of the United States.[4] Nevertheless, FDA still has to inspect foreign manufacturing plants for GMPs in order for the drug to be approved for importation.

Over the years, however, the United States and Canada have agreed to other more general accords, and working groups have been formed by the two countries (and Mexico as well) to exchange information about the regulation of products. These agreements, not the 1973 cooperative agreement, are now the official conveyance for exchanging information between the countries. In 1995, the FDA, in a Memorandum of Cooperation with Mexico and Canada, recognized that all three countries needed to work closely together to prevent safety problems in all FDA regulated products. Over the years, the information exchanged under this memorandum has served to notify officials of proposed changes in regulatory requirements. The Canada, United States, and Mexico Compliance Inspection Group

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[1] Health Canada, Health Products and Food Branch Inspectorate (Online), *Guidance Document on Commercial Importation and Exportation of Drugs in Dosage Form Under the Food and Drugs Act*, May 1, 2003 at [http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/guide_comm_import_e.html].

[2] Agreement of Cooperation Between the Canadian Department of National Health and Welfare and the Food and Drug Administration at [http://www.fda.gov/oia/default.htm].

[3] Personal Communication with Mr. Roger Williams, U.S. Pharmacopeia, Rockville, MD.

[4] Personal communication with Mr. Walter Batts, Office of External Affairs, Food and Drug Administration.

(CUMCIG) is another formal information exchange group, channeling information between regulatory agencies of the different countries. The group holds regularly scheduled meetings to share information about pharmaceutical products and the results of facility inspections for GMPs.[5]

The Answers to Your Questions

1. How many prescription drug wholesalers and pharmacists are licensed in Canada?

According to Health Canada's Health Products and Food Branch Inspectorate, Establishment Licensing Unit, there are approximately 80 drug wholesaling companies currently licensed to distribute pharmaceutical products in Canada. This number reflects the fact that some wholesalers are multiple license holders since they have business operations in more than one province. Subsequently, Health Canada records and lists each of these licenses as separate units.

According to the National Association of Pharmacy Regulatory Authorities (NAPRA), an umbrella trade group representing the provincial pharmacy regulatory authorities, there are 26, 311 pharmacists currently licensed to practice in Canada. In addition, Canada today has 7,441 licensed community pharmacies and 869 hospital pharmacies – accredited by various licensing bodies. The community pharmacy group total includes both traditional pharmacies, and the reported 100 or so licensed on-line/mail-order pharmacies now operating in Canada.

2. Do Canadian regulatory authorities maintain a list of licensed pharmacies in Canada? If so, are those lists available to the U.S. Food and Drug Administration (FDA) or American consumers?

Whether Canadian regulatory authorities maintain lists of licensed pharmacies, and whether they would make the lists readily available to FDA officials or American consumers, varies on the province or territory. According to their respective licensing registrars, for example, community pharmacies in the Yukon Territory and the Northwest Territories (NWT) are not licensed under territorial law. Instead, the few pharmacies located in these vast areas are required to have "municipal" business licences, just as any other entity doing business in the territory. In any event, the Yukon registrar intimated that she was under no legal obligation to furnish FDA with the names and addresses of the six pharmacies in her area, and suggested instead that the information could be easily found in the Yukon Yellowpages. The NWT registrar said that she could supply the FDA with the names of the six pharmacies located in her territory without a problem.

In the 10 provinces, community and hospital pharmacies are licensed under provincial law. Through a self-regulating system, provincial registrars -- whose addresses and phone numbers can be accessed through NAPRA's[6] Web site – issue licenses to both pharmacies and pharmacists. They also maintain computerized databases with the names and addresses of all the pharmacies in the province, including the name(s) of the pharmacist(s) licensed to work at each. Though the licensing of pharmacies and pharmacists is public information in

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[5] Personal communication with Mr. Phillip Broadbent, Office of Legislation, Food and Drug Administration.

[6] National Association of Pharmacy Regulatory Authorities at [http://www.napra.org]

Canada, the registrars all said the information in the databases is not accessible online, mostly for privacy and security reasons. However, they said they would be quite willing to share this information with the FDA, particularly if the agency made a formal request.

3. Must all drug manufacturers, wholesalers, distributors and pharmacists operating in Canada be licensed by the Canadian government?

Yes, all drug manufacturers, wholesalers, distributors, and pharmacists are required to be licensed under Canadian law. Moreover, every drug manufacturing site must have an "Establishment License" and a certificate of compliance verifying that the facility is in full compliance with Canadian GMP requirements. As noted above, in general, pharmacies are licensed according to the laws of the province or territory in which they're located, whereas drug wholesalers are federally licensed and regulated under the Canadian Food and Drugs Act.

4. Are the regulations regarding the approval, manufacture and distribution of prescription drugs in Canada comparable to those in the U.S.?

In the United States, the FFDCA requires that drugs be proven both safe and effective, and be manufactured to strict quality standards, before the FDA can approve them for marketing. Drug products sold in Canada must meet virtually the same statutory requirements. Under the Food and Drugs Act, drugs not only have to be safe and effective, they have to be manufactured to quality standards similar to those for drugs produced in the United States. Furthermore, both the FDA and Health Canada have similar procedures for reviewing and approving marketing applications for new pharmaceutical products.

In the United States, a drug company (or sponsor) seeking marketing approval for a new drug must first file an Investigational New Drug (IND) application – which includes safety data from preclinical (animal) testing – with the FDA for permission to conduct clinical (human) trials. When the clinical studies have been completed, the sponsor submits a New Drug Application (NDA), which includes all of the safety and efficacy data generated during the clinical trials. Typically, the NDA also includes detailed information about the drug's production, packaging, and official labeling. Once the NDA has been reviewed, and FDA is satisfied the drug is safe and effective for its intended medical use, the agency lets the manufacturer know by letter whether the NDA is approved, or 'approvable,' if specified issues are resolved.

Prescription drugs in Canada must go through a similar clinical testing and approval process. If preclinical animal testing shows that a new chemical entity may someday be beneficial to humans, and the pharmaceutical company wants to conduct clinical trials, it must first apply to Health Canada's Therapeutic Products Directorate (TPD). If the clinical studies confirm that the new drug is safe and effective enough to be administered to patients, the sponsor typically files a New Drug Submission with the TPD. When the Directorate is satisfied that the drug's benefits for patients exceed its potential risks, Health Canada issues a Notice of Compliance (NOC) – the official Canadian stamp of approval. All prescription drugs sold in Canada receive a unique Drug Identification Number (DIN), which allows for easy identification during commercial distribution. Currently, the United States and Canada have no mutual recognition of the other's drug identifier system.

5. May Canadian prescription drug wholesalers, distributors or pharmacists stock, distribute, sell or otherwise handle prescription drugs that are not approved for sale on the Canadian market?

Prescription drugs cannot be sold in Canada unless they are first approved by the Therapeutic Products Directorate (TPD) of Health Canada. Once a drug has been approved, the TPD issues a Drug Identification Number (DIN) which allows the manufacturer to market the drug in Canada. DIN numbers are assigned to all approved prescription and over-the-counter (OTC) drugs. According to the Directorate, any drug product sold without a DIN is not in compliance with Canadian law.

6. Does the Canadian Government inspect manufacturing facilities in a manner comparable to the inspections done by the U.S. FDA of U.S. facilities? And distribution facilities?

According to officials with the Health Products and Food Branch Inspectorate, the unit of Health Canada responsible for carrying out factory inspections, all drug manufacturing facilities in Canada must undergo regular inspections by the government. Also, in situations where manufacturing plants fail inspections, Canadian law specifies a variety of penalties depending on the severity of the infraction(s). Similar to the FDA in the United States, the Canadian government has a variety of enforcement techniques at its disposal to encourage or, if necessary, compel corrective action.

7. Does the FDA inspect facilities abroad that produce FDA-approved prescription drugs for the U.S. market?

The FFDCA gives FDA regulatory authority over drugs shipped in interstate commerce. As such, this authority extends to drugs that are produced in foreign manufacturing facilities and then imported into the United States. Section 704 of the act allows FDA to inspect "any factory, warehouse, or establishment in which food, **drugs**, devices, or cosmetics are manufactured, processed, packed, or held for introduction into interstate commerce or after such introduction."[7] According to FDA's Office of Regulatory Affairs, International Inspection Program, the agency has been inspecting foreign prescription and bulk drug manufacturers identified in premarketing applications since the early 1970s.[8] Moreover, the FDA says it has inspected foreign toxicological laboratories and other facilities involved in the pre-NDA approval testing of new drugs since 1977 to assure compliance with Good Laboratory Practices (GLPs) requirements.

8. Do manufacturing facilities producing prescription drugs for the Canadian market have to comply with best management practices comparable to those required of facilities manufacturing products for the U.S. market? And distribution facilities?

If the question about "best management practices" refers to "good manufacturing practices" (GMPs), both U.S. and Canadian law require pharmaceutical companies to comply with strict GMPs when manufacturing their products. According to Health Canada's Health Products and Food Branch Inspectorate, its newly revised Good Manufacturing

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[7] FFDCA, Section 704(a)(1), Factory Inspection.

[8] Food and Drug Administration, Office of Regulatory Affairs, Inspection Reference. [http://www.fda.gov/ora/inspect_ref/default.html]

Practices (GMP) Guidelines issued December 31, 2002, ensure that all prescription drugs in Canada are consistently manufactured to very high quality standards.[9] Based on our discussions with various regulatory officials, Canada and the United States have equivalent GMPs for finished pharmaceutical products. In fact, a drug's marketing authorization in Canada largely depends on whether GMP standards were followed during the production process. Distribution facilities, which are also licensed and regulated by Health Canada, must abide by GMPs as well.

In August 2002 the FDA announced a new initiative to enhance the regulation of pharmaceutical manufacturing and product quality. According to the agency, the initiative will focus on, and reexamine, its current GMP program, and will cover veterinary and human drugs, including human biological products. Laying out three major goals, the agency said it wanted to focus its resources at those aspects of manufacturing that pose the greatest potential risks; ensure that its effort to establish and enforce drug product quality standards does not impede the introduction of new manufacturing technologies in the pharmaceutical industry; and instill more consistency and predictability in its approach to assuring production quality and safety among its centers and field components.[10]

9. Are Canadian and U.S. prescription drug labeling requirements similar? Must the labels be printed in English?

The United States and Canada have similar laws and rules governing the labeling of prescription and OTC drugs. In general, both countries require drugs to be properly labeled before they can be shipped for commercial distribution. More important, the information contained in the label may not be false or misleading to the consumer in any way. Since Canada is officially a bi-lingual nation, warnings and safety information on prescription and OTC labeling are printed in both English and French.

Like the United States, Canadian regulations require different labeling formats for prescription and OTC drug products. For prescription drugs, the official labeling reflects the medical information derived from preclinical and clinical testing, and includes information about approved use(s), and proper dosing, as well as specific warnings about possible adverse effects. Both countries require this label to accompany the drug when and wherever it is shipped during commercial distribution. The information in this label is intended more for the health professional than the patient. Today, in both Canada and the United States, when prescription drugs are dispensed by the pharmacist, the patient can, instead, receive a computer generated leaflet describing, in layman's terms, the medical condition the drug is meant to treat, how it should be taken, and a list of common side-effects. In the case of OTC drugs, the laws of both countries require that they be labeled with information that helps consumers use the product safely, including information about possible side-effects and adequate directions for proper use.

In recent years, the FDA has taken steps to overhaul and simplify the labeling requirements for both prescription and OTC drugs in the United States. In 1999, the agency

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[9] Health Canada, Health Products and Food Branch Inspectorate, GMP Guidelines, 2002 Ed. Version 2, Dec. 31, 2002.
[http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/gmp_guidelines_2002_tc_e.html]

[10] FDA Unveils New Initiative to Enhance Pharmaceutical Good Manufacturing Practices, *FDA*

finalized a rule requiring a new, easy-to-read, standardized format for OTC drug labeling.[11] In addition, the agency proposed new rules in 2000 to revise and enhance the content and labeling for prescription drugs and biological products.[12] It said the revised format would make it easier for health care professionals to access, read, and utilize the information conveyed in product labeling. At present, Canada has no plans to revise its rules for prescription drug labeling. However, for the past several years, Canadian officials have been working on a rule that will, when finalized, require that all inactive ingredients be included in the labeling of OTC drugs.

10. Does the Canadian government require the maintenance of a complete chain of custody record for prescription drugs from manufacturers to distributors/wholesalers to pharmacists?

According to Canada's Health Products and Food Branch Inspectorate, current regulatory requirements governing the distribution of prescription drugs in Canada do maintain a "chain of custody." All approved prescription drugs in Canada are assigned a specific drug identification, or DIN number. The DIN must be displayed on the main panel of the package label. Moreover, all drug wholesalers and distributors must follow certain rules and regulations that add accountability to the system. The Inspectorate information officer pointed out, for example, that all prescription drugs shipped in Canada must, by law, include the name and business address of each company involved along the chain of distribution. As such, since most of the pharmaceuticals sold and distributed in Canada originate from U.S. manufacturers, it's not unusual for a package of prescription drugs to arrive at a Canadian pharmacy with the name of the manufacture, wholesaler, and distributor all identified on the shipping label.

In the United States, the FDA uses the National Drug Code (NDC) System as the universal product identifier for human drugs. The NDC currently lists all drugs manufactured, prepared, propagated, compounded, or processed by drug establishments registered under the FFDCA – including prescription and selected OTCs, insulin, and domestic, and foreign drug products that are in commercial distribution in the United States. Through the use of a 10-digit NDC number, which is printed on the label, the coding system identifies the labeler/vendor, dosage, and package size of the pharmaceutical product.[13] Thus, the NDC number travels with the product as it is shipped from the manufacturer to the wholesaler and then to the retail pharmacy.

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[11] U.S. Dept. of Health and Human Services, Food and Drug Administration, "Over-The-Counter Human Drugs; Labeling Requirements," Final Rule, *Federal Register*, v. 64, no. 51, Mar. 17, 1999, p. 13253.

[12] U.S. Dept. of Health and Human Services, Food and Drug Administration, Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, Proposed Rule, *Federal Register*, v. 65, no. 247, Dec. 22, 2000, p. 81081.

[13] According to FDA, the term "labeler" refers to any firm that manufactures, repackages, or distributes pharmaceuticals.

11. Are there mechanisms in Canada for monitoring and preventing counterfeits on the Canadian market that are comparable to those in places in the U.S.?

In Canada, the risk of counterfeit pharmaceuticals is seen as a non-traditional risk imposed from the outside. Generally, Canadian health officials said they manage the risk of counterfeit drugs much like their regulatory counterparts in the United States. The government takes samples of pharmaceutical products periodically to test whether they are contaminated and/or counterfeit. According to Canadian officials, the chief mechanism for deterring counterfeit drugs is their government's relationship with the pharmaceutical industry; one that allows industry to manage and control the supply chain, while the government assists the industry with the technology and intelligence they both need to detect bogus pharmaceutical products.

Currently, in the U.S., when the FDA receives a report of a counterfeit drug, it works with consumers, manufacturers, wholersalers, distributors, and state agencies to determine the composition of the product, the extent of its distribution, and the remedial action necessary to protect the public health.

12. Is there evidence of counterfeit drugs on the Canadian market? If so, does it suggest that there is more of a problem of counterfeits on the Canadian market than on the U.S. market?

Canadian health officials said there is little evidence of a counterfeit drug problem in their country at this time. As for the United States, the FDA has anecdotal evidence, but little quantitative data, on the number of counterfeit drugs being produced or imported into this country. As one example, we have attached a May 23, 2003 *FDA Talk Paper* warning healthcare providers and patients about the recent recall of three lots of the cholesterol lowering drug Lipitor. The talk paper shows the agency's current approach to dealing with and removing counterfeit drugs when they are found in the distribution pipeline.[14]

The FDA insists that because the U.S. prescription drug production system is "closed" (i.e., all steps in the production process are tightly controlled), it can be monitored in ways that lessen the opportunity for counterfeit drugs to enter the country. Nevertheless, the agency insists there is always the risk that bogus prescriptions could be transhipped through Canada that originated in other countries. To reduce this possible risk, the FDA is in the process of designing screening criteria into their import alert system that will trigger a field analysis when there is a strong suspicion that a shipment of drugs may be counterfeit.

13. Is there post-marketing surveillance of adverse drug reactions in Canada similar to that in the U.S.?

The regulatory requirements for reporting adverse drug reactions (ADRs) in the United States and Canada are very much alike. Both countries employ similar postmarketing surveillance systems to monitor the unanticipated side-effects that often go unseen or detected until the drug has been taken by a larger number of patients. In Canada, the reporting of adverse drug reactions is coordinated by the Marketed Health Products Directorate of Health Canada with the assistance of five Regional Adverse Reaction

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[14] "FDA Alerts Consumers and Health Professionals to Recall of Counterfeit Lipitor," *FDA Talk Paper*, May 23, 2003 at [http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01224.html].

Reporting Centres (British Columbia, Saskatchewan, Ontario, and the Atlantic Region). In the United States, ADRs are reported to and monitored through FDA's MedWatch program.[15] Both countries require drug companies to report within 15 calendar days all serious adverse drug events they become aware of. Although doctors and other health care professionals in both countries are strongly encouraged to report adverse drug reactions, their participation in the surveillance process is strictly voluntary.

14. Is there a mechanism for conducting a recall in Canada similar to that in the U.S.?

The United States and Canada have similar mechanisms for conducting drug recalls. According to the Health Products and Food Branch Inspectorate, Health Canada has a unit that is responsible for initiating drug recalls if the need arises. Recalls are initiated when postmarket surveillance data indicate that the use of a prescription drug may be causally linked with serious, but not necessarily life-threatening side-effects. Health Canada's usual approach is to convince the manufacturer that it would be in its and the public's interest to withdraw the drug from the market voluntarily. The FDA often takes the same approach to persuade drug companies to voluntarily pull prescription drugs from the U.S. market. But, in situations where the drug's side-effects are serious enough to be life-threatening, health officials in both countries have the statutory authority to suspend the product's marketing approval immediately.

15. What testing or other verification of the authenticity or safety of prescription drugs imported into the U.S. by prescription drug manufacturers does the U.S. FDA conduct?

Under the Federal Food, Drug, and Cosmetic Act, only FDA approved drugs can be imported into the United States. Further, Sec. 801(d)(1) of the Act stipulates that only drug companies can legally import drugs into this country. Assuming that these approved drugs were produced in facilities controlled by the manufacturer, under a 'closed' system in compliance with current GMPs, absent probable cause, they would not undergo routine authenticity testing by the FDA before reaching the shelves of retail pharmacies. If the agency discovers, however, that substandard, unsafe, or even counterfeit pharmaceuticals are being shipped into the country, it has the authority to collect samples, inspect facilities, and/or initiate various enforcement actions to stem their further distribution. In situations where consumers 'import' prescription drugs via online mail-order pharmacies, the FDA insists that its ability to monitor the safety and quality of the drugs is significantly hampered.

16. What testing or other verification of the authenticity or safety of prescription drug components imported into the U.S. by prescription drug manufacturers does the U.S. FDA conduct?

In general, the FDA regulates the components used to produce prescription drugs as Bulk Pharmaceutical Chemicals (BPCs). According to an FDA inspection guidance, BPCs are made by chemical synthesis, by recombinant DNA technology, fermentation, enzymatic reactions, recovery from natural materials, or a combination of these processes.[16] The manufacture of BPCs – like the process for finished prescription drugs – must be carried out according to GMPs, whether they are produced here or a foreign country.

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[15] Food and Drug Administration, MedWatch, at [http://www.fda.gov/medwatch/].

[16] FDA Guide to the Inspection of Bulk Pharmaceuticals, May 1994, p. 2 at [http://www.fda.gov/ora/inspect_ref/igs/bulk.htm]

According to the guidance, domestic manufacturers of bulk pharmaceutical chemicals are required to register and must list their products with the FDA under Section 510 of the FFDCA if they meet the definition of "bulk drug substance" under 21 CFR 207.3(a)(4), i.e., a substance that is intended as a drug and, when used, becomes an active ingredient or finished dosage form of such drug. Although foreign firms are not required to register, they are required by regulation to list all of their products with the agency, and products not so listed are subject to detention and/or refusal of entry.[17] Also, the guidance document says that the results of inspections of foreign BPC manufacturers directly affects the status of these products when they enter this country. These chemicals can be sampled, detained, and/or refused entry into the United State if an inspection of the foreign manufacturer suggests that the firm is not complying with GMPs.

17. Does the FDA have the authority under current law to test or otherwise verify the authenticity and safety of prescription drugs brought into the U.S. by drug manufacturers or others? If so, what is the extent of the authority, i.e., does the FDA have the authority to inspect the facilities of [sic] selling prescription drugs into the U.S., such as Canadian pharmacies?

As noted in the response to question 15, although the FDA has regulatory authority over all pharmaceutical products entering the United States, for years now the agency has said it cannot vouch for the authenticity or safety of mail-order prescription drugs purchased online from Canadian pharmacies. This is largely because as a U.S. government agency it has no legal authority over Canadian pharmacies, and therefore has no way of inspecting or assuring the quality of the pharmaceutical products dispensed from these pharmacies.

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[17] 21 C.F.R. 207.40(a).

FDA Talk Paper

T03-38
May 23, 2003

Media Inquiries: 301-827-6242
Consumer Inquiries: 888-INFO-FDA

FDA Alerts Consumers and Health Professionals to Recall of Counterfeit Lipitor

The Food and Drug Administration (FDA) today announced that Albers Medical Distributors, Inc., has voluntarily recalled three lots of 90-count bottles of the cholesterol-lowering drug Lipitor and is warning healthcare providers and others that these three lots of counterfeit Lipitor represent a potentially significant risk to consumers. The product was repackaged by Med-Pro, Inc., of Lexington, Neb., and the labels say "Repackaged by: MED-PRO, Inc. Lexington, Neb." in the lower left-hand corner.

The following lots are involved in this recall:

- 20722V - 90-tablet bottles, Expiration 09-2004
- 04132V - 90-tablet bottles, Expiration 01-2004
- 16942V - 90-tablet bottles, Expiration 09-2004

FDA is urging healthcare providers and patients alike to check the packaging very carefully before using this product. Patients who have any of the product (labeled as "Repackaged by MED-PRO, Inc.") with these three lot numbers should not take it, and they should return the product to their pharmacies.

As part of the FDA's ongoing efforts to investigate and address unscrupulous counterfeiting activities, FDA's Office of Criminal Investigations is investigating the existence of counterfeit Lipitor. Lipitor is a member of a class of cholesterol-lowering drugs that are commonly referred to as "statins."

In carrying out its public health mission, FDA regularly conducts investigations and testing to identify and remove from market products that are counterfeit, have been tampered with, or are otherwise unsuitable.

FDA supports the activities of legitimate manufacturers, in cooperation with FDA, to inform the public about counterfeit products and how to identify them. The agency is committed to rooting out counterfeiting activity and alerting the public to the existence of counterfeit product. Earlier this month, FDA entered into an agreement with a major pharmaceutical trade association to cooperate more closely on cases of suspected counterfeit products.

FDA's investigation into this matter is continuing.

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Mr. BURTON. Thank you, Mr. Sanders. I appreciate your remarks.

We are going to have five votes on the floor which is going to take an hour I am sure. Do any of my colleagues have any comments they want to make before we head to the floor? Mr. Gutknecht, I would be happy to recognize you.

Mr. GUTKNECHT. Just briefly. I would like to introduce in the audience a brave patriot. Her name is Kate Stahl who is 84 years old from Minnesota, and she got involved in the fight to get lower drug prices a number of years ago.

Recently, if any of you saw the latest issue of U.S. News and World Report, there is a picture of Kate and the caption below is, "I hope they will arrest me. I hope they will put me in jail." This is a patriot. This is somebody who is willing to risk going to jail so that she can help seniors in Minnesota save a few dollars on their prescription drugs.

I think the question before this Congress and this committee is will we stand with people, brave American patriots like Kate Stahl, or will we stand with the pharmaceutical industry. That is a very important question. I think in the next several weeks, the American people like Kate Stahl are going to get an answer to that question.

I thank you for allowing me to introduce her. She is one of my heroes.

Mr. BURTON. I don't know that we ought to start the hearing with the votes already in progress. I think we will recess and come back immediately after the fifth vote.

Let me just say to Kate out there, she is not unlike thousands and thousands, in fact, over a million Americans that get their pharmaceutical products from Canada right now. I think a lot of those people feel as she does that they would rather risk being arrested and possibly put in jail by the Food and Drug Administration for buying their products from Canada rather than have their health be jeopardized by not getting the pharmaceutical products at a price they can afford.

When it comes down to whether or not a person gets their pharmaceutical products at a price they can afford instead of losing food or rent or whatever it happens to be, or running the risk of violating a regulation by one of the governmental agencies, I can understand why they are willing to make that risk.

Congress passed a law allowing the reimportation of pharmaceutical products but there was a provision in there that said if the Food and Drug Administration thought there might be a safety risk, and they couldn't guarantee the safety of them, then they could stop them.

With the help of the pharmaceutical companies, the FDA has been able to block reimportation for some time and putting a lot of individual citizens at risk of being arrested if that is how far the FDA wants to go.

In any event, did you have a comment before we break? We have about 5 minutes if you would like to make a brief comment?

Mr. ALLEN. I will be very brief.

First of all, I appreciate very much your allowing Members like me and Mr. Gutknecht who are not members of the committee anymore to be back for this hearing.

I just wanted to mention that I rode part way in Maine with a group of 17 seniors going up to Canada a couple of weeks ago to get medication. These people were wealthy enough, and I use that term advisedly, to be able to buy whatever it was, 90 days or 6 months of their medicine in advance. There are lots of people who cannot. Those 17 senior citizens saved $18,000 on that one bus trip.

Something is wrong in this country when our seniors, people on Medicare, people on the largest health care plan in the country, pay the highest prices in the world for medications they have to take.

I just can't thank you enough for your leadership in bringing this forward.

Mr. BURTON. Congressman Gutknecht has been the driving force on most of this but I appreciate your comments.

We will stand in recess. I apologize to all our witnesses and the people in the audience. We have to go with the floor and vote on these five votes and we will be back. I think that will be it and we will be able to stick with you for the rest of the day until we complete our hearing.

We stand in recess until the call of the gavel.

[Recess.]

Mr. BURTON. Mr. Hubbard, do you have anybody with you that might want to testify or be a part of the testimony?

Mr. HUBBARD. I have no co-witness at the moment, although I would like to have some people available, counsel, if a question comes up we need to bring them up for.

Mr. BURTON. Why don't we have them stand and be sworn in as well.

[Witnesses sworn.]

Mr. BURTON. Congressman Davis, the chairman of the full committee, will be with us shortly. I think what I will do is go ahead and proceed with my statement and what I have to go through and if he and Ms. Watson arrive, we will yield to them.

I would like to start off my remarks with a slide presentation. The first slide deals with FDA safety concerns. Slide two, FDA's assertion is the FDA cannot assure the American public that drugs imported from foreign countries are the same as the products approved by the FDA. I would like you to roll the videotape of Dr. Wennar, a witness at our April 3 hearing. Unfortunately, the FDA had left so I would like Mr. Hubbard to see that.

Mr. Janklow, in the interim, did you have any comments you want to make?

Mr. JANKLOW. No.

Mr. BURTON. The FDA stated they cannot assure the American public that drugs imported from foreign countries are the same as products approved by the FDA. Now can you run the tape? This is Dr. Wennar who was here at the last hearing and you didn't get to hear.

[Video presentation.]

Mr. BURTON. Let us get to slide No. 3 where FDA Commissioner McClellan says reimportation is possible once a tracking system is

in place. Here is what it says, "They keep drugs safe within Canada and I think they do a very good job of that, FDA Commissioner McClellan told FDA last week but they stopped short of saying they can assure the safety of drugs exported to the United States but since we can only assure the safety of drugs within our own regulatory system, there is a risk."

Put up slide four, please. This is a quote from Commissioner McClellan, "There are some steps we can potentially take to improve the technology used in monitoring the distribution of drugs in the entire distribution chain. If we can work that out, maybe there is a way we can work beyond the borders in that effort as well."

Would you put up slide No. 5? The Canadian health officials said, "There is little evidence of counterfeit drug problems in their country at this time. As for the United States, the FDA has anecdotal evidence but little quantitative data on the number of counterfeit drugs being produced or imported into this country." That was the Congressional Research Service report to Congressman Sanders on May 28 of this year.

The reason there is a counterfeit problem is because drugs are so outrageously expensive. "U.S. prescription drug costs have been the fastest growing component of health care expenditures for the last several years, climbing more than 17 percent a year since 1998, twice the growth rate of health costs in general and five times the growth rate of inflation." Look at some of the price comparison charts. These price differences are outrageous. We won't go into all those but it is pretty obvious.

Please go to slide No. 5. "Canadian health officials said there is little evidence of a counterfeit drug problem in their country at this time. As for the United States, the FDA has anecdotal evidence but little quantitative data on the number of counterfeit drugs being produced or imported into this country."

Slide No. 6, please. Here is the FDA assertion. "When purchasing drugs on the Internet, American consumers cannot be certain the drugs they receive are actually dispensed by the person from whom they are ordered." This is Mr. Hubbard and what he said in our last hearing.

Would you roll the videotape of Andy Troszok, a witness at the April 3 hearing.

[Video presentation.]

Mr. BURTON. Would you put up slide No. 7, please?

This is testimony we took from April 3 when Mr. Troszok spoke before the committee, after you left, Mr. Hubbard. He said, "So what we did was mirrored our Canadian International Pharmacy Association certification behind the verified, Internet pharmacy practice sites which issues a non-government seal of approval for U.S. Internet pharmacy site certification."

Let us go to slide No. 8. "IMPAC is the Internet and Mail Order Pharmacy Accreditation Commission made up of pharmacists and physicians from Canada, the United States and Mexico. IMPAC is an accreditation process much like the Joint Commission on Accreditation of Health Care Organizations."

Let us go to slide No. 9. The FDA and Mr. Hubbard assert, "Consumers who buy prescription drugs from foreign countries are at

risk of suffering adverse events, some of which can be lifethreatening."

Go to slide No. 10. This is FDA Commissioner McClellan's speech before the Commonwealth Club in San Francisco on June 9, 2003, "These approved products, while safe and effective, to the best of our knowledge, when used as intended are involved too often in costly and potentially preventable adverse events." We will continue on slide 11 with his comments. "This includes medical errors. As many as 20 percent of Americans have experienced some kind of significant medical error. Preventable errors and complications involving prescription drugs alone are responsible for thousands of deaths, millions of emergency room visits and hospitalizations and billions of dollars in additional health care costs each year, in addition to all of the unnecessary suffering." So far we have found from Internet sales of pharmaceuticals from Canada no adverse events. None. Perhaps today, Mr. Hubbard will have some of those.

Let us go to slide 12. This is the conclusion of Mr. McClellan's quote. "There is too much wasted money that would be better spent on care that actually makes people healthier."

Let us go to slide 13. This is a quote from the Institute of Medical Press Release on November 29, 1999. The subject is "Preventing Death and Injury from Medical Errors Requires Dramatic Systemwide Changes." "The human cost of medical errors is high. Based on the findings of one major study, medical errors kill some 44,000 people in U.S. hospitals each year. Another study puts the number much higher at 98,000."

If you go to slide 14, it says, "Even using a lower estimate, more people die from medical mistakes each year than from highway accidents, breast cancer, or AIDS." That I think shows we have a severe problem in the health care area but we have not found any problems with the reimportation of pharmaceutical products as far as adverse events are concerned.

Slide 16, the FDA asserts, "It is illegal under the Federal Food, Drug and Cosmetic Act to import unapproved, misbranded and adulterated drugs into the U.S."

Let us go to slide 17. This is the Meds Act, Public Law 106–387, Section 1, Conditions, "This section shall become effective only if the Secretary of Health and Human Services demonstrates to the Congress that the implementation of this section will pose an additional risk to the public health and safety and result in a significant reduction in the cost of covered products to the American consumer."

As I have said time and again, we have found no adverse events or problems posed by the reimportation of pharmaceutical products from Canada. The only time, according to the law, that the head of HHS can stop these pharmaceuticals from coming back into the country is if they pose an additional risk to the public's health and safety or result in a significant reduction in the cost of covered products to the American consumer.

Slide 18, this is the letter from Secretary Thompson. We wrote to Secretary Thompson asking for a response. We have not yet received a response.

You have to excuse us because we rushed to get all this together so we could refute some of the arguments that have been made by the FDA in the past.

With that, Mr. Hubbard, we have tried to respond to some of the statements you made in your first appearance before the committee regarding the safety of bringing pharmaceutical products back into the United States. We had a lady who was a doctor talk about the new technology we use on the $20 bill that is on this package here. It shows if there is any tampering with this package, it will be shown very clearly because the colors change as you move the package around. If there is a seal on the package that uses this technology, if anybody tampers with it, it will be very clearly seen. So we can repackage them and bring them back into the country safely from Canada if that is a concern.

The pharmacists we had speak before our committee in the past stated again that they adhere to the same pharmaceutical requirements that we do here in the United States as far as Internet selling and that our Government, working with them, can make sure that only those Internet pharmacists up there are licensed to sell to the United States and are qualified and certified so that they are not dealing in counterfeit pharmaceuticals. They also work with the Canadian Government in that regard.

With that, if you have any comments, we would like to hear them.

STATEMENT OF WILLIAM K. HUBBARD, SENIOR ASSOCIATE COMMISSIONER, FOOD AND DRUG ADMINISTRATION

Mr. HUBBARD. Yes, Mr. Chairman. I have an opening statement prepared for the record but I won't read that. I will just respond to your question in the last hearing that we come back with examples of our concerns. So today I have for you some specific examples of the concerns we have raised if I may show those to the committee.

The first example is some drugs that are coming from Canada, typical of drugs coming in from Canada representing in many cases what we are actually seeing. These first three examples are drugs for osteoporosis, glaucoma and insulin for diabetics. They are required to be refrigerated. If they are not refrigerated, they are very complex proteins that break down and become ineffective. This is the way we took them from the mail.

I will even note in the case of one pharmacy, the place where it says "keep refrigerated" is where they put their label. That is a dangerously ineffective drug in all three cases and those came from Canada, ordered over an Internet site we believe.

A second example is an antidepressant drug and should only be dispensed in very small amounts, about 30. This is several hundred. This drug is prescribed for a relatively high risk population for overdose. This drug should not be given in large amounts to patients. The Canadian pharmacy sent this individual about 10 months worth of that drug.

The next individual apparently had epilepsy and bought a drug usually dispensed in 30 days increments. This is what the Canadian pharmacy sent this gentleman. This is about 4 year's worth of the drug. These drugs start expiring in 6 weeks, so most of the

time this patient takes these drugs, they will have been expired and ineffective.

The next drug is a diuretic for someone with high blood pressure. The interesting fact about this drug is the patient paid $32 for it and you can get in the United States for $20. It has a generic version in the United States, so this patient actually lost quite a bit of money in buying that drug.

This next drug is very, very commonly seen in these Internet sales. It is Lopressor, a high blood pressure drug. When any of us go to the drug store and get drugs from our pharmacist, we get them in the bottle, with the name of the doctor and the pharmacist. It says take before bedtime or with food or how many a day, whatever it is you need to know that your doctor has told you to do is on that bottle. The pharmacist has dispensed that. This is the manufacturer's bottle. This person apparently ordered 30 and he got the standard bottle of 100, so he got too much. All it has is the French and English label and it says what it is in it, no warnings, no labeling. This drug needs to be taken very carefully. You shouldn't drive with this drug, you shouldn't use alcohol. It causes headaches and dizziness and a number of side effects you should report to your doctor. This drug came with none of that. This drug misses all of the standard medical protections that the Congress put into place 50 years ago for medications. It is just a bottle of pills with the manufacturer's name on it.

I also have three drugs that someone bought over the Internet. They are unapproved. We don't know what they are. I think this one may be a Canadian version of Lipitor because it is Lipidil. We are not sure what it is but the person might have thought they were buying Lipitor and they got this other drug. Whatever it is, it is not approved for use in the United States and there is no labeling or information on it as well.

Here is another drug. This one did not come from Canada but I will give you an example of what some folks are getting from these Internet sites. This is a travel book, it has been carved out and the pills are on the inside. These sites say the drugs are safe and effective, FDA approved and all legal, and I don't think they would be carving out travel books to hide them in there in that case. We are concerned about that drug.

Last, we have an example of an 82 year old gentleman who bought two drugs from a Web site that I am going to show you now. I think we can put it on the screen. It is a site based in Arizona which offers to sell you Canadian drugs that are all legal and safe and perfect at a great savings. This gentleman apparently had prostate enlargement and epilepsy.

What he received was a Tupperware container. In that Tupperware container is the drug for prostate enlargement with no labeling, no warnings or anything and the drug for epilepsy. The unique thing about this drug is it had a funny return address on it of India. In fact it says on the package, "Made in India." He was told on that Web site and when he made the phone call that he was getting a U.S.-produced drug sold in Canada and sold back to him. He got Indian drugs that are not approved, have no labeling, no information, and he called the FDA and was outraged, why were we letting this stuff in.

I will also mention phenesteride, a drug that is so dangerous if a pregnant woman even touches it with her hand, it could cause birth defect in her child. It is that dangerous. No warnings of any kind to that effect, so if this gentleman's wife or daughter or someone else handled this drug, just opened the mail not realizing what they were doing, they would be subjecting themselves to serious potential injury.

In summary, we have come back today with the real examples you asked for of drugs that refrigerated that must be, that have no instructions or warnings that should, that are unapproved in the United States, but should be, that are smuggled in, that have no cost savings for the actual consumer and indeed, in some cases, are even made in developing countries where there is no FDA regulation and no assurance of quality and real doubts about what they even are.

With that, Mr. Chairman, I will conclude my remarks but these are the sorts of drugs actually coming in every day at Detroit and Buffalo and the various mail facilities around the country at Americans are buying on Web sites like this that are promising safe and effective, U.S.-produced drugs that are sold in Canada.

[The prepared statement of Mr. Hubbard follows:]

STATEMENT OF

WILLIAM K. HUBBARD

ASSOCIATE COMMISSIONER FOR POLICY AND PLANNING

"CANADIAN PRESCRIPTION DRUG RE-IMPORTATION: IS THERE A SAFETY ISSUE?"

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS

U.S. HOUSE OF REPRESENTATIVES

June 12, 2003

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Mr. Chairman, and Members of the Subcommittee, I am William K. Hubbard, Associate Commissioner for Policy and Planning at the U.S. Food and Drug Administration (FDA or the Agency). I appreciate the opportunity to testify at today's hearing on behalf of FDA. We are pleased to come before the Subcommittee once again to discuss the safety of prescription medicines obtained from foreign sources and to report on our actions since your hearing on this issue on April 3, 2003. We will not repeat information provided in our April 3, 2003, statement, but will focus on additional activities that have occurred over the past eight weeks.

As we have previously testified, the overall quality of drug products that consumers purchase from United States pharmacies is very high. The public can be confident that the drugs they use are safe and effective. In order to help maintain these high standards, FDA works diligently on many fronts to ensure that consumers receive safe and effective drugs. However, FDA cannot offer the same assurances to the public about the safety of drugs they buy from foreign sources.

The issue of U.S. consumers purchasing drugs from foreign sources is a significant concern for FDA. A growing number of Americans are obtaining their prescription medications from foreign locations. They often seek out Canadian suppliers, or sources that purport to be Canadian. As we have said in the past, FDA cannot ensure the safety of drugs purchased from foreign sources.

SAFETY CONCERNS

For public health reasons, FDA remains concerned about the importation of prescription drugs into the U.S. In our experience, many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. FDA cannot assure the American public that drugs imported from foreign countries are the same as products approved by FDA.

FDA has long taken the position that consumers are exposed to a number of risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies licensed under state pharmacy law. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or medication unaccompanied by adequate directions for use. The labeling of the drug may not be in English and therefore important information regarding dosage and side effects may not be available to the consumer. The drugs may not have been packaged and stored under appropriate conditions to avoid degradation. There is no assurance that these products were manufactured under current good manufacturing practice (cGMP) standards. When consumers take such unsafe or inappropriate medications, they face risks of dangerous drug interactions and other serious health consequences.

Over the last twelve to eighteen months, FDA identified a proliferation of websites that sell drugs purportedly from Canada directly to U.S. consumers. A number of these websites claim it is legal for Canadian pharmacies to sell drugs to U.S. consumers. This is false. Some websites are merely ordering services, taking orders from consumers that are then filled

by other pharmacies. In some cases, American consumers cannot be certain that the drugs they receive are actually dispensed by the person from whom they are ordered.

A number of Canadian drug websites and ordering services indicate that the Canadian drugs are dispensed pursuant to existing prescriptions that are rewritten by a Canadian doctor in order to comply with Canadian law. However, dispensing medication based on a prescription written by a physician who has not seen the patient or conducted a physical exam is contrary to medical practice standards. In addition, the Canadian Medical Association has stated that under the Canadian Code of Ethics, physicians have a responsibility to do a patient history, conduct a physical exam and discuss the risks and benefits of the medication with the patient. In many cases, these activities simply do not occur.

Consumers who buy prescription drugs from foreign countries are at risk of suffering adverse events, some of which can be life threatening. These risks include potential side effects from inappropriately prescribed medications, dangerous drug interactions or side effects due to drug contamination. Patients are also at risk because there is no certainty about what they are getting when they purchase some of these drugs. Although some patients may receive genuine product, others may unknowingly buy counterfeit copies that contain inert ingredients, legitimate drugs that are outdated and have been diverted to illegitimate resellers, or dangerous sub-potent or super-potent products that were improperly manufactured. Moreover, consumers who are desperately seeking a cure for a serious medical problem may be more willing to accept a product of unknown origin.

In the case of foreign-based sources, if a consumer has an adverse drug reaction or any other problem, they have little or no recourse either because the physical location or operator of the pharmacy often is not known or the seller is beyond the consumer's reach. In addition, as a condition of doing business, many of these foreign operators require the U.S. consumer to sign a document releasing the operator from all potential liability. FDA has little or no ability to take effective action against these foreign operators to assist U.S. consumers.

In addition to these safety concerns, it is also important to point out that it is illegal, under the Federal Food, Drug, and Cosmetic (FD&C) Act, to import unapproved, misbranded, and adulterated drugs into the U.S. This includes foreign versions of U.S.-approved medications. It is also illegal for anyone other than the drug's manufacturer to re-import a prescription drug that was originally manufactured in the U.S.

UPDATE ON FDA ACTIVITIES AND NEW ACTIONS

At the April 3, 2003, hearing, we discussed our efforts to address the potential safety concerns of illegally imported prescription medicines by: 1) increasing consumer awareness of the potential risks associated with imported drugs, 2) working with the states to crack down on Internet pharmacies selling illegal products, and 3) analyzing the quality of drugs coming into the U.S. from foreign sources.

I would like to provide you with an update on our activities and some ongoing activities that were mentioned when we last testified before this subcommittee nine weeks ago.

1. Rx Depot

At the April hearing we told you about a warning letter that was issued on March 21, 2003, to a storefront operation known as Rx Depot. We commenced this action in conjunction with the Arkansas State Board of Pharmacy. Rx Depot generally obtains unapproved drugs from Canada for U.S. consumers, exposing the public to the significant potential risks associated with unregulated imported prescription medications. Rx Deport and similar companies have often stated incorrectly to consumers that FDA condones their activities and even that their prescription medications are "FDA approved." This could lead consumers to conclude mistakenly that the prescription drugs sold by the companies have the same assurance of safety as drugs actually regulated by FDA.

FDA believes that operations such as Rx Depot expose the public to significant potential risks associated with unregulated imported prescription medicines. FDA's "warning letter" notified the firm that the Agency considers the firm's operations to be a risk to the public health, and in clear violation of the drug safety laws that protect Americans from unsafe drugs. Although FDA addressed its "warning letter" to the Rx Depot in Arkansas, FDA also sent a letter to the President of Rx Depot, in Tulsa, Oklahoma. The "warning letter" applies to all locations of Rx Depot and its affiliates. While Rx Depot responded to FDA's "warning letter," that response was inadequate.

We issued our "warning letter" in conjunction with action by the Arkansas State Board of Pharmacy. The Arkansas State Board of Pharmacy issued its own letter to the firm on the same day as our "warning letter" instructing the firm to cease violating state law immediately.

2. Additional Information on Counterfeit Drugs

On April 22, 2003, the Pharmaceutical Research and Manufacturers of America (PhRMA) announced the adoption of a voluntary program to report counterfeit drugs to FDA. PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies. The announcement affirmed that the information provided by PhRMA members under this program will assist FDA in carrying out its responsibilities to protect the safety and integrity of the nation's drug supply by quickly and effectively removing counterfeit drugs from the marketplace.

Under the voluntary program, PhRMA member companies agree to notify FDA's Office of Criminal Investigations within five working days of determining that there is a reasonable basis to believe that a product has been counterfeited. The program also applies to counterfeits discovered in foreign countries if there is clear evidence that the counterfeits are intended for distribution in the U.S. The reporting program went into effect on May 1, 2003.

In an April 22, 2003, press release, FDA praised PhRMA's commitment to actively help FDA identify and remove counterfeit drugs from the U.S. market. "This action adds to our tools for protecting the public against counterfeit drugs," said FDA Commissioner, Mark B. McClellan, M.D., Ph.D. "The FDA works with local, state, and Federal law enforcement authorities to protect Americans from the health risks of bogus drugs. PhRMA's members already assist in these efforts by actively investigating credible reports about the distribution

of counterfeit drugs. This formal collaborative agreement will strengthen the FDA's ability to assure the safety and effectiveness of drugs used by Americans."

FDA supports the activities of the manufacturers of legitimate drugs to identify counterfeit products and inform the public about counterfeits. The Agency is committed to rooting out counterfeiting activity and alerting the public to the existence of counterfeit product.

3. NABP Annual Meeting

On May 7, 2003, FDA officials spoke at the National Association of Boards of Pharmacy (NABP) Annual Meeting in Philadelphia, Pennsylvania. FDA reiterated the message it delivered in the call it hosted in February 2003 with 38 state boards of pharmacy, other state regulatory agencies and consumer groups. FDA is working with states to address concerns regarding the importation of foreign prescription drugs. The Agency is actively engaged with a number of states in jointly pursuing illegal Internet prescription drug sites. FDA continues to expand its cooperative activities with states in order to effectively address the many challenges of prescription drugs sales via the Internet.

4. Statement by U.S. and Canada Pharmacy Groups

On May 7, 2003, the NABP and the Canadian National Association of Pharmacy Regulatory Authorities endorsed a statement opposing illegal importation of prescription drugs. In the statement, the two groups state that they are mutually committed to working together to support the individual members of their organizations as they fulfill their regulatory mandates. The Canadian and American regulatory bodies are calling on law enforcement agencies to promote compliance with Federal, state, and provincial pharmacy laws and standards of Canada and the U.S. in their respective jurisdictions. This is the first time that the regulatory

authorities of the two nations have jointly responded to the growing practice of importation of drugs into the U.S. from Canada.

On May 13, 2003, 44 U.S. pharmacy groups joined forces with the Canadian Pharmacists Association (CPhA) to endorse a statement opposing illegal importation of prescription drugs. These groups include many of the state boards of pharmacy and academic institutions schools of pharmacy.

5. Other actions with states

FDA sent a letter to the Executive Director and General Counsel of the West Virginia Board of Pharmacy expressing support for the May 13, 2003, "warning letter" issued to Discount Prescription Center of Fairmont, West Virginia, telling that firm to cease violating the law. Discount Prescription Center solicits patients and arranged for a Canadian pharmacy to dispense and ship prescription drugs to the patients. FDA considers the firm's operations to be illegal and a risk to public health. FDA expressed support for the Board's effort to stop this firm from violating the law. In addition, FDA offered assistance in any future efforts by the Board to stop similar firms.

FDA stated in the letter that we believe that operations such as Discount Prescription Center expose the public to the significant potential risks associated with unregulated imported prescription medications.

We have been working closely with our partners in the states such as West Virginia on this issue, and we intend to continue working closely with the states in support of our mutual efforts to protect the public health by curtailing illegal and potentially dangerous operations.

6. Lipitor investigation

On May 23, 2003, FDA issued an alert on counterfeit Lipitor. The alert warned health care providers and others that three lots of counterfeit Lipitor represent a potentially significant risk to consumers. One in five people have high cholesterol that may lead to cardiovascular disease, such as heart disease and stroke. According to the American Heart Association (AHA), every 33 second, someone in the U.S. dies due to cardiovascular disease. (Source: AHA 2002 Heart and Stroke Statistical Update) Lipitor is the number one prescribed cholesterol-lowering medication, and is currently used by more than 18 million people. Lipitor is proven to lower total cholesterol and decrease the risk of developing cardiovascular disease. FDA investigators have aggressively pursued a variety of leads all along the supply and distribution chain in an effort to identify the source of this counterfeit activity.

In conjunction with the manufacturer of this product, FDA published a list of lot numbers to identify the counterfeit product. We urged health care providers and patients alike to check the packaging very carefully before using this product. Patients who have any of the product (labeled as "Repackaged by MED-PRO, Inc.") with the specified lot numbers were told not to consume it, and to return the product to their pharmacies. On June 3, 2003, FDA announced that its continuing investigation of counterfeit Lipitor identified additional counterfeit quantities of the cholesterol-lowering product. The investigation is ongoing.

FDA's advice to health care providers and consumers remained the same as when the Agency issued its original *alert on counterfeit Lipitor*. They should check the packaging very carefully before using Lipitor. Patients who have any of the product with any of the lot numbers we identified should not take it, and they should return the product to their pharmacies. We want to reemphasize this warning today.

As part of the FDA's ongoing efforts to investigate and respond to unscrupulous counterfeiting activities, FDA's Office of Criminal Investigations is investigating this case of counterfeit Lipitor in carrying out its public health mission. FDA regularly conducts investigations and testing to identify and remove from market products that are counterfeit, have been tampered with, or are otherwise unsuitable.

FDA is working closely with the individual states and with health professionals, particularly pharmacists and pharmacy associations, to alert them to this counterfeit product. Many patients taking Lipitor do not receive it in the 90-tablet bottles, but in smaller quantities from their pharmacists. Patients who are not sure whether they have the tainted product were instructed to check with their pharmacist.

FDA will continue to work closely with the manufacturer of Lipitor, Pfizer, Inc., on this counterfeiting problem. FDA supports the activities of legitimate manufacturers to inform the public about counterfeit products and how to identify them. In addition the manufacturer of Liptor, Pfizer, issued their own press release supporting the vigorous enforcement of the

law to protect patient safety. The company continues to work closely with the FDA and other regulatory authorities to help prevent the importation of counterfeit medicines.

7. CPhA public statement

On May 31, 2003, the CPhA Board of Directors approved a public statement on international prescription services. The statement emphasizes that there is potential for the existing public protection safety net to be bypassed by illegitimate operators or unaccredited pharmacies, or by licensed pharmacies that do not comply with practice standards and regulation. Such practices can undermine the drug regulatory systems established to protect consumers and could expose the public to improper prescribing, monitoring or dispensing of pharmaceuticals, or to harmful or ineffective drugs.

In part, this statement criticizes international prescription services provided to residents of foreign countries. Some of the key elements of their public statement emphasize that:

1. A relationship between the patient and pharmacist is essential for medication management and to ensure that patients understand how to use their medications safely and effectively.

2. Face-to-face communication between patients and pharmacists builds a relationship that is critical to the optimal management of drug therapy and is a key element of the expanded role of pharmacists on the primary health care team.

3. All pharmacies operating in Canada, including those that provide distance dispensing or offer prescription drug services over the Internet, must comply with Federal/provincial/territorial legal and regulatory requirements as well as meet established standards of practice for patient care and dispensing.

4. CPhA opposes international prescription services where the patient does not have a relationship with the pharmacist and the prescriber. CPhA also opposes international prescription services if such services violate laws in the jurisdiction that the patient resides in.

CONCLUSION

FDA is working to address its continued safety concern about increased importation of prescription drugs. However, despite continued efforts to identify ways to assure the safety of imported drugs, FDA for many years has consistently stated that it cannot assure the safety of prescription drugs that are obtained outside its comprehensive regulatory system.

We appreciate the subcommittee's interest in assuring that the American public has access to safe and affordable medicines and we look forward to working with you in furtherance of this goal. Thank you for the opportunity to update you on events and activities since our last hearing. I will be happy to answer any questions you may have.

Mr. BURTON. Let me make a few comments and I will yield to my colleagues.

The IRM report in 1999 said there is between 44,000 and 98,000 deaths in the United States due to errors in this country. You have talked about a lot of these things and I appreciate your going to all the trouble you have to bring in these examples. We asked you to bring a list of adverse events where people were hurt.

I would like to ask you, were any of these products and these violations reported to the Canadian or the provincial government in charge?

Mr. HUBBARD. We certainly have communicated at the highest levels in the Canadian Government including the head of the Canadian FDA about our concerns. We have not shown them these actual examples.

Mr. BURTON. You saw the pharmacist from Canada and he clearly said that they are getting a stamp of approval, they are going to be regulating themselves, they are going to make sure that only those pharmacies there with the stamp of approval will be the ones we would want to buy Internet products from. That seems to me, along with the packaging which would prove they were sealed properly and they couldn't be counterfeited, would eliminate almost every one of the problems you pointed out.

As far as adverse events where people have been harmed by Canadian drugs coming across the border, did you bring any examples for us?

Mr. HUBBARD. We have very little evidence. We only have anecdotes as your earlier report mentioned, for instance, a lady with breast cancer who bought Taxol from Canada and got something else and a few other isolated examples. We believe people would tend not to report these sort of adverse events, plus the system is not set up to track adverse events from drugs like this.

The IOM report you referred to about hospital dispensing errors where the doctor prescribes one drug and the nurse mistakenly gives say an infant an adult dose, those are principally based medical errors, not the kinds of errors you see from people buying drugs this way.

Mr. BURTON. Obviously mistakes are made here in the United States, that is why 44,000 and 98,000 people got the wrong pharmaceutical product and died. You can't give me one example where somebody other than this one lady that got the wrong prescription has been hurt by getting pharmaceutical products from Canada.

That one required refrigeration and it shouldn't have been sent and some of them got an oversupply and they may not have come from a registered, approved pharmacy in Canada. That is why that should be policed by not only the Canadian Government, which they are doing, but as well as the FDA.

The problem is as this older lady said she was willing to go to jail to get her pharmaceutical products from Canada because they cost so much less, the same product, the same pharmaceutical product in Canada in many cases costs 10 times, 5 times, twice as much here in the States as it does up there. Why should Americans bear the brunt of these additional costs here in this country when in Canada it costs so much less?

The argument was made, what was the one in the paper yesterday that Representative Gutknecht talked about, was that Taxol. What was the name of the pharmaceutical company?

Mr. GUTKNECHT. Smith-Kline-Beecham.

Mr. BURTON. Smith-Kline-Beecham had a patent on Taxol and made $9 billion last year?

Mr. GUTKNECHT. Since the drug was introduced.

Mr. BURTON. Since the drug was introduced, they have made $9 billion. Almost all of the research and development was paid for by the Federal Government of the United States which was $484 million. We gave them the patent and they were supposed to give us royalties. They made $9 billion and the Federal Government got $35 million back and Medicare paid $687 million for that product which we paid for as taxpayers to be developed. Yet it could have been purchased for a lot less in Canada if it was for sale up there.

These are things that really concern us and the American people should not be bearing the brunt of that. I won't belabor that point any further.

The chairman of the full committee is here, Chairman Davis, and he has a statement he would like to make. Then I will start yielding to my colleagues for questions.

Chairman TOM DAVIS. Thank you, Mr. Chairman.

I want to thank our witnesses for being here today and say to the chairman, I think we all want more affordable prescription drugs. That is the purpose of the hearing. Obviously it is more complicated than meets the eye. I think you have just shown some of the pitfalls we face when we just approach this thing willy-nilly.

U.S. consumers experience a high level of confidence when we purchase prescription drugs with our country, thanks to the efforts of the FDA. The FDA will only approve a prescription drug after a thorough investigation into the safety and effectiveness of the medication which includes inspecting the manufacturer's facilities.

Proponents of importation from Canada argue that Health Canada, the Canadian version of the FDA, has health and safety standards similar to those in the United States. However, the FDA which has the responsibility and expertise could not conclude that imported drugs would be safe. In fact, the HHS under the Clinton and Bush administrations declined to certify that drugs from Canada are safe under the Meds Act passed in 2000.

While importation supporters focus on the lack of evidence that importation has contributed to the deaths of American consumers, there are important risks we have to address as we evaluate the issue of importation. My colleagues have highlighted a growing trend of seniors traveling over the border to Canada in order to purchase prescription drug medications from Canadian pharmacies but the bulk of American seniors like those in my districts, don't have the option of traveling to Canada in person to purchase prescription drugs. This has led to the use of Canadian Internet pharmacy sites. Seniors who may not be computer savvy have children and grandchildren to assist in utilizing these Internet sites.

There are multiple challenges to ensuring prescription drug purchase over the Internet from allegedly Canadian sources via the Internet are safe. A patient loses the safeguards of receiving a prescription for an FDA-approved source.

Some Canadian pharmacy Web sites advertise they sell FDA-approved drugs and that they are FDA-approved pharmacies but these statements are false. The FDA does not approve foreign pharmacy and doesn't approve drugs that are resold or not manufactured for use in the United States.

Additionally, not all Canadian pharmacy Web sites are actual pharmacies. Some of these Web sites are simply prescription drug warehouses with no affiliation to a Canadian pharmacy or doctor.

When purchasing prescription drug medication from a Canadian Web site, an American consumer has no guarantee that he or she is actually receiving medication from the address provided. The FDA has uncovered Web sites that provide consumers with a Canadian address but are actually located in foreign countries. Unknowingly purchasing drugs from countries other than Canada takes even Health Canada safety guarantees completely out of the picture.

Consumers may receive counterfeit or adulterated medications from countries with little or no drug guidelines. The effectiveness and safety of a drug can be compromised from purchase from Canadian pharmacy Web sites. Drugs like food have expiration dates. In addition, the effectiveness of certain medications can be reduced when exposed to heat or cold or in shipping.

In U.S. pharmacies, consumers are provided with a medication label that lists specific warnings as to how to take and the possible side effects of the medication. Prescription drugs purchased from Canadian Internet sites may arrive to the consumer in the manufacturer's original container as we say, particularly if they are shipped from a drug warehouse. This poses a significant risk to consumers who may not be privy to a drug's side effects or interaction with other medications.

In addition to the testimony of Mr. Hubbard of the FDA, I would be interested to hear from officials with the DEA and Customs. I would like a better understanding as to how the FDA, Customs and DEA would address the problems of adulterated, counterfeited or mislabeled drugs that might enter the United States through reimportation.

Do these law enforcement agencies have the proper tools to resolve the issues that reimportation may present to American consumers? Congress must have a complete record on these issues to ensure drug safety.

We should also be concerned about both the safety of drugs imported into this country and the impact on drug development that such importation might have. Importing price controls of lower Canadian drugs may be beneficial to consumers in the short run and in fact, buy today's medications cheaper but we may not see tomorrow's medications developed that offer further cures. We have to be cognizant of that balance.

Competition from the lower prices in Canada that reduce investment in drug companies could diminish drug development in this country which is also a large employer and has in many cases pro-

duced some of the miracle drugs we see sold today. It could delay some drugs from coming to the market permanently.

The American Pharmacists Association has a statement I would like to enter into the record along with other related materials.

[The prepared statement of Chairman Tom Davis follows:]

Statement of Chairman Tom Davis
Government Reform Human Rights and Wellness Subcommittee Hearing
"Canadian Prescription Drug Importation: Is there a Safety Issue?"
June 12, 2003

Mr. Chairman, thank you very much for holding this hearing. It is important that we hold an open and frank discussion on providing safe and affordable medication to American consumers and examine the whether importing drugs from Canada is a viable option for achieving these goals.

United States consumers experience a high level of confidence when purchasing prescription drugs with our country thanks to the efforts of the FDA. The FDA will only approve a prescription drug after a thorough investigation into the safety and effectiveness of the medication, which includes inspecting the manufacturer's facilities.

Proponents of importation from Canada argue that Health Canada, the Canadian version of the FDA, has health and safety standards similar to those in the United States. However, the FDA, which has the responsibility and expertise, could not conclude that imported drugs would be safe. In fact, the HHS under the Clinton and Bush Administrations has declined to certify that drugs from Canada are safe under the MEDS Act, which was passed in 2000.

While importation supporters focus on the lack of evidence that importation has contributed to the deaths of American consumers, there are important risks we must address as we evaluate the issue of importation. My colleagues have highlighted a growing trend of seniors traveling over the border to Canada in order to purchase prescription medications from Canadian pharmacies. However, the bulk of American seniors do not have the option of traveling to Canada in person to purchase prescription drugs. This has led to the use of Canadian internet pharmacy sites. Seniors who may not be computer savvy have children and grandchildren to assist them in utilizing these internet sites.

There are multiple challenges to ensuring that prescription drugs purchased over the internet from allegedly Canadian sources via the internet are safe. A patient loses the safeguards of receiving a prescription for an FDA-approved drug from a licensed doctor and having that prescription filled from a licensed pharmacist. Some Canadian pharmacy

websites advertise that they sell FDA-approved drugs or that they are FDA-approved pharmacies. These statements are false – the FDA does not approve foreign pharmacies and does not approve drugs that are resold or not manufactured for use in the United States. Additionally, not all Canadian pharmacy websites are actual pharmacies. Some of these websites are prescription drug warehouses, with no affiliation to a Canadian pharmacy or doctor

When purchasing prescription medication from a Canadian website, an American consumer has no guarantee that he or she is actually receiving medication from the address provided. The FDA has uncovered websites that provide consumers with a Canadian address, but are actually located in foreign countries. Unknowingly purchasing drugs from countries other than Canada takes even Health Canada's safety guarantees completely out of the picture. Consumers may receive counterfeit or adulterated medications from countries with little to no drug guidelines.

The effectiveness and safety of a drug can be compromised when purchased from Canadian pharmacy websites. Drugs, like food, have expiration dates. In addition, the effectiveness of certain medications can be reduced when exposed to heat or cold during shipping. In United States pharmacies, consumers are provided with a medication bottle that lists specific warnings as to how to take and the possible side effects of the medication. Prescription drugs purchased from Canadian internet sites may arrive to the consumer in the manufacturer's original container, particularly if they are shipped from a drug warehouse. This poses a significant risk to consumers who may not be privy to a drug's side effects or interactions with other medications.

In addition to the testimony of Mr. Hubbard with the FDA, I would be interested to hear from officials with the DEA and Customs. I would like a better understanding as to how the FDA, Customs, and DEA, would address the problems of adulterated, counterfeited, or mislabeled drugs that might enter the United States through reimportation. Do these law enforcement agencies have the proper tools to resolve the issues that reimportation may present to American consumers? Congress must have a complete record on these issues to ensure drug safety.

We should be concerned about both the safety of drugs imported into this country and the impact on drug development that such importation might have. Importing price

controls of lower cost Canadian drugs may be beneficial to consumers in the short run. But competition from the lower prices in Canada that reduce investment in drug companies may diminish drug development in this country, delaying some drugs from coming to the market, in some cases permanently.

The American Pharmacists Association has a statement that I would like to enter into the record, along with other related materials. APhA has significant concerns regarding the affect importation would have on patient safety and care.

In addition, I have two letters I would like entered into the record. The first is from Dr. Anthony Lordon, a Canadian physician who shares his views on how Canada's price control on prescription drugs has negatively affected elderly Canadian patients by delaying the introduction of new drugs and restricting patients' choice of prescription medicines.

The second letter is from Better Pharmacare Coalition located in British Columbia. Better Pharmacare Coalition is a collection of national and provincial health-professional and consumer advocacy groups. The Coalition discusses how the Canadian health system has placed numerous limits on allowing patients access to new medications in a timely manner.

Making prescription drugs safe and affordable for Americans is an important issue facing Congress. Providing a prescription drug benefit through Medicare will enable seniors to buy safe and effective drugs in the United States at affordable prices. The buying power that will result from such a benefit will also reduce the costs of drugs in America, ensuring that the high costs of drugs is not simply shifted to the taxpayer. As a result, seniors will no longer need to seek lower cost drugs from Canada at potentially greater risk to their health and safety.

I look forward to the witnesses' testimony.

Testimony
of the

American Pharmacists Association

On Canadian Prescription Drug Importation: Is There a Safety Issue?

Submitted to the Government Reform Committee Human Rights & Wellness Subcommittee

June 12, 2003

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Testimony of the American Pharmacists Association

Submitted to the Committee on Government Reform
Subcommittee on Human Rights and Wellness

On Canadian Prescription Drug Importation: Is There a Safety Issue?

June 12, 2003

The American Pharmacists Association (APhA) appreciates the opportunity to provide our perspective on the critically important topic of the patient safety issues that arise with illegal, personal importation of prescription medications. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 50,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, and pharmacy technicians. APhA is the oldest and largest national association of pharmacists in the U.S.

Prescription medications have proven to be a valuable tool in our health care system, but that's only true when their safety and efficacy can be protected. Thus, it is critically important to maintain the safety net that exists to maintain the integrity of our medication supply — to assure that patients get what "the doctor ordered". This statement addresses patient safety issues associated with personal importation of medications.

Patient Safety

Patient safety is the one overriding reason for the myriad of laws and regulations that help assure that Americans receive safe and effective medications and represent "what the doctor ordered" The current U.S. regulations were put in place after several critical incidents resulted in patient harm. When patients were harmed by contaminated or ineffective medications, Congress took action to protect patients who place their trust with the health care system, trusting that the medications will do what's expected and nothing that's unexpected. Those actions included requiring evidence of safety and effectiveness, controlling the production and distribution of products, and other efforts to limit the presence of counterfeit and contaminated medications. The current closed system protects American consumers from unsafe products.

In the U.S., the manufacturing, distributing, and dispensing of all prescription medications are subject to extensive regulation and control. Consumers may not understand the risks they face when they receive a prescription medication from outside of the U.S. system. Purchasing prescription medications outside of the US creates risks for patients that they may be receiving a contaminated product, an inactive product, a product not recognizable by American pharmacists or doctors (possibly different strengths or name), a product that is not manufactured, distributed or regulated in the country where they are purchasing the drug, or simply, the wrong product. And once a product leaves the U.S. regulatory system, the patient loses access to legal recourse if they are harmed by the product.

Opening the Closed System – Beyond Canada

The idea of a opening our current "closed" system is critical to this discussion. It's true that some countries, such as Canada, may have a system in place to regulate medications that appears to be as strong as the system in the U.S. However, opening the door to Canada opens the door — period. With that open door, it's possible for unscrupulous providers from countries without strong regulatory systems to provide drugs to U.S. consumers.

Additionally, and in some ways more frightening, is the issue of counterfeit medications. Even with the comprehensive U.S. system, counterfeit products have penetrated our system. In February, 2003, 11,000 boxes of counterfeit Epogen and Procrit products (anemia drugs often given to cancer, AIDS and kidney failure patients) were found in the U.S. More recently (May, 2003) the FDA announced the a manufacturer had voluntarily recalled three lots of Lipitor (cholesterol lowering medication). The FDA's continuing investigation found two additional lots of the same drug.

The risk of counterfeit products is real. Opening our closed system creates gaps in our current safety net for patients. By their very nature, medications are highly susceptible to counterfeiting: the products are expensive, necessary for our health, and it is difficult, if not impossible, to detect a fake product just by looking at it. For patients who depend on their medications to keep them alive, this is a lethal threat.

Impact on Patient Care

Not only do imported drugs directly impact patient health, but imported drugs and their questionable quality create a situation for health care providers that's best described as "working in the dark". Physicians and pharmacists have no way of knowing what a patient is taking because of the differences in names and physical appearances of foreign drugs, even those from Canada or Europe. Pharmacists' ability to identify drug-to-drug interactions is hindered to the point of nonexistence without knowing the drug's content and strength. Consider the scenario that a patient is in need of an "acute" (immediate) prescription. If that patient has been getting their medications from a different source, the pharmacist is unable to determine whether the acute prescription will create an adverse drug reaction, is a duplicate of a current prescription, or whether it's mere presence suggests other medical problems for the patient that should be followed-up with the patient's physicians. This "blindness" compromises the ability of physicians to care for their patients and the ability of pharmacists to ensure that medication therapy of their patients is safe and effective.

Allowing patients to purchase drugs from someone other than their local, U.S. pharmacist circumvents one of the most important interactions for a patient — direct contact with a prescriber. This practice bypasses yet another part of the U.S.'s safety net. Medications have become a critical aspect of patient care. But prescription medications are only safe and effective when patients understand how to use them appropriately, and for what side effects they should watch. Direct interaction between the prescribers, pharmacists and patients is critical to ensuring appropriate medication use. To remove such a basic component of our health care delivery

system's safety net seems diametrically opposed to the "pro patient safety" environment we are all working to achieve.

Addressing Seniors Access to Prescription Medications

Clearly, as the profession who makes providing safe and effective medication therapy their priority on a daily basis, pharmacists are supportive of efforts to enhance patients' access to prescription medications. But undercutting the regulatory system that tries to assure patients receive safe and effective medications is not the way to address the access problem. Importation may offer short-term savings, but creates the potential for long-term costs in patient harm.

APhA recommends direct, immediate action to help patients access medication through the U.S. healthcare system. Our country needs a pharmacy benefit in Medicare that provides access to the critical medications patients need every day. In the interim, consumers should work with their pharmacist and prescriber before making any changes in their drug therapy regimen. Generic medications are cost-effective alternatives to brand-name products — even brand-name products imported from other countries — and pharmacists can provide guidance on using generic medications as well as accessing assistance programs. The most expensive medication is the one that doesn't work — or worse, causes harm. Patients should use pharmacists as a valuable resource to make the best use of their medications and to get the most value from their money.

Conclusion

Importation creates safety hazards by circumventing the current medication safety safety net. We should allow the FDA to continue its work to keep patients safe by critically reviewing manufacturing and distribution practices that assure medications that American patients receive are safe, effective, and exactly "what the doctor ordered".

APhA thanks you for the opportunity to provide comments on this important issue. We look forward to working with the Committee to develop a safe and effective system of providing prescription medications to all Americans.

Chairman TOM DAVIS. The American Pharmacists Association has significant concerns regarding the effect importation would have on patient safety and care.

In addition, I have two letters I would like to enter into the record. The first is from Dr. Anthony Lorton, a Canadian physician who shares his views on how Canada's price control on prescription drugs has negatively effected elderly Canadian patients by delaying the introduction of new drugs and restricting patient's choices on prescription medicines.

The second letter is from Better Pharmacare Coalition located in British Columbia, a collection of national and provincial health professional and consumer advocacy groups. The Coalition discusses how the Canadian health system has placed numerous limits on allowing patients access to new medications in a timely manner.

[The information referred to follows:]

Dr. J Anthony Lordon

Congressman Tom Davis
Chairman
Committee on Government Reform
2157 Rayburn House Office Building
Washington, D.C. 20515

Dear Congressman Davis:

I understand that one of your subcommittees is considering holding a hearing on the issue of importation of drugs from Canada to patients in the United States. I would like to offer you my perspective on the Canadian health system and how it denies patients in Canada timely access to innovative medicines.

American seniors should be wary of those that think that issues of prescription drug access can be resolved by re-importing price-controlled drugs from Canada. A more prudent approach is to insure that seniors have access to the best new medicines through appropriate drug plan coverage. Instead of Canadian-style price controls, Americans would do better to have a Medicare prescription drug benefit that provides both coverage and choice: one that Canadian seniors would envy.

Pharmaceutical price controls in Canada attract a lot of attention among the media and policy makers in America. Years ago, Canada had a health care system that was the envy of the world. Unfortunately years of cost controls and rationing have taken their toll.

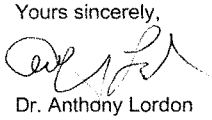
As a Canadian physician with a family medicine practice in Saint John, New Brunswick, I treat a number of elderly patients. On a daily basis, I deal with the impacts that government cost controls, and restrictive drug plans have on my ability to prescribe the best possible treatments for my patients.

In Canada, price controls mean that the introduction of new drugs that treat illness and disease more effectively and with fewer side-affects are delayed, sometimes for years. Rationing, cost controls and expenditure caps in Canada are further exacerbated by the "one size fits all" approach that does not allow patients the choice to access services outside of the government-run system in Canada.

Price controls provide no limits on a senior's financial exposure to drug or other treatment costs, should they be faced with a serious illness. Proper health plan coverage, which includes a prescription drug benefit, protects seniors from potentially devastating drug costs while at the same time reducing prescription drug prices through negotiated discounts. Perhaps, most importantly, proper drug plan coverage allows patients and physicians to make choices that result in the most appropriate treatment.

I would appreciate it if you would include this letter in the hearing proceedings.

Yours sincerely,



Dr. Anthony Lordon

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Better Pharmacare
Coalition
#35 Parkgrove Crescent, Delta BC V4L 2J8

June 11, 2003

Congressman Tom Davis
Chairman
Committee on Government Reform
2157 Rayburn House Office Building
Washington, D.C. 20515

Dear Congressman Davis:

I have heard that a subcommittee you are involved with may be examining the issue of importing pharmaceutical medications from Canada to patients in the United States. It may be helpful to you and others involved in that process to have our thoughts and observations on the Canadian health system and how it negatively affects Canadian patients in terms of gaining timely access to new and existing medicines.

The Better Pharmacare Coalition is a collection of national and provincial health-professional and consumer advocacy groups. A complete list of the member organizations that make up the coalition appears at the end of this letter.

The common denominator that brings us together as a coalition is our belief in access to necessary medications. It is vital that the patients and consumers we represent get the medications they need. Their quality of life is tied to those medications; in some cases their lives depend on it.

In British Columbia, as in all provinces in Canada, citizens are eligible to have all or a portion of their pharmaceutical drugs paid for as part of the overall health care system. In BC the program is called Pharmacare. The system however is by no means open ended in term of access to medications. The government decides which drugs will be covered for payment and under what conditions. If they deem a certain drug not worthy of coverage, then patients requiring that medication must fully pay for it themselves.

The access limitations imposed by this system can be onerous for both patients and the physicians who treat them. For example, under a scheme in British Columbia known as the Reference Drug Program (RDP[1]), patients facing some illnesses must "qualify" for certain drugs by first failing on

[1] The RDP currently applies to five classes of drugs: Histamine 2 receptor Blockers (H2 Blockers), Non-Steroidal Anti-inflammatory drugs (NSAIDS), Nitrates, Angiotensin Converting Enzyme Inhibitors (ACE inhibitors), and Dihydropyridine Calcium Channel Blockers (Dihydropyridine CCBs).

older, usually cheaper medications. Doctors have described such requirements as a dangerous practice that threatens the health of patients.

Our coalition, along with doctors, pharmacists and an array of other organizations are frustrated by such policies which restrict patient access to medication. Keeping patients from getting the medications they need is not only detrimental to their health but also threatens the very integrity of our entire health care system especially if RDP-type practices are allowed to expand into other illness categories.

Once governments get involved in funding the delivery of a service, it seems they quickly identify ways to control and restrict that service. The Reference Drug Program is not the only means by which the government, through Pharmacare, controls and restricts patient access to medications. Therapeutic substitution is a popular practice currently being tested by Pharmacare. We have written to the Minster of Health and to the Premier on this subject as follows:

"Therapeutic substitution is the practice of substituting one drug for another, even though both drugs are chemically different. The health consequences of imposing such a practice can be hazardous. It may make sense to some accountants, but it doesn't make sense to doctors, pharmacists and certainly not to patients. Therapeutic substitution will diminish the overall quality of health care in BC. By embracing therapeutic substitution, the government is promoting inequality amongst the population. In terms of access to medication, people who have money are less impacted by reference-based pricing and other forms of therapeutic substitution."

"Therapeutic substitution aims for mediocrity, nothing more than that. It is embarrassing to know that BC has chosen to shoot for such a low level of achievement when it comes to providing patient access to medication. It certainly doesn't qualify as "improving the quality of health care in BC." It is the practice of assembly-line medicine. It treats patients as being all the same, regardless of their unique and often conflicting health circumstances."

While we, along with others, may have been successful in helping to slow (hopefully halt) the government's plans to expand the Reference Drug Program and further the practice of wide-spread therapeutic substitution, they are relentless in coming up with new ways to restrict patient access to new medications. Recently they moved to de-list certain drug products altogether. On the surface the delistings didn't appear to be a big deal. It turned out to be otherwise. Here's what happened.

Among other things, Pharmacare delisted four products used to treat people who suffer severe nasal related allergies. They did so in a most unsatisfactory way. The drugs that were delisted were all relatively new drugs. Coverage was maintained for three other generic (older) drugs. What caused us concern was that the generic drugs that remain covered were not generic copies of the brand name drugs delisted. They are completely different drugs.

The bottom line for patients is that they and their doctors are no longer able to choose those delisted medications regardless of their medical benefit, unless the patient is willing and able to pay the full cost of those medications. The delistings compromise the individual nature of the doctor/patient relationship by compelling patients to switch to a different medicine that does not have an equivalent therapeutic value in treating their ailment.

I began this letter by offering to give you some perspective on how the Canadian health system affects patients here in Canada in terms of timely access to new medicines. I have touched briefly but on three ways in which Pharmacare in British Columbia does that – RDP, therapeutic substitution and product delistings. Our system is far from perfect. Our Coalition, along with Physicians and Pharmacists will remain diligent in our effort make improvements on behalf the patients and families we represent.

Please feel free to include this letter as part of any formal hearing proceedings you may be undertaking.

Yours sincerely,

BETTER PHARMACARE COALITION

Brian Battison
Coordinator

Members – Better Pharmacare Coalition

The Arthritis Society – a Canada-wide network of health care professionals and volunteers that advocates on behalf of the interests of people affected by arthritis, including quality of care issues.

BC Lung Association – plays a major role in the fight against lung disease and respiratory illness - ranging from lung cancer, asthma, emphysema, tuberculosis, and occupational health disease.

CARP – Canada's Association for the 50+ – a national non-profit organization with over 300,000 members, 50 years and older, retired or not retired. CARP has over 35,000 members in British Columbia.

Parkinson Society of British Columbia– provides information and support to patients, family members and health care professionals in the province.

The Business and Professional Women's Clubs of BC & Yukon (BPWC) – part of a national network formed in 1929, which amongst other things, is dedicated to the improvement of economic, employment and social conditions for women.

The Federation of Medical Women of Canada – a national organization of women doctors dedicated to the professional advancement of women in medicine and the promotion of women's health issues.

Arthritis Consumers Experts (ACE) – is a national organization that advocates on behalf of Canadians suffering from Arthritis.

BC Schizophrenia Society (BCSS) – The British Columbia Schizophrenia Society (BCSS) is a non-profit organization founded in 1982. BCSS has 34 Branches, 14 Regional Coordinators, 3 Program Coordinators and over 1600 members who are dedicated to supporting each other, educating the public, raising funds for research, and advocating for better services for people with schizophrenia and other serious and persistent mental illness.

Chairman TOM DAVIS. Making prescription drugs safe and affordable for Americans is an important issue facing Congress. I applaud the chairman for highlighting one of the aspects of that here today. This is an important issue and we need to understand all aspects of it. It is a complicated issue but I think the chairman in holding this hearing can highlight some of the issues and some of the problems we face here in America where we do seem to pay higher drug prices on balance than we see across the border.

Providing a prescription drug benefit through Medicare will enable seniors to buy safe and effective drugs in the United States at affordable prices and perhaps therein lies part of the solution. The buying power that will result from such a benefit would also reduce the cost of drugs in America ensuring that the high cost of drugs isn't simply shifted to the taxpayer. As a result, seniors will no longer need to seek lower cost drugs from Canada at a potentially greater risk to their health and safety.

Again, Mr. Chairman, thank you for holding the hearing to try to get to these questions. I think there are a lot of issues we need to understand in their entirety before we proceed but I congratulate you on that and look forward to witness testimony.

Mr. BURTON. Thank you, Mr. Chairman.

Mr. Sanders.

Mr. SANDERS. Thank you.

Let me be very blunt. Let me start off by mentioning an article that appeared in the Washington Post a little while ago, July 2002. According to the Washington Post, in July 2002, the Republican National Committee hosted a fundraiser that brought in over $30 million in one night. The chief operating officer of drug giant, GlaxoSmithKline, Robert Ingram, was the chief corporate fundraiser of the event. His firm contributed $250,000 as did the drug company's trade group, Pharma; Pfizer contributed $100,000, blah, blah, blah.

[The informatin referred to follows:]

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HEADLINE: U.S. Netted Little From Cancer Drug, GAO Reports

BYLINE: Reuters

BODY:
The U.S. government spent hundreds of millions of dollars to help develop Taxol, the best-selling cancer drug ever, but failed to get much money back on the investment, according to a government report issued yesterday.

Drugmaker Bristol-Myers Squibb earned $ 9 billion from Taxol, which has been used to treat 1 million cancer patients, but the National Institutes of Health received only $ 35 million in royalties, the General Accounting Office found.

The GAO also found that Medicare, the cash-strapped federal health insurance plan for the elderly, spent $ 687 million on Taxol for its beneficiaries over five years. That is triple what other federal programs paid for other widely used cancer drugs.

"NIH's financial benefits from the collaboration with Bristol-Myers Squibb have not been great in comparison with [Bristol-Myers Squibb's] revenue from the drug," the GAO said in its report, released by Sen. Ron Wyden (D-Ore.).

"The federal government repeatedly dropped the ball," Wyden said at a news conference.

Wyden said the government should negotiate harder to ensure that when drugs are turned over to private companies, taxpayers get more back. "I am not accusing Bristol-Myers Squibb of anything other than being very aggressive in dealing with NIH," Wyden said.

NIH does the early, riskiest research on many drugs and then turns them over to companies for further development. "I don't think that NIH feels at this point that they have any other obligation than to do the research and get the product out," Wyden said. "But you also have to be looking out for the patient and for the taxpayers."

Based on bark extract from the Pacific yew tree, Taxol was tested as part of the National Cancer Institute's natural products program.

NIH took the drug through Phase II clinical trials, the longest and riskiest part of drug development and the segment that shows whether a drug is safe and may work in people.

The GAO, the investigative arm of Congress, said NIH spent $ 484 million in research on Taxol through 2002. Under a 1991 contract called a cooperative research and development agreement, or CRADA, Bristol-Myers Squibb then took over development and marketing of the drug.

Mr. SANDERS. In the last two election cycles, the Republican Party and candidates received over $31 million in campaign contributions from the pharmaceutical manufacturers. In the last two election cycles, the chairman of the House Commerce Committee received over $125,000. In the last election cycle, the chairman of the House Ways and Means Committee received over $180,000 in campaign contributions from the pharmaceutical industry. Not to be partisan, the ranking member of the Commerce Committee received $131,000.

In other words, Mr. Chairman, this institution is afloat with money and lobbyists that come from the most powerful industry in the United States of America. Their goal is not about safety; their goal is profits, profits, profits, and paying their CEOs exorbitant compensation packages. If they were concerned about safety and the well being of the American people, they would not force a million Americans to go to Canada to buy the same prescription drug sold in this country for substantially lower prices.

Mr. Hubbard, in a very theatrical display shows us some of the problems that exist but I did not hear you say one word, Mr. Hubbard, about the senior citizens in this country who die because they cannot afford the outrageously high prices they are forced to pay. I did not hear you say one word about the thousands of senior citizens, 1 in 5 senior citizens cannot afford to purchase the medicine their doctors prescribe. They are suffering, they are dying. I didn't hear you say one word about that.

Mr. Hubbard, let me ask you this. On April 22, the FDA sent out a press release, "FDA commends drug industry commitment to report counterfeit drugs. Food and Drug Administration commends Pharma, the Nation's largest representative of the drug industry" and by the way the group which will spend $150 million to make sure Congress and State legislatures do nothing but you commend Pharma for "its commitment to actively help FDA identify and remove counterfeit drugs from the United States market."

Mr. Hubbard, you are under oath. Did you in preparation for your presentation today coordinate with the drug companies about today's hearings?

Mr. HUBBARD. No.

Mr. SANDERS. Would you tell this committee the details of any conversations you have had with representatives of the drug companies, Pharma or any other affiliated groups including the date and location of the communication whether it was in person, by phone or in writing, the people involved and the substance of the communication?

Mr. HUBBARD. I would be happy to. It has been very, very limited.

Mr. SANDERS. How limited? To whom did you talk?

Mr. HUBBARD. I had a conversation with a Pharma representative last week about some joint efforts to combat counterfeiting.

Mr. SANDERS. Would that include their help in your presentation? Did you talk to any representatives of public organizations that are trying to fight for lower prices and help people get safe medicine from Canada?

Mr. CANNON. Would the gentleman yield? Is the gentleman talking about in preparation for this hearing in both the last question and the current question?

Mr. SANDERS. We can start off with preparation for this hearing and go beyond that.

Mr. HUBBARD. Almost no contact on this hearing if that is your question.

Mr. SANDERS. What does almost mean?

Mr. HUBBARD. Glaxo was nice enough yesterday to e-mail me their testimony for today which I have not read but I do have a copy somewhere in my brief case. I believe that was pretty much the limit of that.

Mr. SANDERS. Did you have any discussions with representatives of the drug industry?

Mr. HUBBARD. Not in preparation for this hearing, no.

Mr. SANDERS. When is the last time you spoke to representatives of the drug industry?

Mr. HUBBARD. I spoke to a Pharma representative last week about joint efforts with them and other groups on combating counterfeiting.

Mr. SANDERS. Which includes very much the same material that your talking about today?

Mr. HUBBARD. It is not really this issue.

Mr. SANDERS. It sounds to me like it is this issue.

Mr. HUBBARD. It is related because counterfeiting is a related issue.

Mr. SANDERS. Let me ask you this. Are you aware of any communications between other FDA personnel, the Department of HHS or any other member of the Bush administration with representatives of the pharmaceutical industry?

Mr. HUBBARD. I have no knowledge of any such contact. I would not likely have such knowledge.

Mr. SANDERS. Have you had any communications with anyone else in the FDA, the Department of HHS or any other department or agency about the subject of reimportation of prescription drugs?

Mr. HUBBARD. Certainly in the past we have had conversations with Secretary Thompson and his staff and before that with Secretary Shalala and her staff.

Mr. SANDERS. I am out of time and I yield back.

Mr. BURTON. Thank you, Mr. Sanders.

I think Mr. Gutknecht was next.

Mr. GUTKNECHT. Thank you. I really appreciate this hearing. Mr. Hubbard, I appreciate your being here.

We may differ on our view of this but we do agree that we do want safety for American consumers.

With regard to the large stack of drugs, is it not possible that the individual who ordered those drugs was ordering on behalf of other people because earlier we had an 84 year old young lady who described herself as a drug runner and who regularly goes to Canada to help other seniors get drugs. I would not be surprised if from time to time she brings back more than a month's supply. Would that surprise you?

Mr. HUBBARD. No. The vast majority of these imports are small shipments such as this obviously intended for one patient. This was apparently intended for one patient.

Mr. GUTKNECHT. But we don't know and the fact of the matter is we know it was addressed to one individual but may or may not have been for one individual.

I want to come back to the basic issue of safety. It is the Food and Drug Administration, is it not?

Mr. HUBBARD. Yes, it is.

Mr. GUTKNECHT. So you are also responsible for the food supply of all the foods that come into the United States. Are you aware of how much food comes into the United States every day?

Mr. HUBBARD. Quite a bit.

Mr. GUTKNECHT. What do we do about that?

Mr. HUBBARD. There is an entirely different statutory structure over food but we do have authority to examine all imported food.

Mr. GUTKNECHT. How much do you examine?

Mr. HUBBARD. Less than 1 percent.

Mr. GUTKNECHT. Let me give you some numbers. For the benefit of the committee, according to the NIH, each year they estimate 76 million Americans suffer foodborne illnesses and according to them, 325,000 of those are hospitalized and 5,000 die.

You were asked earlier about anecdotal evidence versus facts and so far what I have learned from the FDA, and I could be wrong, there is no evidence of any American yet who is taking a legal, FDA-approved drug from another country who has died. Am I correct in that? Yes or no, either there is evidence or there isn't.

Mr. HUBBARD. If I may, you wouldn't know.

Mr. GUTKNECHT. I only have 5 minutes.

Mr. HUBBARD. When this drug doesn't work, it is not that you die, it is you are not cured, not treated.

Mr. GUTKNECHT. I understand but the bottom line is there is no evidence of anyone who has died from taking a legal drug from Canada, isn't that a fact?

Mr. HUBBARD. I have on evidence of that, correct.

Mr. GUTKNECHT. That is all I asked you was yes or no.

Let me talk about the numbers in terms of foods and vegetables and the FDA is responsible for fruits and vegetables. You are not responsible for meat for the most part. Fruits and vegetables last year we imported $1.1 billion worth of bananas. Do we certify that all those bananas are safe?

Mr. HUBBARD. No, we do not.

Mr. GUTKNECHT. If you go down the list, the countries that we import from, let me give you some examples of numbers we do know of fruits and vegetables coming into the country.

According to a report done by your agency, in 1996, 1,469 people became seriously ill from eating raspberries from Guatemala. What did you do about it?

Mr. HUBBARD. We banned raspberries from Guatemala in that case.

Mr. GUTKNECHT. You didn't ban them for very long because the very next year, 1,012 people got sick from raspberries from Guatemala. This is not your fault and I am not trying to badger you but I think the members of the committee and the Congress need to

understand that yes, we are concerned about safety but let me say this. It is not the statute of security sitting in New York harbor. Americans take risks every day.

I don't want Americans to take any unnecessary risks whether they are buying Coumadin from Munich, Germany or raspberries from Guatemala. I have a long list and would be happy to share with members of the committee of the thousands and thousands of tons of fruits and vegetables that we bring into this country every day and blithely eat them and by the FDA's own admission, less than 1 percent are ever inspected.

One of the arguments we are hearing some critics of reimportation is that somehow terrorists are going to use the drug supply. I find that almost amazing that it is easier for a terrorist to open a Fed-Ex box package coming in from Munich, Germany, open the sealed package, put in some kind of poison, reseal it and somehow reseal the Fed-Ex package and affect the life of one American.

It seems to me if they are really serious about using that kind of terrorism, wouldn't it be easier to put strychnine in orange juice? Don't we import millions of gallons of orange juice every day?

Mr. HUBBARD. And FDA is very concerned about the safety of food in that way, yes.

Mr. GUTKNECHT. But you are not doing anything about it.

Mr. HUBBARD. In fact, we are but many of those we cannot talk about.

Mr. GUTKNECHT. Relative to what you do with prescription drugs, is it fair to say the effort by the FDA on reimportation of drugs is enormous and all we do in the thousands and thousands of tons of fruits and vegetables that come into this country every day is almost nonexistent? Isn't that a fact?

Mr. HUBBARD. Yes, but the regulatory structure is very different for Food and Drug. Drugs are supposed to be shown to be safe and effective but that is under a congressional requirement going back to 1938.

Foods are presumed to be safe unless they are shown to be unsafe. It is very different.

Mr. GUTKNECHT. I understand there is a different standard but for those 5,000 people who died of food borne pathogens, the result is worse, isn't it? They are still dead, aren't they?

Mr. HUBBARD. If they are dead, they are dead.

Mr. GUTKNECHT. All I am saying is if the logic and rationale is the same, shouldn't we make the standard for imported fruits and vegetables the same for imported drugs? If the idea is the purpose of the FDA is to help secure the safety of Americans, it seems to me you are a lot more likely to die of eating an imported strawberry than you are from taking Coumadin from Munich, Germany. Isn't that a fact?

Mr. HUBBARD. The way you describe it is, but I would argue differently that in fact what is happening is people that take these drugs are not having their treatment occur and they are getting no treatment. They are spending money on ineffective treatment and therefore that hurts them in two ways. It hurts both their health and their pocketbook.

Mr. GUTKNECHT. That is true and we don't want that to happen. Let me come back to one last point. I know my time has about ex-

pired but the reason you are seeing more of this coming in, I understand there are people in Miami who are experts at importing drugs. They import $10 million worth of cocaine every week. We do all we can to try and stop them but it still comes in. These are business people. They have started to figure out that you can make as much money on Glucophage as you can on cocaine so why wouldn't they get into that business? It is only rational. It is just a rational business decision.

More importantly, they are not amateurs, they are professionals. They know how to import drugs. We are going to see more and more of it, and this is not your responsibility, this is our responsibility, if we don't do something to level the prices we pay versus the rest of the world, you are going to see more and more of these illegal drugs coming into this country. That is a fact, an absolutely predictable fact.

Mr. Hubbard, I appreciate your coming. I am not here just to badger you but it seems to me we have to have an equal standard for safety whether it is food or drugs. It seems to me we have a responsibility to American consumers but at the end of the day I don't think, and you probably saw the article of the lady who was here earlier who says in the article, I would like nothing better than to be thrown in jail.

You may think she is a lawbreaker but I think she is a patriot. I think she stands on the shoulders of the patriots and those like the sons of liberty who began throwing tea in Boston Harbor. They are mad as hell and they are not going to take it anymore.

Thank you.

Mr. BURTON. Ms. Watson.

Ms. WATSON. Thank you. Let me apologize. We were downstairs hosting POW Shoshana Johnson. I was looking forward to the testimony of this committee and I am very impressed at the work ethic of our subcommittee and the timeliness of this issue.

Medicare reform is right around the corner and a proscriptive drug benefit is at the center of the solution. I commend your efforts toward good public policy and the education of the American people.

We all must agree that Americans pay higher prices for their prescription drugs than the residents of any other country in the world. When you strip pharmaceutical controversy to the core, the bottom line is that prescription drug prices are way too high. We spend twice as much as any other country in the world for health care, yet we are ranked 39th in the world for health care delivery according to the WHO.

Restricted access to prescription drug markets is one major factor in this anomaly. Unprecedented medical knowledge creates a domestic quality of life issue for the United States. Seniors, low income families, working class families, parents with children, are all segments of America that should be included in the access to prescriptive drugs.

Lower drug prices abroad have led many Americans to purchase drugs from foreign sources. Our neighbor to the north, Canada, has a long affiliation with the United States and business relations with the same pharmaceutical manufacturers that sell products here. I cannot in good conscience discourage any constituent from

going across the border to save 40 to 70 percent on the same drugs that are offered here.

Until recently, the FDA stood by the long-standing personal use policy by which the agency exercised its enforcement discretion to allow individuals to import a 90-day supply for personal use. Now, under pressure from the industry, the FDA is threatening prosecution of my most needy constituents plus the Canadian wholesalers and pharmacists who sell products to them.

I want you to correct me if I misinform. I cannot find, and I have asked my staff to search, one documented case of harm attributed to prescription drugs obtained in Canada. Research has also revealed that only cases of prescription drug counterfeiting are either domestic or from Third World countries. In most Canadian situations, prescription drugs are placed in the same packaging, retain the same name and are made by the same manufacturer.

Americans pay substantially more for prescription drugs than purchasers in other countries. The problem is particularly acute for our Nation's uninsured seniors. So I applaud efforts to offer programs such as Together RX and the Orange Card but I stress those efforts simply are not enough. These programs are well intentioned and well thought out but they do not reach the entire target population and do not address the fundamental problem. Prescription drug prices are just too high.

Pharmaceutical companies make billions in profits, spend millions to advertise to potential consumers and spend hundreds of thousands of dollars here in Washington, DC. Many of the patents used today are derived from Federal research facilities. American taxpayers paid for much of this research and they deserve to be able to afford the benefits of the results of this research.

Mr. Chairman, despite incessant pharmaceutical industry complaints to the contrary, research by the committee staff demonstrates that international pricing disparities are not explained either by the duration and the cost of the FDA approval process or by disproportionate U.S. research and development costs.

It is within our power to correct this problem but it will require a public/private partnership and a fierce resolve to value American quality of life. I look forward to the testimony and to being convinced that we are doing something wrong in terms of public policy and you are right, but I think that we are right because our policy will do no harm and will give the best benefit for the largest number of Americans.

Thank you and I yield the balance of my time.

Mr. BURTON. Thank you, Ms. Watson.

Mr. Janklow, I think you were next.

Mr. JANKLOW. Thank you.

Mr. Hubbard, I too appreciated the dramatic display but can you order those diabetic drugs through American Internet?

Mr. HUBBARD. Absolutely.

Mr. JANKLOW. Do they come refrigerated?

Mr. HUBBARD. They come in a thing called an ice pak.

Mr. JANKLOW. They come in an ice pak but in the event it were to take an extra day or two for you to get it from the post office, it would end up about the same temperature as that stuff on your desk, wouldn't it?

Mr. HUBBARD. If that happened, the drug should be thrown away at that point.

Mr. JANKLOW. We allow that though, don't we?

Mr. HUBBARD. I believe we would require it to be handled properly.

Mr. JANKLOW. If there was a day or two delay in the post office, if it is mailed on say Friday or Saturday and there is no Sunday movement, it will come at that same temperature sometimes, won't it?

Mr. HUBBARD. I think very little refrigerated product is sold over the mail but it would certainly be shipped in a way that it would arrive while it was still cold.

Mr. JANKLOW. My second question, you told us about the diuretic that cost $32 that sells for $20 in America. Are you familiar with some of the other drugs sold in Canada versus the United States, drugs like Zantac?

Mr. HUBBARD. Generally, Mr. Janklow.

Mr. JANKLOW. No, are you familiar with Zantac is my question?

Mr. HUBBARD. I know of it.

Mr. JANKLOW. Are you aware you can buy Zantac from CVS.com for $236.99 in this country and CrossBorder Pharmacy.com in Canada for $56.54, a difference of $180.45. Are you aware of that?

Mr. HUBBARD. That sounds consistent with price differentials I have heard.

Mr. JANKLOW. Are you aware also that Paxil, 10 mg tablets, you can get at CVS.com for $82.59 in this country through the Internet, through Canada's Internet, $52.35, a difference of $30.24?

Mr. HUBBARD. Again, that sounds consistent with price differentials I have heard.

Mr. JANKLOW. So the example you used, you had to kind of search to find one where it was actually more expensive in Canada, didn't you?

Mr. HUBBARD. The example I was trying to give was this was a generic drug.

Mr. JANKLOW. Did you or didn't you have to search to find one that was more expensive in Canada, yes or no?

Mr. HUBBARD. I think every generic drug.

Mr. JANKLOW. My question calls for a yes or no, did you or didn't you have to search to find one more expensive in Canada?

Mr. HUBBARD. This was randomly pulled out. I would suspect that every generic drug would be cheaper in the United States.

Mr. JANKLOW. By not answering, you have answered it. Thank you.

All the examples you use are Internet sales, correct?

Mr. HUBBARD. Yes.

Mr. JANKLOW. For Americans that go to Canada to buy their drugs, tens of thousands of them if they are fortunate enough to live in the border States, do you have any examples of where they are buying the bad product with the ability to do that under Canadian regulatory operations?

Mr. HUBBARD. My own view is it is somewhat safer to go across the border that way.

Mr. JANKLOW. I didn't ask for your view, I asked you if you had any evidence of the fact that anybody who has gone to Canada to

buy drugs as opposed to getting them through the Internet has had any problem pursuant to Canadian regulatory climate?

Mr. HUBBARD. What I was trying to say, Mr. Janklow, was if you personally go there you are more likely.

Mr. JANKLOW. Do you or don't you have evidence? The question is do you or don't you have evidence?

Mr. HUBBARD. I have no evidence about anything that happens in Canada if that is your question.

Mr. JANKLOW. You are familiar with the way the Canadian regulatory scheme works, aren't you, given the fact you are the Senior Associate Commissioner of our Food and Drug Administration?

Mr. HUBBARD. Not particularly.

Mr. JANKLOW. How familiar are you with Canada's scheme, sir, for regulatory control of drugs?

Mr. HUBBARD. I have talked to Canadian health officials a half a dozen times to try to get an understanding of their system, I have not visited Canada, I have not done an examination, nor has anyone at the FDA to my knowledge.

Mr. JANKLOW. Have you ever been briefed by anybody in the FDA about the Canadian regulatory scheme?

Mr. HUBBARD. I don't think anyone at FDA is capable of briefing me because we don't have a need to know that.

Mr. JANKLOW. If you don't understand my question, I will try and restate it.

Mr. HUBBARD. The answer is no.

Mr. JANKLOW. Have you ever been briefed by anyone at the FDA about the Canadian regulatory scheme?

Mr. HUBBARD. No, Mr. Janklow. I have only talked to Canadians.

Mr. JANKLOW. Have you ever read any materials about the Canadian regulatory scheme?

Mr. HUBBARD. I have read some limited material the Canadians have given me.

Mr. JANKLOW. How many materials have the Canadians given you, sir?

Mr. HUBBARD. Two or three different little packets.

Mr. JANKLOW. Have you read them?

Mr. HUBBARD. Yes.

Mr. JANKLOW. Is there anything about them that you would disagree with, dispute or find of concern?

Mr. HUBBARD. There were a lot of things I didn't understand and in trying to understand them, we talked to them orally to try to understand the extent to which they would protect the drugs coming into this country.

Mr. JANKLOW. I am talking about their regulatory scheme?

Mr. HUBBARD. They have described a scheme that is analogous to that of the FDA.

Mr. JANKLOW. If it were to be a requirement, would the FDA be opposed to a system whereby an American pharmacist could bring in the drugs from Canada and resell them in the United States? Would that be the kind of scheme around which you would be willing to work if someone could try to design a scheme like that?

Mr. HUBBARD. That was the precept behind the Meds Act that Mr. Sanders and others referred to that was enacted by Congress

in 2000. We gave some technical assistance to the drafters of that bill.

Mr. JANKLOW. Is it something about which you think you could effectively regulate if it was sold through pharmacists in the United States based on imported drugs from Canada?

Mr. HUBBARD. Secretaries Shalala and Thompson determined that the standards set up by that statute required there be no loss of safety protections and they determined they could not certify no loss of safety protections, so they did not certify that bill could be safely implemented.

Mr. JANKLOW. Did you concur in that and if the answer is yes, what was your basis for concurring in their decision?

Mr. HUBBARD. I did because it required certain testing and pedigree requirements or documentation that we did not believe could be successfully implemented.

Mr. JANKLOW. My time is up. Thank you.

Mr. SANDERS. Would the gentleman yield for one brief second?

Mr. JANKLOW. Sure.

Mr. SANDERS. I appreciate his line of questioning. I happen to be the chief author of that legislation, so let us get the facts straight. FDA sat in our office and the offices of other Members of Congress, Republican, Democrat, Independent, to make sure the standards for safety were very, very strong. They signed off on those. They helped us write the legislation.

When you had quoting Shalala and others, what they are saying is we built into it, we said it is going to take a certain amount of money to implement and for a variety of reasons, there was a concern that money might not be available but will you deny today that the FDA actively participated in developing the safety standards of that legislation and signed off on them?

Mr. HUBBARD. I will agree with the first half and disagree with the second half of your statement. We did participate, we gave technical assistance, we did not agree with the end result of that bill, that it could be safely done.

Mr. SANDERS. That is not accurate to the best of my knowledge, sir.

Mr. BURTON. The gentleman's time has expired.

Mr. Crowley.

Mr. CROWLEY. Thank you for letting me sit in as someone who is not a member of the committee.

Mr. Hubbard, I wasn't here earlier. Do you have any evidence of any American citizen being harmed or sickened by drugs reimported from Canada?

Mr. HUBBARD. As I explained earlier, we have only very limited anecdotal examples of that. Our answer is really more that when people get these drugs, you don't have the sort of frank harm you might get where someone would immediately die or be seriously injured. You have failure to treat the individual.

Mr. CROWLEY. But you have no evidence of anyone dying from this?

Mr. HUBBARD. We have a couple of examples of allegations that I would not want to put a great deal of strength behind.

Mr. CROWLEY. We would like to see some of that if you do.

How often does the FDA actually apprehend counterfeit drugs coming over the border?

Mr. HUBBARD. Fairly rarely. Counterfeiting is fairly common around the world. Some estimates are that in many countries, it is over half the drugs sold. In the United States, it is very, very rare, however, fortunately.

Mr. CROWLEY. Do you know of any counterfeit operations in Canada actually creating drugs?

Mr. HUBBARD. The Royal Canadian Mounted Police seized several thousand Viagra pills in April that were counterfeit.

Mr. CROWLEY. Couldn't that have been created in Canada?

Mr. HUBBARD. These were Canadian-produced, counterfeit Viagra intended we believe for export to the United States.

Mr. CROWLEY. The false drug, the counterfeit drug, was produced in Canada?

Mr. HUBBARD. According to the RCMP sources yes, but this was not our case, so I can't give you much information about that.

Mr. CROWLEY. Are counterfeit drugs produced in the United States?

Mr. HUBBARD. Yes. The few cases we have seen have tended to be domestic.

Mr. CROWLEY. Is there a great deal of emphasis on going after them?

Mr. HUBBARD. Absolutely. We are very aggressive in that because it presents a very frank health risk.

Mr. CROWLEY. One looks at the fact that the cost of prescription drugs in Canada is considerably less, as pointed out by Congressman Janklow, than in the United States. There doesn't really seem to be much of a market for striving counterfeit drugs as one would imagine in the United States. Obviously if the cost of drugs in the United States is a great deal higher, that you would see more counterfeit production here in the United States. I just wanted to point out the market itself doesn't say to me that is what is going to happen in Canada. Obviously people in the business of selling drugs in Canada are going to make a great deal of profit if that drug is sold to the United States.

Let me point out for your edification, Mr. Hubbard, and that of my colleagues, I am going to be dropping a bill known as the NATA Drug Act. It stands for the New Aid for Trustworthy Affordable Drugs Act. Under this bill, under the auspices of NAFTA allow prescription drug importation and exportation among NAFTA nations provided drugs meet strict importation standards, standards which would be set by the U.S. Trade Representatives working with HHS, FDA and their counterparts in the NAFTA countries.

Pharmacies that achieve these standards will be registered and would receive counterfeit resistant seals for their drugs. Only drugs with these seals would be allowed to be received in the United States under this bill.

It prevents drug companies or registered pharmacies within NAFTA nations from hindering customers from purchasing any approved drug based on customer residence. I am really recalling that GlaxoSmithKline had threatened to cutoff the supply to Canadian pharmacies supplying Americans.

This bill only covers FDA approved drugs. The bill is paid for by requiring drug companies to reimburse HHS for the National Institute of Health research that benefits all drug companies.

I am just letting my colleagues know we will be dropping off that bill. If anyone is interested in joining that, we would be happy to put them on as a co-sponsor.

I yield back.

Mr. BURTON. The gentleman yields back his time.

Representative Duncan.

Mr. DUNCAN. Thank you, Mr. Chairman, and thank you for continuing to call attention to this very serious, nationwide problem.

Mr. Gutknecht brought in this article from last week's U.S. News and World Report called, "Health on the Borders, Elderly Americans head north and south to find drugs they can afford." The first paragraph says, "It has become something of a joke along the main Canada border that so many busloads of retired people crisscross the line looking for affordable drugs that the roadside stands should advertise lobsters, blueberries, Lipitor, Coumadin, except that such a market in prescription drugs would be illegal."

I can tell you that as most of you know, I represent a district in Tennessee. My senior citizens are unable to go to Canada or Mexico and yet I can tell you they are just as concerned as anybody else because they read and hear about how much more we are paying for these drugs than people in other countries.

Mr. Gutknecht has a comparison here of the total that people pay for certain listed drugs. The most common drug in Munich, Germany, a developed country, $373; $1,039 for the same drugs in the United States, almost three times as much. This is a problem people are not going to stand for. With all due respect to my friend Mr. Sanders, this is not a partisan issue. There are more Republicans here today than Democrats and we are all concerned about this. This is the third hearing I have participated in on this and at the last hearing, Howard Biehls, the Director of the Bureau of Consumer Protection at the FTC was one of the main witnesses. I asked, "How many people are buying drugs over the Internet as best you can tell and has the FTC received complaints about these drugs being fake in some way or can you tell us do you know of anybody who has been hurt by any of these drugs? I am wondering about the scope of the problem." Mr. Biehls' answer, "We don't know of particular instances of cases where somebody has tried to buy a drug that turned out not to work or to be the wrong thing. We don't know of specific instances in prescription drugs." Not one instance could he cite.

For the young people here, I will tell you until the FDA became so big and bureaucratic, we didn't have this problem and 35, 40 and 50 years ago we didn't have this problem. You heard nothing about this. Because we have allowed the Government to get so big and so bureaucratic, we have seen articles and I am not blaming this on Mr. Hubbard, but I can tell you I have seen all kinds of articles in the Wall Street Journal and many other publications, where we have reached the point, and I think the FDA has been trying desperately to correct this in the last year or two, where it was taking an average of 10 years to get a drug to market and costing between $650 million and $850 million.

That means if somebody came up with a pill that would cure cancer and went to someone and said let us go into business, you would have to find somebody that would loan you $1 billion a speculative venture and that would be impossible.

Like any highly regulated industry, the drug industry ended up in the hands of a few big giants because of big government. I can tell you I am a pro business conservative but these pharmaceutical companies are going to kill the goose that has laid the golden eggs. The way it works is this. In every industry big companies hire former high ranking employees of whatever agency they are dealing with to go to work for them or the lobbying firms who lobby for those businesses hire these former high ranking employees and every big government contract goes to these companies that hire these former employees. What happens is the big keep getting bigger and the small go by the wayside.

I will give you one example of that. Several years ago I read about a small company in Bloomington, IL that had come out with these breast cancer detection pads. They got approved within months in every country, in Europe, Canada and everyplace else they wanted to be approved. It was 9 years later and they still hadn't been approved when I read this article and they had all kinds of medical evidence saying thousands of women had died from breast cancer because the FDA had not allowed these pads to be approved in the United States. The reason was it was a small company that didn't have the lobbyists, didn't have the connections in Washington and hadn't hired former FDA employees, so it is big government that has caused this problem.

People are going to come in and demand the government regulate it even more and that would be a terrible mistake. Unless we decrease the size and cost of the FDA, unless the FDA purposely starts working closer with some of the smaller companies and changes the whole culture, this problem is going to get worse instead of better.

I will say again, these big giants that control the industry now are going to kill the goose that laid the golden egg if they keep going the way they are because everybody in this country is concerned about it.

I have run out of time. Thank you.

Mr. BURTON. Thank you, Mr. Duncan.

Mr. Allen.

Mr. ALLEN. Thank you and thank you for holding this hearing.

Mr. Hubbard, I heard you describe a problem and regrettably I wasn't here for much of your testimony. I have heard several people say the FDA is concerned about the quality of drugs coming across the border from Canada and you have been challenged over and over on that. Like others, I don't know of any such cases. It seems to me a very small risk at the moment, very small risk.

On the other hand, back home in Maine, every single day, someone doesn't take prescription drugs because they can't afford them and you talk to people who deal with lower income people and we have a very good low income program in Maine for prescription drugs and still many people are going through tremendous emotional stress, not taking the prescription drugs they really need because they simply can't afford them.

I can give you a long history of phone calls to my office and meetings I have had with constituents. For example, the couple that both need a fair number of prescription drugs and the way they solve the problem is the wife takes them for 1 month and the husband takes his for the next month and they rotate like that or break their pills in half or do whatever. This is a huge national problem.

My question is why does the FDA focus on what is a relatively small, social problem today, itty bitty problem to use a current phrase, compared to this enormous challenge that we face. Is it simply because one, the little bitty problem is in your jurisdiction and the other is not and if that is the case, is there any hope for leadership from your organization on the larger issue?

Mr. HUBBARD. I think you have said it right, Mr. Allen. Safety, we were created to enforce a drug standard that the Congress created that worked very well. It has caused us to have the safest and most effective drug supply in the world but you point out it is also an expensive drug supply. The expensive part is just not our job and we don't have any particular expertise in that area and can't really play on that field. All we can do is say to you if Congress wants to let these drugs in, that is Congress' policy decision to make but we believe there will be a diminution of safety and then Congress has to decide whether that diminution of safety, whatever it is, whether 1 percent or 90 percent, is worth the savings that would accrue.

We are saying these examples, which are ordinary drugs coming in every day at the mail centers, typical examples, not special order ones we found, all the drugs in my view are dangerous.

Mr. BURTON. Would the gentleman yield briefly?

Mr. ALLEN. Absolutely.

Mr. BURTON. Canada's right north of us, it is not halfway around the world like France, Germany or Spain. They have a health agency just like ours up there. Why in the world can't you coordinate with them to make sure the same safety standards apply? I talked to them this past week and if the same safety standards apply, then it is just a matter of being able to transport these same pharmaceutical products back and forth which shouldn't be that difficult a problem.

The problem is profit. That is the problem. You guys don't say that. You say we don't have anything to do with that but the fact is by virtue of the fact you are blocking these products from coming into the country, you are guaranteeing the huge profits the pharmaceutical companies are making because you are not letting the lower price, same product into the United States. Don't tell us when you come here, we don't have anything to do with that because you are the problem. You are the one blocking the American consumer from getting lower priced pharmaceutical products because you say there is a question of safety when one has not been proven. There is no proof. You keep saying there is a safety concern but you can't give us one iota of evidence there is a problem. Yet you are the one blocking, like a lineman blocking for a quarterback, saying my gosh, we can't let them in because there is a safety concern when in fact the only real concern is the profit of the pharmaceutical companies because you can't show us anything else.

I thank the gentleman.

Mr. HUBBARD. May I respond?

Mr. BURTON. Sure.

Mr. HUBBARD. May I just read from Congress' latest direction to us that "Drugs being reimported into the United States pose a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping. The effect of practices and conditions is to create an unacceptable risk that counterfeit, adulterated, misprinted, subpotent or expired drugs will be sold to American consumers." This is the congressional direction to us, Mr. Chairman. This is the Prescription Drug Marketing Act of 1988. This is what you told us to do.

Mr. BURTON. We passed a law subsequent to that which allows for the reimportation. You didn't mention that law and that law says we can reimport these drugs into the United States unless you have a safety concern and you haven't found a safety concern. You have been here twice and you have not once shown us where someone has been hurt by these pharmaceutical products. So you are blocking American congressional legislation that says we want to allow reimportation unless there is a safety concern. You cannot show us a safety concern and yet you are blocking the reimportation. I am saying why don't you work with the Canadians to make sure we don't have that problem but you don't want to do that because you are blocking for the pharmaceutical companies making billions.

Mr. ALLEN. If I could have one concluding comment. I can't say it any better than the chairman did. Do you understand, Mr. Hubbard, the risk to your agency? Your agency has a long and distinguished history. By your action on this issue, you are destroying that reputation. You are creating the impression in Congress and across this country that you are in the grip of the most powerful lobby in this country, the pharmaceutical industry, a lobby which just the other day did a $150 million budget for Pharma. In one line of that budget, they set aside $1 million to lobby to change the Canadian health care system.

There is a lot people in this country don't understand about the Canadian health care system but one thing they don't understand is they have better cancer survival rates than we do because at the lower third of the economic strata in Canada, there are a couple of studies which show this, people get health care. At the lower third of the economic strata in the United States, they don't. Early detection works. I am just giving you one example but it is time for the FDA to live up to a broader responsibility than just dealing with itty bitty problems that you may feel fall within your jurisdiction.

Thank you, Mr. Chairman.

Mr. BURTON. Mr. Cannon.

Mr. CANNON. Thank you. I appreciate the recognition.

This is obviously a very intense issue. You have been here before, Mr. Hubbard, and I take it you have been a bit prepared for this today. Let me point out while there is a great deal of concern about this issue, you just said the FDA provides the safest and most secure drug supply in the world. You used those terms because that is the brief the FDA has. Isn't it true there is another thing that

goes with that which is quite important to this debate and that is we have the most innovative drug supply sources in the world.

I had a PhD molecular biologist in my office today and we were talking about some of these things. He said 80 percent of referenced drug patents are American. I don't know what the total number of patents are in the world but the ones that are important because they are referenced in other drug patents, 80 percent come from America. That is not your brief but isn't that an important factor in this debate?

Mr. HUBBARD. Yes, I think the evidence does show that so-called breakthrough drugs, the really important drugs that treat diseases that didn't exist before tend in the vast majority of cases to come to the United States first. That innovation has been a benefit to patients. However, the costs are there.

Mr. CANNON. Why is that?

Mr. HUBBARD. We like to think it is because FDA creates a higher standard and the manufacturers see both a regulatory climate and an economic climate here.

Mr. CANNON. And that economic climate is a free market?

Mr. HUBBARD. That is correct.

Mr. CANNON. Part of that free market includes a patent period. In that regard, you were asked a question earlier about generics and you were trying to answer a question a little different but were you going to say there is a difference in pricing on generic drugs between the United States and Canada, and if so, which way does that pricing cut?

Mr. HUBBARD. In fact, there is. Generic drugs are cheaper in the United States on average by one recent study by about 7 percent.

Mr. CANNON. Why is that, is there some kind of dynamic here that causes that to happen?

Mr. HUBBARD. Presumably when drugs go generic in the United States, competition takes over, several manufacturers step in and make them and the price drops fairly dramatically.

Mr. CANNON. As compared with Europe and Canada, what percentage of drugs in America are generic and what are patented?

Mr. HUBBARD. It depends on the condition and patient populations but generally about half of drugs can have generic competition.

Mr. CANNON. In America?

Mr. HUBBARD. Yes.

Mr. CANNON. Isn't it true that in Canada and Europe where prices tend to be lower, prices are controlled by the State, that you end up with similar prices for generics and for patented drugs and therefore, people have no incentive to buy generic drugs?

Mr. HUBBARD. I have heard that but I am not familiar enough with the Canadian system to give you a definitive answer on that.

Mr. CANNON. I think that we have had a discussion here about safety and assuring safety versus proving injury. Those are significantly different things. Do you want to comment on that for a moment?

Mr. HUBBARD. Yes. The question we often get is show us people that are injured, show us people that take a drug and fall over ill or dead. That doesn't happen in the cases we are describing. We are talking about drugs that don't have proper information for how

to use them so the patient might use it improperly, drugs that are ineffective or expired and therefore, the patient is not being treated. The individual, for instance, that has high blood pressure, his blood pressure is not being treated or instead of coming down 40 points, it is only coming down 10 or 15 points. He is at danger of a stroke. You won't know that from any reporting system.

Mr. CANNON. So there is a distinction in your mind between injury and safety in the system?

Mr. HUBBARD. I am talking more the safety issue of failed treatment or ineffective drugs which many of these are that we have brought today.

Mr. CANNON. Would the use of counterfeit proof seals and labels on each pack of drugs imported from Canada to the United States as proposed by Dr. Wennar satisfy the FDA's concern about safety? If so, would it be possible for the Medicine and Drug Safety Equity Act just passed in the 106th Congress to be finally and fully implemented?

Mr. HUBBARD. Mr. Gutknecht and Mr. Burton asked us to look at that and we had already been looking somewhat at this issue of technology. We agree with you that is a very fruitful area for examination.

Mr. CANNON. If I can get in one more question before my time ends. Ms. Watson said the World Health Organization, not the same as our free market to world conception, has ranked America as 39th in delivery of medical care. Would you like to comment on why that would be the case?

Mr. HUBBARD. I am afraid I wouldn't be qualified to comment.

Mr. CANNON. Thank you. I think America is the best in the world.

Mr. HUBBARD. That is what I would suspect but I am not familiar with that data.

Mr. CANNON. Thank you, Mr. Chairman. I yield back.

Ms. WATSON. Mr. Chairman, if I could take 1 second to followup on that comment.

Mr. BURTON. While you are doing that, let me check and find out where we stand on the vote so I can inform the committee.

Ms. WATSON. Maybe I can light on why we are ranked No. 39. It has to do with access to health care as well. In talking to some of the pharmaceutical companies prior to today's meeting, they have wonderful programs but the outreach has not been extensive enough to cover Americans. We have 40 million uninsured, 8 million are in my State, the State of California. So when we look at health care delivery and the quality of health care, our outreach has not been effective and successful.

Mr. CANNON. Would the gentlelady yield?

Ms. WATSON. Yes.

Mr. CANNON. What we are dealing with here from the policy perspective of our level is how do we create a system that improves health care in the best way over the longest period of time so that ultimately everyone gets the best health care. Since no other country is innovating like America, no other country is in the ballpark. Certainly we could have some benefit in the way we distribute, but the fact is we have drug companies that have these two programs you mentioned that are beginning and expanding their outreach

and maybe some of our focus ought to be to help them expand that outreach so that with their profits they can help people who are poor but not change the system in a way that would crimp this incredible innovative machine we have that is making the world so much better for everyone. I might just point out America has now taken the absolute moral lead in the world with the commitment of $15 billion to fighting AIDS. That is a function, as the President pointed out when he spoke, of the amount of dollars and the technological process that has resulted in the ability to treat AIDS worldwide. That allows America to be the leader but I think it is really important we consider that as we deal with these difficult issues.

I yield back.

Mr. BURTON. Thank you, Mr. Cannon.

We have three votes and I want to apologize to those who are representatives of the pharmaceutical industry who are here. We will be able to conclude as soon as we return. We have three votes and it will probably take us about half a hour and we should be back. I would all the members of the committee to get back as quickly as possible so we can get to the members of the industry because I am sure we have a lot of questions.

Thank you, Mr. Hubbard. We appreciate your testimony.

With that, we will stand in recess until the call of the gavel which should take about 30 minutes.

[Recess.]

Mr. BURTON. Mr. Viehbacher is president, U.S. Pharmaceuticals, GlaxoSmithKline?

Mr. VIEHBACHER. Correct.

Mr. BURTON. You are here in place of David Stout whose father passed away?

Mr. VIEHBACHER. That is correct.

Mr. BURTON. Would you please extend to him our sympathy? I had an opportunity to meet with him and he seems like a very nice fellow.

Mr. VIEHBACHER. I will pass that on.

Mr. BURTON. I am sure it has been a very difficult time for him.

David Brennan, you are the executive vice president for North America, AstraZeneca?

Mr. BRENNAN. That is correct.

[Witnesses sworn.]

Mr. BURTON. Do you have opening statements, either of you?

Mr. VIEHBACHER. I do.

Mr. BURTON. Proceed.

STATEMENT OF CHRIS VIEHBACHER, PRESIDENT, U.S. PHARMACEUTICALS, GLAXOSMITHKLINE PHARMACEUTICALS; AND DAVID BRENNAN, EXECUTIVE VICE PRESIDENT FOR NORTH AMERICA, ASTRAZENECA PHARMACEUTICALS

Mr. VIEHBACHER. Mr. Chairman and members of the committee, I am Chris Viehbacher, president, U.S. pharmaceuticals for GlaxoSmithKline. I appreciate the opportunity to be here today to address your concerns about an issue that is important to all of us, ensuring that all Americans have access to safe and effective prescription medicines.

At the outset, let me say that I do not think that importing either pharmaceuticals or price controls from foreign countries is the best solution for the problem. Let me explain why.

There are a number of misconceptions underpinning discussions about cross border sales of prescription medicines. People are being led to believe that medicines sold across the border from Canada are made in the United States. The reality is that of the approximately 230 products GSK sells in Canada, well over 200 are supplied from non-U.S. sources. The Canadian version of the GSK antibiotic Augmentin, which is often cited as being the same as the U.S. version, is not manufactured in the United States and is not made in the same plant as the U.S. product.

A second often quoted myth is that cross border sales of medicines are regulated by Health Canada. In a recent letter to the Washington Post to correct an erroneous article, Health Canada stated, "The Government of Canada has never stated that it would be responsible for the safety and quality of prescription drugs exported from Canada into the United States." The letter further clarifies that drugs imported to or manufactured in Canada but not intended for sale to Canadians are not subject to Health Canada's approval standards.

Myth No. 3, drugs sold in Canada are FDA approved. The reality is that none of the medicines on pharmacy shelves in Canada are approved by the FDA. There are differences between medicines in the United States and Canada and they can be significant. One example is Flovent which is an asthma inhaler. The form used in Canada differs from the FDA-approved version and as a consequence the spray delivered to U.S. patients would feel softer and not as strong as they are used to, although the same amount of medication would actually be delivered.

Without proper advice about the difference, a U.S. patient taking this medication might be confused and overmedicate which brings me to Myth No. 4, cross border sales are managed by licensed, reputable pharmacies. As the executive director of the Canadian Pharmacists Association has said, "With the Internet, it is definitely a buyer beware situation. Some of the Web sites may not be pharmacies at all because there is no licensed pharmacist at the helm." Let me give you an example.

A Google listing of Canadian Internet pharmacies earlier this year identified one of the following URLs, bedouinbellydance.com. The description said patients could get not only the lowest price on Combavir, a life saving drug for the treatment of AIDS, but also bellydance tapes, tips, workshops, photos and performance information. This description no longer exists on Google but we can share with the committee a copy of the display we saw. This site and many others are registered in Barbados. What that means, we don't know but that is not the point. The origins and reliability of prescription drugs Americans take should not be a mystery.

Mr. Chairman, sending seniors across the border to get their prescription medicines is not the way to address concerns over costs in excess here in the United States. I would urge any American who believes he must choose between food and medicines to contact GlaxoSmithKline and the other pharmaceutical companies for help. Last year, GlaxoSmithKline gave away medicines worth almost

$168 million through our patient assistance programs. Through the GSK Orange Card and Together RX Card, close to 1 million people have made savings of about $117 million. These programs do make a difference and one of the many patient letters we received said, "I utilized your patient assistance program for my mother for a number of years working with her physicians to obtain the needed medications. She did not have to choose meds versus living expenses on her fixed income. I felt you should know what a blessing this program is."

As valuable as these programs are, they are only a stop gap, Mr. Chairman. I am a Canadian citizen and have lived in various European countries over the last 15 years. I have had the privilege of living in the United States for the past 5 months. From my perspective, the United States has the best quality health care in the entire world. On top of that, other countries benchmark against the United States for its ability to generate investment, jobs and R&D. We must find a way to provide access and preserve innovation which is why the current deliberations over Medicare reform in Congress are so important. A Medicare drug benefit that provides affordable drug coverage to all American seniors while preserving the market-based system that drives innovation will ensure that we maintain the highest quality health care in the world.

I look forward to your questions. Thank you.

[The prepared statement of Mr. Viehbacher follows:]

Testimony of
Christopher A. Viehbacher
President, US Pharmaceuticals

Subcommittee on Human Rights and Wellness
Committee on Government Reform
United States House of Representatives

June 12, 2003

Congress decided long ago that prescription medicines are both critical to improving the nation's health and highly dangerous if unregulated; therefore, our nation must have a regulatory system that: one) controls which medicines are approved for American patients; and two) develops sufficient safeguards to protect us from being exposed to fraudulent, unsafe, or adulterated drugs.

Mr. Chairman, members of the committee. I am Chris Viehbacher, President of US Pharmaceuticals for GlaxoSmithKline (GSK). While I cannot speak for the entire industry on the issue of Canadian Internet pharmacies, this hearing enables me to discuss GSK Canada's efforts to protect the safety and welfare of patients on both sides of the border, and to comment on the larger issues of cross-border importation of medicines.

Importing or reimporting prescription drugs from other countries through the Internet is a far bigger issue than actions taken by GlaxoSmithKline, Astra Zeneca or any other company.

It is, on the one hand, a complex issue of US law and the enforcement capabilities and priorities of both the Canadian regulatory system and the FDA. On the other hand, it is a straightforward issue about the integrity of the American drug supply and the safety of American patients.

We are fortunate to live in one of the last free markets for health care in the world – and as a consequence, the United States also remains the center of medical innovation for the world. Nowhere is there a better climate for innovation, which results in new and better treatments against disease – medicines that save lives and improve the quality of life for patients in America and across the globe.

The American public is normally the first to benefit from those innovations; however, it is true that such medical advances are subsidized largely by those of us living in the United States. Yet Americans subsidize the rest of the world in many ways: from the $15 billion we will spend to help address the epidemic of AIDS in developing countries, to the $15-20 billion we send to other countries in direct foreign aid.

Our system for regulating prescription drugs – including stringent controls on testing required for marketing approval – is based on the principle of preventing harm before it happens. Charged with that mission, the FDA does an exemplary job – despite its limited resources – of ensuring that the prescription medicines available to American patients are safe and effective.

Overseeing our national incubator for pharmaceutical innovation is the US Food and Drug Administration, which remains the gold standard for regulatory agencies across the globe. Congress decided long ago that prescription medicines are both critical to improving the nation's health and highly dangerous if unregulated; therefore, our nation must have a regulatory system that: one) controls which medicines are approved for American patients; and two) develops safeguards to protect us from being exposed to fraudulent, unsafe, or adulterated drugs.

Our system for regulating prescription drugs – including stringent controls on testing required for marketing approval – is based on the principle of preventing harm before it happens. Charged with that mission, the FDA does an exemplary job – despite its limited resources – of ensuring that the prescription medicines available to American patients are safe and effective.

It must be recognized that the cross-border trade of pharmaceuticals violates a well-considered federal law intended to ensure the safety of the American people. As such, GSK is acting in compliance with and upholding US law. You may not agree with the law, and consumers may be frustrated with the law, but it was a restriction that was put in place by Congress after extensive hearings and review of the drug approval and distribution system. Most importantly, this law was enacted not to protect the business interests of the US pharmaceutical industry, but to protect the safety of American consumers.

US Food and Drug Administration officials, whom Americans trust and depend on to ensure the safety of our drug supply, have explicitly stated - in Congressional testimony, in public speeches, and in written advisories posted on their web site – that sales of Canadian drugs to US patients are illegal and expose patients to a variety of risks.

Yet, in the absence of adequate government enforcement actions, companies like GSK must manage the rapid development of the cross-border Internet trade of pharmaceuticals to the best of their ability. In our case, GSK Canada found that the fast-growing Internet trade began to pose a number of concerns, including potential interference with the supply of drugs to Canadian patients and the possible exposure of American patients to degraded or counterfeit drugs. With these patient safety considerations foremost in mind, GSK Canada therefore acted to enforce its terms of sale that prohibit cross-border diversion of our medicines.

US Food and Drug Administration officials, whom Americans trust and depend on to ensure the safety of our drug supply, have explicitly stated – in Congressional testimony, in public speeches, and in written advisories posted on their web site – that sales of Canadian drugs to US patients are illegal and expose patients to a variety of risks.

In a recent Warning Letter, issued to US-based representatives of Canadian pharmacies that sell drugs across the border, the FDA stated:

> *"Prescription drugs purchased from foreign countries generally are not FDA-approved, do not meet FDA standards, and are not the same as the drugs purchased in the United States. Drugs from foreign countries do not have the same assurance of safety as drugs actually regulated by the FDA. Because the medications are not subject to FDA's safety oversight, they could be outdated, contaminated, counterfeit or contain too much or too little of the active ingredient. In addition, foreign dispensers of drugs to American citizens may provide patients with incorrect medications, incorrect strengths, medicines that should not be used in people with certain conditions or with other medications, or medications without proper directions for use."*

The unregulated proliferation of cross-border Internet pharmacies offers an easy opportunity for counterfeiters and other rogue operators to blend into the crowd and profit from the sale of ineffective or otherwise questionable medicines that present a real danger to patients.

In the same warning letter, the FDA also highlighted the risk of fraud and deception posed by drugs purchased from abroad over the Internet. The unregulated proliferation of cross-border Internet pharmacies offers an easy opportunity for counterfeiters and other rogue operators to blend into the crowd and profit from the sale of ineffective or otherwise questionable medicines that present a real danger to patients.

To discuss these points more fully, it is a mistake to assume that even when a drug has the same name and active ingredient in both the US and Canada, the Canadian drug has all the safeguards of FDA approval. Canadian drugs are simply not FDA-approved.

FDA approval extends beyond the name and active ingredient and is specific to the product as a whole, including (1) its exact labeling establishing permitted conditions of use; (2) its exact formulation, including specified active and inactive ingredients in specified amounts; (3) its exact conditions of manufacturing, including approved manufacturing sites; and (4) its exact specifications, which include specified quality control tests for assessing product performance.

The bottom line is that approvals from Health Canada may not now, and should not, be freely substituted for FDA approvals, as far as American law and the expectations of the American drug-consuming public are concerned.

The extent of differences between Canadian and US versions of GSK medicines will vary from product to product, but the undeniable fact is that there are differences, and they can be significant.

Here is just one example of how differences – in this case labeling differences – can have a real impact on patients. In the US, the FDA has asserted authority to require that manufacturers supply – and that pharmacists be legally obligated to dispense – written patient information leaflets called "Medication Guides" for certain drugs that pose serious and significant public health concerns. Some GSK products – such as the HIV drugs Ziagen® [abacavir sulfate] and Trizivir® [abacavir sulfate, lamivudine, & zidovudine] – and products of other manufacturers as well – are the subject of required Medication Guides.

Canadian pharmacists who dispense to US patients do not have the mandated, FDA-approved patient information sheets at their disposal, and may be unaware of the requirement under US law that they be given to patients with each prescription. While GSK does make detailed patient information available in Canada, it is not identical to the FDA-mandated Medication Guides, which are in a required standard format that FDA has specified. Canadian pharmacists also do not have the same distribution obligation as their US counterparts.

It is appealing to point to the high regulatory standards of Health Canada and argue that these products offer a safe alternative to patients who have trouble affording their medicines. A recent *Washington Post* article erroneously reported that Health Canada had committed to ensure the safety of drugs exported to the US. But in a letter to the *Washington Post* to correct that error, Health Canada stated:

> *"The Government of Canada has never stated that it would be responsible for the safety and quality of prescription drugs exported from Canada into the United States. . . ."*

Quite appropriately, GSK is not free to introduce its drugs into the American market on the basis of approvals from Health Canada or another foreign country. If pharmaceutical companies did such a thing, the FDA would object forcefully, and potentially bring enforcement action. The bottom line is that approvals from Health Canada may not now, and should not, be freely substituted for FDA approvals, as far as American law and the expectations of the American drug-consuming public are concerned.

Even if Congress and the American public were prepared to treat Canadian regulatory approval as a full substitute for FDA approval – and we don't believe they are – it should not be naively assumed that all drugs offered for sale on the Internet as Canadian are in fact authentic.

Nothing prevents an unscrupulous operator from taking orders from unwary US patients on the pretext of being a licensed Canadian pharmacy, but in fact filling those orders with outright counterfeit drugs, or with merchandise that originated outside Canada and was never imported into Canada in the first place.

The uncertainty about these Internet sites, and the inability of consumers to really know who is behind them and what their source of supply might be, is why this practice is so risky.

The proliferation of cross-border Internet pharmacy sales, which are effectively beyond regulatory oversight, will significantly increase the risk that patients will receive the wrong drugs; counterfeit drugs that have entered the Canadian market; outdated and improperly stored drugs that may or may not work properly; or drugs of unknown origin that are shipped to the US by Internet vendors fraudulently claiming to be in Canada. What could we possibly say to the family of a patient if someone dies because their asthma or heart failure medicine was stored improperly and is ineffective? Or perhaps didn't contain any active ingredient at all?

The uncertainty about these Internet sites, and the inability of consumers to really know who is behind them and what their source of supply might be, is why this practice is so risky.

Raising still more concerns for patient safety, cross-border Internet pharmacies may not conform to regulatory and non-governmental requirements for pharmacy practice. US mail order and US Internet pharmacies can be certified by the National Association of Boards of Pharmacy (NABP) and are fully regulated by the states in which the pharmacies are located, and in some cases the states in which patients receive medicines.

The Verified Internet Pharmacy Practice Sites (VIPPS) program issues a non-governmental seal of approval for US Internet pharmacy sites. To be VIPPS certified, a US Internet pharmacy must, among other things, comply with the licensing and inspection requirements of their state and each state to which they mail pharmaceuticals. They must also comply with other important VIPPS criteria, providing adequate protection of patient rights to privacy, authenticating prescription orders and ensuring their security, ensuring the quality of medicines, and providing meaningful consultation between patients and pharmacists.

In December of 2002, the Canadian National Association of Pharmacy Regulatory Authorities (NAPRA) announced that, in cooperation with the NABP, they would implement the VIPPS program in Canada. They stated that "on-line pharmacies that ship drugs into the United States will not be eligible for Canada's seal of approval."

Compliance with pharmacy practice standards designed to protect patients is a very real concern. For example, according to press reports, in May 2002, the Ontario College of Pharmacists, the regulatory body with responsibility for enforcing pharmacy practice standards in the Canadian province of Ontario, charged The Canadian Drugstore Inc. with 15 different violations, including operating an unlicensed Internet pharmacy without registered pharmacists from November 2001 to February 2002.

Lack of regulation in the cross-border trade in pharmaceuticals presents other risks as well. To cite one chilling example, patients who receive drugs across borders may entirely miss critical public advisories and warnings that regulatory authorities in the exporting country might issue through local media about the discovery of counterfeit lots in the distribution system and the need to take immediate protective steps. With cross-border pharmacy, there are no established mechanisms for managing drug recalls or adverse event reporting.

In these unregulated circumstances, Americans may essentially have access to prescription drugs without a prescription, without the advice and supervision of a doctor or pharmacist, and perhaps with no legal recourse if something goes wrong.

In these unregulated circumstances, Americans may essentially have access to prescription drugs without a prescription, without the advice and supervision of a doctor or pharmacist, and perhaps with no legal recourse if something goes wrong. Many Internet sites require patients to simply fill out a form and the Internet pharmacy physician prescribes the requested drug. Many also require the customer to sign a waiver giving up any rights to sue the Internet provider or their physician for any reason.

FDA is quite right to focus on these dangers even in the absence of documented cases of serious patient harm. And the FDA is not the only organization that opposes the cross-border sales of prescription drugs because they are illegal and unsafe. That position is mirrored by major pharmacy associations in Canada and the US.

The American Pharmacists Association (APhA) along with 44 US pharmacist groups, joined the Canadian Pharmacists Association (CPhA) in endorsing a landmark Cross-Border Communiqué between the US-based National Association of Boards of Pharmacy (NABP) and the Canadian National Association of Pharmacy Regulatory Authorities (NAPRA) opposing the issue of illegal cross-border importation of prescription drugs. In the Communiqué, the two associations stated:

> *"[P]rovincial pharmacy regulatory authorities in Canada and state pharmacy regulatory authorities in the United States agree that the international movement of prescription drugs between Canada and the United States undermines the regulatory systems established in each country to protect consumers. . . ."*

In addition, Craig Fuller, president and CEO of the National Association of Chain Drug Stores, wrote in November, "If the illegality of these schemes does not concern patients, the risks associated with buying drugs of questionable quality from unknown pharmacies in Canada certainly should."

"[P]rovincial pharmacy regulatory authorities in Canada and state pharmacy regulatory authorities in the United States agree that the international movement of prescription drugs between Canada and the United States undermines the regulatory systems established in each country to protect consumers. . . ."

Earlier this year, a number of Canadian Internet pharmacy sites attempted to get the Canadian Competition Bureau (the Canadian equivalent of the US Federal Trade Commission) to investigate GSK Canada for alleged breaches of Canadian competition law. In dismissing complaints about GSK Canada's action, the Competition Bureau specifically referred to advice they received from the FDA that cross-border dispensing of drugs to US patients violates the US Food and Drug Act.

In their press release, the Canadian agency stated, "From the Bureau's perspective, the fact that these cross-border sales violate US law [as FDA had advised] supports the position that GSK has a reasonable business justification for blocking the exports, while continuing to supply the Canadian market."

Yet despite the safety risks, Americans are drawn toward cheaper prices in Canada because of their concerns over the cost of those prescription medicines in the US. This is particularly true of seniors who, on average, consume more medicines than other age groups. For them, obtaining lower cost medicines from Canada understandably must seem to be an attractive option.

GSK's Patient Assistance Programs helped more than 400,000 Americans last year by giving away free products worth $168 million.

Prescription drugs are generally cheaper in Canada primarily because prices are capped by the Canadian Patented Medicines Price Review Board. But even without price controls, prescription medicines, like many other products, might still be cheaper in Canada due in part to differences in purchasing power and generally lower price levels between the two countries. Consider automobiles: according to an Associated Press article last year, a Dodge Caravan costs $31,000 in the US but just $21,000 in US dollars in Canada.

Some Members of Congress have asserted that the United States should allow importation of prescription drugs from Canada in the interests of "free trade." Yet allowing importation of drugs from Canada has absolutely nothing to do with the concept of free trade.

The US government supports free trade where fair trade exists, and takes action to protect US industries from unfair trade where governments interfere in the market and put US industries at an economic disadvantage. When one market is significantly distorted by government intervention, free trade cannot exist.

America's research-based pharmaceutical industry is in a difficult position in Canada. Price controls that Canada imposes benefit Canadian consumers, but do not allow US and European life sciences companies to realize a fair return on the value of innovative medicines, which often provide extraordinary life-saving benefits to many patients. We believe that Canada's price controls, like other such systems around the world, raise serious questions under the World Trade Organization (WTO) agreements.

The Canadian government's drug price controls cause more profound market distortions than the subsidies provided for Canadian wheat, softwood timber, dairy and other commodities. Yet the US Government has taken action and imposed tariffs to protect the economic interests of those US industries from the "unfair trade" represented by cheaper imports of such goods from Canada, although American consumers may have benefited from lower prices for food, housing, and other products. The United States is challenging the trade-distorting export practices of the Canadian Wheat Board in the WTO. In the case of pharmaceuticals, however, market dynamics assume a new dimension in terms of the very real risk to patient safety presented by unregulated cross-border trade of pharmaceuticals and the trade-distorting effects of Canadian price controls.

GSK understands the valid concerns of Americans who have difficulty paying for their medicines. That's why we have instituted a number of programs to help ensure access to medicines for Americans with lower incomes.

For years, GlaxoSmithKline and its heritage companies have provided Patient Assistance Programs to low-income patients without drug coverage. GSK's Patient Assistance Programs helped more than 400,000 Americans last year by giving away free products worth $168 million.

We recently enhanced and expanded these programs, increasing the eligibility requirements to $25,000 for a single person and 250% of the federal poverty level per family – approximately $46,000 for a family of four. For our oncology products, the income eligibility ceiling is even more generous – up to 350% of the federal poverty level – or $31,430 for a single person or $64,400 for a family of four.

We also pioneered the pharmaceutical industry's patient-savings card programs with the Orange Card™, which offers savings on GSK medicines to Medicare eligible seniors and the disabled of modest means who lack prescription drug coverage.

We also pioneered the pharmaceutical industry's patient-savings card programs with the Orange Card℠, which offers savings on GSK medicines to Medicare eligible seniors and the disabled of modest means who lack prescription drug coverage. After we introduced the Orange Card in 2001, GlaxoSmithKline also became a founding member of the Together Rx Card™ with six other companies. Combined, the Orange Card and the Together Rx Card have enrolled more than 943,000 patients, saving them an estimated $117.35 million since the program began.

Patients using either card are able to realize up to 40% savings on their GSK medicines -- prices that can be comparable to those advertised by Canadian Internet companies. And those patients have the protection and peace of mind that comes with using medications that meet the FDA's federally mandated safety and efficacy requirements, and that are dispensed at a trusted and accountable local pharmacy where they can speak face-to-face with a trained pharmacist if they have any questions or problems.

Forcing Americans to import drugs from other countries outside the jurisdiction of the FDA is simply not a sustainable system for meeting the healthcare needs of Americans, either from the standpoint of public health or continued medical innovation.

GSK's commitment to helping those with low incomes or who are otherwise in need extends well beyond these two programs. Last year, GSK invested more than $350 million in global community outreach programs, including product donations and charitable contributions.

As a percentage of pre-tax profits, that amounts to more than four times the average donated by the top 250 companies in the US. Our global programs include joining with the World Health Organization in an effort to eliminate a disease called Lymphatic Filariasis from the face of the earth. You may have not heard of this disease, but it affects 120 million people and threatens the lives and livelihood of billions in 80 countries.

GlaxoSmithKline will donate approximately six billion doses of medicines free over the next 20 years to eradicate this disease in what has been described by London's Financial Times newspaper as "the biggest single act of corporate philanthropy in any industry." We have also been a leader in providing access to HIV/AIDS medications at preferential prices through extensive programs in developing countries.

GSK urges the Congress to reject the very flawed premise that American consumers who cannot afford their medicines must take the risk of purchasing drugs from abroad, effectively beyond regulatory oversight or control. Drugs that are unsafe or ineffective are no bargain, no matter how low the price.

Yet any industry-sponsored program that offers prescription drug savings to Americans is only a stopgap until meaningful Medicare reform is passed by Congress. I recognize the complex political and substantive issues surrounding access to health care in general, and to prescription drugs specifically. But the only sustainable approach is to first enact a Medicare drug benefit that will both maintain free-market competition and ease the burden of concern for seniors. Then we can focus on providing appropriate incentives to make health care insurance affordable for the 40+ million uninsured.

Forcing Americans to import drugs from countries outside the jurisdiction of the FDA is simply not a sustainable system for meeting the healthcare needs of Americans, either from the standpoint of public health or continued medical innovation. GSK urges the Congress to reject the very flawed premise that American consumers who cannot afford their medicines must take the risk of purchasing drugs from abroad, effectively beyond regulatory oversight or control. Drugs that are unsafe or ineffective are no bargain, no matter how low the price.

Mr. BURTON. Mr. Brennan.

Mr. BRENNAN. Mr. Chairman and members of the committee, my name is David Brennan. I am the executive vice president for North America of AstraZeneca with responsibility for United States and Canadian operations.

AstraZeneca is a global, research-based pharmaceutical company employing 58,000 people. We provide a wide range of medicines for cancer, heart disease, mental illness, and other diseases. I am here today in response to your letter of June 3 to address the safety issues surrounding drug importation to the United States and to discuss the steps AstraZeneca Canada has recently taken to ensure the availability of our products for Canadian patients.

Let me start by saying we believe the fundamental issue confronting millions of Americans is lack of access to prescription drugs. Timely access to today's increasingly innovative medications improves health and saves lives, thereby reducing the health system costs of hospitalization, emergency care and long-term illness.

A meaningful first step to solving this problem is the enactment of a Medicare prescription drug benefit not drug importation legislation. Congress must pass a reasonable Medicare drug benefit this year. For 25 years, AstraZeneca has been doing its part to help individuals without coverage obtain the medicines they need. We are a founding member and active participant in Together RX, an industry drug savings program servicing more than 800,000 Americans. In 2002 alone, AstraZeneca gave more than $1 million Americans medicines worth over $400 million through our various patient assistance programs.

You asked me to testify today about the safety of pharmaceuticals imported to the United States by someone other than the manufacturer. To answer this question, it is important to clarify what safety means in the pharmaceutical industry. When it comes to medicines, safety involves many factors, the patient, product, packaging, storage and handling, transportation, labeling and shelf life among other things.

There are provisions in place to help ensure the safety of our products being sold through AstraZeneca in Canada for use by patients in Canada. However, the safety of product that leaves Canada outside of our distribution chain cannot be assured. The truth is there is little regulation of drugs exported from Canada. The Canadian Government itself has stated it cannot assure the safety of medications exported to the United States. That is why the FDA, including the agency's current leadership and 10 former commissioners, 2 Secretaries of Health and Human Services, the U.S. Customs Service and the Drug Enforcement Administration are on record as stating that importation of drugs from Canada or any foreign country would make it impossible to assure the safety of the American prescription drug supply.

As Secretary of Health and Human Services Tommy Thompson said in 2002, "Opening our borders to reimported drugs potentially could increase the flow of counterfeit drugs, expired and contaminated drugs, and drugs stored under inappropriate and unsafe conditions. That is a risk we simply cannot take."

The opening of U.S. borders to products from other countries including Canada would undoubtedly increase the risks of counterfeit

and contaminated medications circulating through our system. We are aware of previous testimony before Congress that included video of machines that counterfeiters utilize to mimic blister packs used by legitimate manufacturers. We believe that neither blister packaging nor any other technology solution will outwit counterfeiters and protect public safety.

It is in this context that AstraZeneca Canada has taken steps with respect to drug distribution in Canada to uphold the laws of the United States that provide a very important protection for our citizens.

Another important element of this decision was to ensure that the company had sufficient inventory of our products for citizens of Canada. No Canadian supplier has been precluded from purchasing the products necessary to meet the needs of Canadian patients.

AstraZeneca is actively participating in the debate about how to improve our health care system. What we do know is we should not put at risk a system that provides Americans with a continuing supply of safe, effective and innovative medicines that often make dramatic improvements in the health and lives of people of all ages.

Thank you.

[The prepared statement of Mr. Brennan follows:]

STATEMENT OF

DAVID R. BRENNAN

EXECUTIVE VICE PRESIDENT

ASTRAZENECA, LP

BEFORE THE

HOUSE GOVERNMENT REFORM

SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS

ON

"CANADIAN PRESCRIPTION DRUG

RE-IMPORTATION: IS THERE A SAFETY ISSUE?"

THURSDAY, JUNE 12, 2003

Testimony to the Sub-Committee on Human Rights and Wellness of the Committee on Government Reform by David M. Brennan, Executive Vice President, AstraZeneca, LP

Mr. Chairman, Members of the Committee, my name is David Brennan. I am the executive vice president for North America of AstraZeneca *LP*, with responsibility for US and Canadian operations. AstraZeneca is one of the world's leading pharmaceutical companies. Backed by a strong research base and extensive manufacturing and commercial skills, the company provides a powerful range of products for seven important areas of healthcare - gastrointestinal, cardiovascular, cancer, respiratory, neuroscience, pain control and infection. Headquartered in the UK, with R&D headquarters in Sweden and a strong presence in the US market, AstraZeneca sells in more than 100 countries, employs 58,000 people worldwide and values the diversity of skills and abilities that they bring to the business. The company is recognized as having one of the best development pipelines in the industry working to maintain a flow of new medicines designed to meet patients' needs. AstraZeneca is committed to building on this success, using its leading position in many important areas of medicine to make a difference to the lives of patients and the healthcare professionals who treat them.

I am here today in response to your letter of June 3, 2003, to address the safety issues surrounding drug importation into the US, and to discuss the steps AstraZeneca Canada has recently taken to ensure the availability of our products for our Canadian patients. Let me start by saying we believe that the fundamental issue confronting millions of Americans is the lack of access to prescription drugs. Timely access to today's increasingly innovative medications improves health and saves lives, thereby reducing the health system costs of hospitalization, emergency care and long-term illness. A meaningful first step to solving this problem is the enactment of a Medicare Prescription Drug Benefit, not drug importation.

Congress must pass a responsible Medicare Prescription Drug Benefit this year.

In the meantime, AstraZeneca is doing its part to help individuals without drug coverage obtain the medicines they need. We are a founding member and active participant in Together Rx, an industry drug savings program, servicing more than 600,000 Americans. In 2002 alone, AstraZeneca gave more than one million Americans medicines worth over $400 million through our patient assistance programs.

You asked me to testify today about the safety of pharmaceuticals imported into the United States. To answer this question, it's important to clarify what safety means in the pharmaceutical industry. When it comes to drugs, safety involves many factors—the patient, product, packaging, storage and handling, transportation, disclosures and labeling and shelf life.

There are provisions in place to help ensure the safety of our products being sold through AstraZeneca in Canada for use by patients in Canada. However, the safety of product that leaves Canada, outside of our distribution chain, cannot be assured. The truth is, there is little regulation of drugs exported from Canada. The Canadian government itself has stated that it cannot assure the safety of medications exported to the US.

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As Secretary of Health and Human Services, Tommy Thompson said in 2002, "Opening our borders to reimported drugs potentially could increase the flow of counterfeit drugs, expired and contaminated drugs, and drugs stored under inappropriate and unsafe conditions....That's a risk we simply cannot take."

Dr. Mark McClellan, Commissioner of the FDA, testifying before the House Agriculture Appropriations Subcommittee said: "There is absolutely no guarantee that those drugs are up to the standard."

The opening of US borders to products from other countries including Canada would undoubtedly increase the risks of counterfeit and contaminated medications circulating through our system.

The head of Global Corporate Security for another pharmaceutical company has testified before a subcommittee of the House Energy and Commerce Committee. He described one instance in which millions of yellow tablets were discovered, indistinguishable from a genuine product, consisting of boric acid, floor wax and lead-based, yellow road paint. He showed video of machines that counterfeiters are using to mimic blister packs used by legitimate manufacturers. We believe that neither blister packaging nor any other "technology" solution will outwit the counterfeiters and protect the public safety.

It is in this context that AstraZeneca Canada has taken steps with respect to drug distribution in Canada: to uphold the laws of the United States that are in force to provide a very important protection for our citizens. Another element of this decision was to ensure that the company had sufficient inventory of our products for citizens of Canada. No Canadian supplier has been precluded from purchasing the products necessary to meet the needs of Canadian patients.

There are many people around the world, like those in Canada, who believe that governments should control prices and direct the allocation of healthcare, rather than individuals. Some in Congress advocate changing to such a system. Regardless of which view prevails, I hope you would agree that it would be a terrible disservice to the people of this country to hide the fact that the consequences of making such a system change would substantially erode the many benefits that our free market healthcare system in the US provides. We currently enjoy access to safe, effective and break-through medications for the American people, and we must continue to provide this access. Clearly, our

health care system is not perfect and there are many changes needed, such as a Medicare Prescription Drug Benefit. AstraZeneca is a company that is thinking through the policy issues and is willing to be part of the debate. We should not put at risk a system that broadly does what the American people want it to do – provide them with a continuing supply of innovative, effective and safe medications that often make dramatic improvements in the health and lives of people of all ages. Thank you.

Mr. BURTON. Thank you, Mr. Brennan.

Mr. Viehbacher, do you see those charts over there? We have them up on the screen too. Flonase, do you make Flonase?

Mr. VIEHBACHER. We do.

Mr. BURTON. Do you see that blue part of the graph?

Mr. VIEHBACHER. Yes, sir.

Mr. BURTON. That is what you charge Americans for Flonase. You see the red part there?

Mr. VIEHBACHER. Yes.

Mr. BURTON. That is what you charge in Canada. Do you see the yellow part?

Mr. VIEHBACHER. Yes.

Mr. BURTON. That is what you charge in the UK. Can you tell me why the difference?

Mr. VIEHBACHER. Basically, pricing outside the United States is controlled by governments. I would say that the pricing comparisons are actually difficult to make because the way the U.S. system works means we often negotiate rebates with managed care organizations, also as you know Medicaid prescriptions.

Mr. BURTON. I understand that but if you go to a pharmacy in the United States and you buy Flonase, the blue graph is accurate and the same thing is true for the Canadian price and the UK price.

We have a very difficult time, as do most Americans, understanding why it costs three, four or five times as much for the very same product 50 miles apart. You can't explain that, can you?

Mr. VIEHBACHER. I can actually. I explained the price controls.

Mr. BURTON. Are you making a profit in Canada?

Mr. VIEHBACHER. We are.

Mr. BURTON. Are you making a profit in Great Britain?

Mr. VIEHBACHER. We are.

Mr. BURTON. You make a hell of a profit here.

Mr. VIEHBACHER. We make a profit in the United States as well.

Mr. BURTON. Where do you make the biggest profits? Any country in the world where you do business, where do you make the biggest profit?

Mr. VIEHBACHER. I can't speak for all the countries. We make a significant profit in the United States.

Mr. BURTON. Wouldn't you say you make the biggest profit by far in the United States?

Mr. VIEHBACHER. I don't have the profit numbers for all the countries in my head, Mr. Chairman.

Mr. BURTON. You do for Flonase, don't you?

Mr. VIEHBACHER. Yes.

Mr. BURTON. Let us look at that other graph we have up there, the other chart. That other chart is Pfizer. I can't go into Pfizer because you wouldn't be conversant with that.

Your plants in Canada that produce products sold here in the United States, are they inspected by the Food and Drug Administration?

Mr. VIEHBACHER. If we have a plant in Canada that produces for the United States, it would be normally inspected by the FDA.

Mr. BURTON. If you are producing a product in Canada that is approved by the FDA and sold in Canada, why does it cost so much less there than here because of the price controls in Canada?

Mr. VIEHBACHER. Yes.

Mr. BURTON. What kind of profit margin do you have in Canada?

Mr. VIEHBACHER. I couldn't tell you that off the top of my head.

Mr. BURTON. But it is a lot smaller than it is in the United States?

Mr. VIEHBACHER. It would be smaller, yes.

Mr. BURTON. Why is it that you make more money here in the United States than you do in Canada?

Mr. VIEHBACHER. The price is higher.

Mr. BURTON. Why is the price higher? If you are making a profit in Canada, why is it that it costs so much more here in the United States?

Mr. VIEHBACHER. Could I explain a bit about how international drug pricing works? With your indulgence, perhaps I could show a little bit about how we operate internationally and what the benefits are.

Mr. BURTON. I don't think we need to go into it in great detail. I think we pretty much have an idea how it works. If there are price controls, you have to negotiate with the government in question to sell your product and you agree upon a price, and that is the price charged.

In a free market like the United States, you charge whatever the market will bear. If it is a pharmaceutical product that is under patent, you have complete control over the pricing of that product.

Mr. VIEHBACHER. Subject to negotiation with managed care.

Mr. BURTON. I understand but you have the complete control over the price of that product because you have a patent for 16 or 17 years?

Mr. VIEHBACHER. We have an effective life of about 10 to 11 years.

Mr. BURTON. So 10 to 11 years, you have complete control over the patent price of that product and you negotiate with it used to be HMOs, not so much them anymore but hospitals, Wal-Mart and all those, but you set the wholesale price. You know what the wholesale price is. The wholesale price is kind of an arbitrary figure, isn't it? You come up with it, you have the patent, who knows what the wholesale price is.

Mr. VIEHBACHER. Pricing is basically based on competitive forces within the United States.

Mr. BURTON. Tell me about competitive forces. If you have a pharmaceutical product that is under patent, how do they compete against that? Tell me about competitive forces?

Mr. VIEHBACHER. Because managed care will look at the cost of therapy, there are alternative therapies. You may have a patent on a product but there may be comparable products.

Mr. BURTON. But there are drugs of choice. If a physician says this is the drug that is going to help my wife with breast cancer, Tomoxaphen, pretty much that is what she is going to use. She is not going to be shopping around saying my gosh, I am not going to go in the face of my doctor, she is going to use Tomoxaphen. So

you have pretty much a captive market if that is the drug of choice?

Mr. VIEHBACHER. If you think about Paxil, the antidepressant, basically managed care will look at the daily cost of therapy of Paxil, and there are other SSRIs on the marketplace. If that price were out of line, you can bet managed care would suddenly say to doctors, we will move this to a third tier co-pay for example.

Mr. BURTON. Sure, but what about a drug that deals with breast cancer that is the drug of choice?

Mr. VIEHBACHER. There again, we try to find out what the competitive forces are and look at the market.

Mr. BURTON. What competitive forces are you talking about in this particular case?

Mr. VIEHBACHER. Again, there are always various therapies. It is very rare that you have the only drug available.

Mr. BURTON. But if you do, you set the price?

Mr. VIEHBACHER. Yes.

Mr. BURTON. Wholesale, retail, whatever?

Mr. VIEHBACHER. Yes.

Mr. BURTON. Do you guys take doctors out to lunch and dinner and go into their offices with lunches for the people on the staffs?

Mr. VIEHBACHER. No. You may be aware there is a new voluntary code adopted by Pharma last year and basically things like that we don't invite doctors for dinners or things like that.

Mr. BURTON. My son-in-law is a doctor and he went to four dinners last week. Don't tell me that doesn't happen. Of course it happens, and he gets invited to golf courses and outings where they pay him $100 to go. You don't know about that? Does your company do anything like that?

Mr. VIEHBACHER. If we have an event organized on speaker program.

Mr. BURTON. A speaker comes in and shows a slide show about your product?

Mr. VIEHBACHER. Yes. We do invite doctors to that.

Mr. BURTON. I have gone to them. They don't want me to go anymore but I have gone to them. Can you guess why they don't want me to go?

To make a long stab in the dark, the fact of the matter is a lot of money is spent by the pharmaceutical companies to get the doctors to tout their products and to prescribe their products and that is understandable because in a free market, you do that, but if you have a captive product or a product in competition and the doctor prescribes it, and you charge a huge profit margin like you do in the United States and the doctor says, you can get that a lot less in Canada, it is to your benefit for them to buy it here in the United States, isn't it?

Mr. VIEHBACHER. The pricing is basically there on a patent life to make a return on your investment on the big risk we take on research and innovation.

Mr. BURTON. Let us talk about the big risk you take on research and development. The Boston Globe article of April 5, 1998 said "45 of the top 50 selling drugs got Government subsidies of $175 million. The average net profit on these drugs was 14 percent. NIH spent at least $1 billion on drug and vaccine development in fiscal

year 1996 but got $27 million in royalties. They spent $1 billion and got $27 million back in royalties. NIH is supposed to protect the public's investment by monitoring the drugs that have developed but in most cases, they can't even tell if the agency contributed to the development of the drug.

"The research and experimentation, the R&E tax credit, has never been a permanent component of the Federal Tax Code although it has been in effect almost continuously since 1981." Both your companies benefit from that. "The R&E tax credit was enacted only to help the economy recover during the recession of the early 1980's. Currently it assists pharmaceutical companies with as much as 20 percent of their research and development costs. According to the National Institutes of Health, they have assisted to subsidize the research and development of at least drugs recently that profited at least $500 million a year. In addition, the NIH granted almost $1 trillion, 1,000 thousand million, to for profit entities such as pharmaceutical companies for their research. The Joint Committee on Taxation estimates that the revenue lost from a permanent extension of the credit alone would total $56.4 billion from fiscal year 2004 through fiscal year 2013 on top of the nearly $1 trillion they already give."

So the pharmaceutical companies are getting all kinds of tax breaks and incentives and in many cases, the NIH is fully subsidizing the research and development you benefit from. Isn't that correct?

Mr. VIEHBACHER. No, sir.

Mr. BURTON. It is not correct? Let me give you an article in the paper yesterday.

Mr. VIEHBACHER. Could I quote another study, sir?

Mr. BURTON. On Taxol, who produces Taxol? Squibb. This is just one example. Squibb spent $1 billion but they have gotten $9 billion in worldwide sales. The NIH spent $484 million over 25 years to develop Taxol for research and development. The NIH received $35 million in royalties while Squibb got $9 billion and $684 million from beneficiaries over 5 years from Medicare. This was almost all the research and development money or the vast majority of it paid for by the taxpayers of this country and yet they made $9 billion worldwide and only paid royalties of $35 million.

Mr. VIEHBACHER. I can't comment on one specific.

Mr. BURTON. Has this happened to your company at all?

Mr. VIEHBACHER. Not to my knowledge. I can quote an NIH study which looked at the 47 top selling drugs in the United States. Only four of them were developed in part with technologies created by the NIH.

Mr. BURTON. Four of the top 47?

Mr. VIEHBACHER. Yes, sir.

Mr. BURTON. Who gave you that information?

Mr. VIEHBACHER. That is a study from the NIH. I can provide the committee with a copy of that.

Mr. BURTON. I guess it depends on who you are listening to because here the information I have is that 45 of the top 50 selling drugs got government subsidies of $175 million.

Mr. JANKLOW. Will the chairman yield for a moment?

Mr. BURTON. Sure. I will be happy to yield to my colleague.

Mr. JANKLOW. I would ask one quick question.

Sir, do you know Janey Kenney?

Mr. VIEHBACHER. Yes.

Mr. JANKLOW. I received a letter from her on February 28 of this year. It says, "Because of the great investment in R&D in the United States, approximately $24 billion through the National Institutes of Health and more than $30 billion from the pharmaceutical industry, the U.S. is the source of most of the innovative drugs in the world." Do you agree with the fact that Janey sent myself and other congressional people a letter that said "of $54 billion in investment in R&D for drugs, $24 billion came from the Federal Government and about $30 billion from the drug industry?"

Mr. VIEHBACHER. I am not actually familiar with that letter but if it is from Janey Kenney.

Mr. JANKLOW. I would like to put it in the record.

Mr. BURTON. Let us put it up on the board because I would like you to be able to read it. You said you know who she is.

Mr. JANKLOW. She is here, I believe.

Mr. BURTON. Oh, you are here. Come on up, we would love to hear from you. Would you like to join us here?

Let me read to you what she said. "Question: Why should American consumers and only American consumers bear the cost of pharmaceutical industry research and development."

Mr. VIEHBACHER. Mr. Chairman, we spent $4.3 billion.

Mr. BURTON. Let me finish and then you can comment.

Ms. Kenney said, "The fact is that the U.S. is one of the few relatively free markets in the world and Americans do subsidize the discovery and development of new medicines for the rest." Why don't they spread that around a little bit? Why is it that we in the United States have to pay for all this instead of spreading it around to Spain, France, Canada and Germany?

Mr. VIEHBACHER. As I explained, price controls exist in other countries, but because of the innovative nature and the free market, most of the R&D and most of the important R&D is actually being done in the United States. I believe it was Congressman Cannon who earlier mentioned that 80 percent of the referenced patents are filed in the United States.

Mr. BURTON. But why? You didn't answer my question. Why should the American consumer, a little old lady who is buying a product that will save her life or Flonase or something to make her life better, why should she pay four or five times as much as she could pay for it in Canada? Why should she, especially when it says we are subsidizing the research and development of new medicines for the rest of the world?

You say it is a shame but we are negotiating the contracts with these other countries who have price controls. When you are negotiating, why don't you throw that into the formula? Why should we bear the huge on Flonase?

Mr. VIEHBACHER. Mr. Chairman, the pricing is actually fixed by law. We have no opportunity to negotiate.

Mr. BURTON. You don't have to sell to them, do you?

Mr. VIEHBACHER. If you don't, we have seen in the past Canada has had compulsory licensing and you can imagine the price we would have if we withheld treatment from other countries.

Mr. BURTON. I don't want to monopolize this but the fact of the matter is we are paying for the rest of the world according to what you are saying. When we try to allow American citizens to buy either through the Internet or to go to Canada to buy these products at the lower price they might be able to afford, and a lot of these people can't afford to eat and pay for their pharmaceutical products, then you guys try to stop them by saying there is a safety issue. I think that is a red herring you guys keep hanging onto along with your supporters at the Food and Drug Administration.

Mr. Sanders.

Mr. SANDERS. Thank you.

Mr. Viehbacher, my understanding is that your company's reported profits grew 8 percent to nearly $27 billion in 2002 and your net profit before tax was $9.7 billion in pre-tax profit. The United States, which represents 54 percent of your company's total business, sales grew by 13 percent. Does that sound roughly right?

Mr. VIEHBACHER. Yes, sir, the net profit is about 18.5 percent for our company.

Mr. SANDERS. 18.5 percent. That is pretty good.

Mr. VIEHBACHER. That compares to Coca Cola at 22.5, Weight Watchers at 18.1, and Microsoft at 36.6.

Mr. SANDERS. But the difference between Coca Cola and that is a good point. Let us deal with that, two issues. One, year after year, the pharmaceutical industry, not just your company, leads all other industries in the profits they make. When you talk about the difference between Coca Cola and prescription drugs, what you are talking about are products that keep people alive, ease suffering as opposed to quenching our thirst on a hot day. So the issue here is why is it that year after year, your industry leads all other industries in profits. I know Bristol-Myers-Squibb is not here but it is important to place on the record former chairman and CEO Mr. Heinboldt made $75 million in compensation, actually $150 million, in 1 year.

Mr. Chairman, what you are talking about is an industry that has incredible sums of money because they make incredible profits and provide huge amounts of compensation to their CEOs. The other thing they are able to do is with all these profits, buy the U.S. Congress and the White House through huge campaign contributions.

I would ask Mr. Viehbacher maybe you can explain to some who might not know the answer but last year, above and beyond the money you put into Pharma which will spend $150 million this year trying to influence us not to lower the cost of medicine but Glaxo spent $4 million on lobbying in the 2002 election cycle, fielding 36 paid lobbyists.

The chairman of your company, Robert Ingram?

Mr. VIEHBACHER. No, he was the chief operating officer. He is now vice chairman of pharmaceuticals.

Mr. SANDERS. Headed a fundraiser which raised $30 million for the Republican Party in one night. What do you expect? Why would Glaxo presumably involved in producing drugs for the American

people, spend so much money on campaign contributions and lobbying? Does it have anything to do with the fact you want the American people to continue to pay by far the highest prices in the world?

Mr. VIEHBACHER. Mr. Sanders, we are the most regulated industry on the Earth.

Mr. SANDERS. You are the most regulated industry on Earth? You just told the chairman that in the United States you can do anything you want in terms of your prices. How are you regulated?

Mr. VIEHBACHER. In terms of the quality, which products we can sell, how they are used.

Mr. SANDERS. But not in terms of price.

Mr. VIEHBACHER. Sorry, you are right. I didn't mean that in terms of price. Yes, we have lobbyists. My understanding is we have seven lobbyists on staff. We may work with some outside.

Mr. SANDERS. But you hire other lobbyists when you need them?

Mr. VIEHBACHER. The thing about the United States is, unlike some countries, everything is transparent. All the lobbyists are actually registered, all the amounts of money we spend are publicly known. There are hundreds, there are thousands of lobbyists in Washington. We believe it is important that we participate in the democratic process that our side of the story is heard because if it isn't, the very things that make this industry so important to the United States, risks being eroded and lost.

Mr. SANDERS. Your side of the story is being heard. We cannot turn on radio or television without hearing your side of the story because with all of your profits, you are able to spend hundreds and hundreds and hundreds of millions of dollars a year defending your point of view. In fact, there are negative ads against Members of Congress who are trying to lower the cost of prescription drugs in this country and stand up for consumers. Do you want to comment on that?

Mr. VIEHBACHER. Mr. Sanders, first, when we pay for advertising, it has to do with our products, not for policy issues and to the best of my knowledge, we have never specifically paid for ads against candidates.

Mr. SANDERS. But Farmer(?) has?

Mr. VIEHBACHER. I can't answer that.

Mr. SANDERS. Trust me, they have.

Let me ask Mr. Brennan a question. You manufacture a product called Tomoxaphen, is that correct?

Mr. BRENNAN. Yes, we do.

Mr. SANDERS. Three or 4 years ago, I was the first Member of Congress to take constituents over the Canadian border to buy medicine that was less expensive. On that trip, we went with a number of women who were struggling with breast cancer. When they realized that they could buy Tomoxaphen, here is the latest chart I saw in American dollars, in the United States you charge for Tomoxaphen, which is a widely prescribed breast cancer drug which saves lives of women in this country, $233 and in Canada the charge is $29, a savings of 87 percent. When we took women over the border, they could not believe it. They were really in a state of shock to believe they could get such a discount.

My questions to you are, how many women in America have died because they cannot afford the outrageously high price at which you sell Tomoxaphen in this country which is about 10 times higher in Canada? How many children do you think are orphans in this country because of your pricing practice?

Mr. BRENNAN. I can't answer that question.

Mr. SANDERS. I understand it is a hard question to answer. Mr. Burton and I have asked for a GAO report to help us get this information. I would suspect that there are many women who have died in this country because you are charging them 10 times more for an antibreast cancer drug than our Canadian friends.

Mr. Burton asked a very important question.

Chairman TOM DAVIS. Would the gentleman yield? Your time has expired and we have indulged you. Would the gentleman yield, I haven't had an opportunity to ask questions. The chairman took 25 minutes and I wonder if the gentleman would yield on that point so I could also ask a question?

Mr. SANDERS. I would be happy to yield in 1 second. My question is you don't know how many women have died and my second question is, how do you sleep at night knowing that women in this country are suffering because they can't afford a product to keep them alive?

Mr. BRENNAN. We have made Tomoxaphen available in our Together RX Program for hundreds of thousands of people and we have given away for 25 years in our Patient Assistance Program Tomoxaphen to tens of thousands of women manufactured by us. Right now, the Tomoxaphen and the Together RX Program is less expensive than the generic version from Canada or is about the same price, about $11 or $13.

Chairman TOM DAVIS. Mr. Chairman.

Mr. BURTON. We are going to give you the time, Mr. Chairman.

Chairman TOM DAVIS. Let me ask you this.

How many lives have you saved because you developed this drug under a system that allows you to invest your money in research and development, not Federal tax dollars, but your money? Do you have any equation of that?

Mr. BRENNAN. I don't know the answer to that. It is tens of thousands of women who have benefited from this product.

Chairman TOM DAVIS. This is, in fact, a complicated equation, isn't it?

Mr. BRENNAN. Yes, it is very complicated.

Chairman TOM DAVIS. The difficulty with Mr. Sanders' perspective and the others, in my opinion, is that you can get today's drugs cheaper because we can pass a law and be heroes but tomorrow's drugs may save hundreds of thousands of lives would never be developed under a system where there are no rewards for sinking billions of dollars of private dollars in investment. Isn't that the issue?

Mr. BRENNAN. That is correct, Mr. Davis. The other point I would make is that the product Tomoxaphen was available generically in Canada and the patent had not yet expired in the United States, so we are comparing the price of a branded product with a generic product.

Chairman TOM DAVIS. Isn't it also a fact that there are HMOs and other groups that buy in bulk, that these products are available to Americans at much cheaper rates than the rates quoted by Mr. Sanders?

Mr. BRENNAN. That is correct. The prices that are handled through managed care and other contracting as Mr. Viehbacher said, are significantly less than the retail prices charged at pharmacy by people paying cash.

Chairman TOM DAVIS. I applaud Mr. Burton for highlighting the fact that in many cases, because Canada has price controls, their consumers get drugs cheaper than Americans and none of us up here feel very good about that. We feel that in some ways Americans are subsidizing the world. We create the jobs in America, the products and everything and none of us are comfortable with that. I am sure you aren't either. The question is what do we do about it?

The problem is that the solutions they are coming forward with also raise a number of concerns raised by the FDA which no PAC influences to my knowledge, and the professional scientists and so on that look at this raise concerns. I think instead of sitting and pointing fingers and worry about someone making a profit, we need to look at ways we can make these drugs more available on a cheaper basis to Americans. To the extent that our questions and concerns focus on that, we are going to come up with something good, not just a press release back home. That is my concern about this.

When the chairman and I talked about this, I think there are some legitimate issues we need to explore on the Canadian front because of what we discussed. Aren't there laws right now that make it difficult to reimport drugs even if we wanted to or maybe within Congress' control but not within your control, correct?

Mr. VIEHBACHER. Yes, it is illegal to import medicines which are not FDA approved into the United States. So medicines sold in Canada are not FDA approved so it is illegal to bring those into the country.

Chairman TOM DAVIS. So beating up on your, or your position on it, doesn't do us any good. We ought to beat up ourselves if we don't like that or the FDA. I think this is a complex issue. I think sometimes with the questions and rhetoric, we make this appear too simple. We heard the previous speaker talk about some of his concerns raised by the FDA. I am with the chairman, we want to try to meet the concerns they raise, not to use those as an excuse. I am concerned the line of questioning doesn't go in that direction.

Those are the questions I have right now, Mr. Chairman. I just wanted to make my position clear on this. I appreciate the witnesses being here today voluntarily. I would say on the political front, Mr. Sanders, they give large amounts of Democrats, they used to give more, they give to both parties. Your highlighting of the fact they gave a lot to the Republican Party last time hides the fact that a lot of Democrats have received and solicited money through the years and they have been active in the political process as have people on the other side of this issue.

Mr. SANDERS. Would the gentleman yield?

Chairman TOM DAVIS. I would be happy to.

Mr. SANDERS. I agree with them. I think they are buying both political parties. I think it is quite nonpartisan.

Chairman TOM DAVIS. It is called free speech.

Mr. SANDERS. Right now the Republicans are in control, so that is where the money is going. If the Democrats were in power, that is where the money would go.

Chairman TOM DAVIS. The soft money, the difficulty under campaign finance reform now, they can't give the parties soft money, so they will spend their own soft money, run their own ads and it won't be within the ambient of the two political parties. We have in effect under campaign finance reform, created a monster.

Mr. SANDERS. That is another issue.

Chairman TOM DAVIS. Right and left.

Mr. SANDERS. I would be interested in asking, since I know you have experience and background in this area, is this the most powerful industry in the United States of America in terms of their lobbying capabilities?

Chairman TOM DAVIS. No. I think it would be the trial lawyers or the AFL–CIO, in my opinion.

Mr. SANDERS. Not in terms of the money.

Chairman TOM DAVIS. In my opinion, Mr. Sanders, but you know more about them than I do because you have been on the receiving end of tens of thousands or hundreds of thousands from those groups.

Mr. SANDERS. That is right.

Mr. BURTON. Who is next? Mr. Allen.

Mr. ALLEN. Thank you, Mr. Chairman.

Let me say a couple of things by way of introduction. You are not the tobacco industry, you don't make a product which used as directed kills you or kills others. On the other hand, the concern that Mr. Sanders has expressed about the effect on our democracy is terribly worrying because your industry is, as you said, regulated in certain ways. The Government is fundamental to the success of your industry. You are not just another industry out there selling widgets. A lot of the basic research is federally funded.

When you bring a product to market, it is highly regulated, has to go through the FDA, and you are dependent on your patents. When your patents run out, you are in trouble. That is obviously true. So the entire structure of the industry is very dependent both on Federal dollars initially and on the structure of Federal laws.

That is why it is so troubling to see that your industry as a whole is always the most profitable industry in the country and at the same time the largest participant in terms of dollars than any other industry in terms of campaign contributions, lobbying expenses and independent television ads. So it looks to many of us like what has occurred here in this democracy that we all value is a combination of political and economic power that feeds off each other. The political power is dependent on the economic power and the economic power allows you to have political power. It is very alarming to many of us, particularly because we have so many constituents who would be helped by your products if they could only afford them.

You mentioned the Together RX card. I had one of my staff members try to get her mother registered for that Together RX card. It

was a challenge. There are very few people in Maine who know about it, it is not being advertised. She worked on the phone for a very long period of time in order to finally, it took months, to get registered. We tend to think from experience that is more of a PR function than something that is readily available to a lot of seniors. I am just saying that was our experience as she tried to go through this.

Mr. BURTON. Would the gentleman yield for just a second because I think this is relevant?

Mr. ALLEN. Yes.

Mr. BURTON. Glaxo spent $2.9 billion last year promoting their full price drugs and only $3-$4 million to promote the Together RX Program, so a lot of that was under the radar screen while they spent almost $3 billion on the regular full-priced program.

Mr. VIEHBACHER. Could I respond to that?

Mr. CANNON. Would the gentleman yield for a clarification? You said you're concerned about the domino effect of this industry on our political system which is founded on the Madisonian idea of factions. We believe that factions ought to compete pretty aggressively. Are you suggesting this industry is so powerful it overwhelms all the other factions in America?

Mr. ALLEN. On these issues, absolutely.

Mr. CANNON. On these issues? This is their business, their industry.

Mr. ALLEN. This is their business, but reclaiming my time, we are not talking about widgets or automobiles or toasters, we are talking about public health. That is why public health is both a public and private enterprise. In other aspect of the health system in this country, the Government exercises some leverage over price through reimbursement rates. The people come here, the doctors come here, the hospitals come here, the nursing homes come here and say we are not getting enough reimbursement from Medicare or Medicaid. Only the pharmaceutical industry runs free, only you can charge what you want.

Mr. Brennan, it might have been you or Mr. Viehbacher, one of you said that cash prices are much higher than what the insurance companies pay and that is true, we all know that. It is all about market power. So my question to you is what is wrong, what is so terribly wrong about Medicare, the largest health care plan in the country exercising the market power of those 40 million people who belong to Medicare like Aetna, CIGNA and the Blue Cross plans do for their beneficiaries? What is so terribly wrong about having them negotiate as a block, Medicare prices with your industry?

Mr. VIEHBACHER. Mr. Allen, I would say first of all I think that is exactly why a prescription benefit within Medicare is so important because that is a population that is largely uncovered today. We fully support efforts to try to get a prescription benefit passed.

Mr. ALLEN. Do you support a provision in that Medicare package which would authorize the Secretary of Health and Human Services to negotiate prices with pharmaceutical companies for Medicare beneficiaries?

Mr. VIEHBACHER. Mr. Allen, we believe that actually price controls and this has been demonstrated in many other countries, and I have personal experience with this, will damage overall the U.S.

economy because all of these things are interlinked. We tend to look at price but we can't ignore the fact that the quality of health care and the extensiveness of the research and development investment done here which generates so many jobs, if you look at the biotechnology industry, there are more people employed here than in Europe. I personally served on something called the High Level Working Group in Europe, invited personally by two European commissioners, to address the eroding competitiveness of research and development in Europe. Why? Because price controls kills the return for necessary innovation.

If we bring in too much price controls, we are going to have exactly the same level of R&D done in Canada. The PMPRB which is the Canadian agency that controls pricing also evaluates research and development done in Canada. It gave extremely low and critical marks to Canada for its failure to generate any kind of investment in R&D. So for the people waiting for the cures of things we can't invest in today, we will kill our ability to invest. The American people benefit from the fact they get first crack at the most innovative medicines in the world.

To give you an illustration of that, when Premiere Bourassa of Quebec suffered form leukemia, he came to the United States for treatment. When Gianni Angelli, the patriarch of the Fiat family, suffered from prostate cancer, he didn't rely on the Italian health care system, he came to the United States because the most innovative and most recent therapies are available here. We must not put that at risk.

Mr. ALLEN. Mr. Chairman, may I make one final comment?

Mr. BURTON. Sure.

Mr. ALLEN. I wish I could remember the name of the company because I rode from Europe to the United States about a year and a half ago with someone who worked for one of the European pharmaceutical companies. He gave me a different story, a very different story. I asked him specifically was there more research and development going on in the United States than in Europe, assuming there was, because of price controls present in Europe. He said, no, that is not it. He said the difference is to do your research, you have to go where the talent is. He said, in the United States, it is much easier to get someone from Texas to move to Delaware or Pennsylvania than it is in Europe to get a German to move to France or to Britain. He said, it is getting the talent that is the critical component. That is what he told me. I know the spin and I have heard it over and over again but it was someone who was a high official in one of the European companies who was directly involved in research.

With that, Mr. Chairman, I yield and I thank you.

Mr. BURTON. Mr. Gutknecht.

Mr. GUTKNECHT. Thank you.

I want to thank the witnesses for coming. It takes courage to come before this group and talk about this issue because it is so controversial and there is an awful lot of emotion built into this.

I want to come back to some of the issues. Let me say, first of all, I am a Republican and I don't think the word profit is a dirty word but I think there is something wrong with the word profiteer. I think we have seen such a dynamic change in this entire industry

in the last 5 years. For your people to even admit that you will use $2.9 billion promoting your full priced drugs this year, that is a phenomenal number. That makes Coca Cola look like small potatoes. I just think the nature of this business has changed.

I want to come back to the issue of the differentials in prices and the way different countries operate because this is a mystery. In fact, it is a bigger mystery than the average wholesale prices. You referred to that. Would you be willing to share with us what your average wholesale prices actually are on some of your various products or is that public information?

Mr. BRENNAN. Our average wholesale prices?

Mr. GUTKNECHT. Yes.

Mr. BRENNAN. Yes. I think that is public information. It should be readily available.

Mr. GUTKNECHT. For example, how are the prices for patent drugs set in Germany? It is my understanding there are no price controls on patented drugs in Germany.

Mr. VIEHBACHER. There are actually. Most of the health care in Germany is financed through quasi-public insurance companies. There is something called the BKK with whom you have to negotiate. It is not actually a free pricing environment as we sometimes think.

Mr. GUTKNECHT. But if I walk into a pharmacy in Munich, Germany, are those prices set by the government? I understand they are not.

Mr. VIEHBACHER. The price is basically not in competition. There isn't negotiation like you would have in France but there are basically negotiated limits and you won't be able to get your product reimbursed if you exceed certain levels.

Mr. GUTKNECHT. No, we are not talking about reimbursement. I am talking about an average American who happens to be in Munich, Germany and goes in and buys drugs. Those prices aren't set, are they? Here is the real issue. We bought 10 of what we think are the largest selling drugs in the United States and some are from each of your companies. The total in Munich, Germany came to $373.30 American. We priced those same drugs here in the United States, again cash prices, but remember a large chunk of America pays cash price, not just seniors, there are 41 million uninsured Americans, what do you think they pay and there are lots of Americans who have insurance with perhaps modest prescription drug coverage. So we are not talking about just a handful of people who pay cash price. It is actually a pretty good sized number but the total here in the United States was $1,039. How do we explain that difference to our constituents, especially based on what I know and what I have been told, they really don't have price controls in Germany?

Mr. VIEHBACHER. You will not be able to launch a product at the American price, I can assure you of that. I have to say there is no question that prices in the United States are somewhat higher. There are a number of factors and we have talked about those. One economist has clearly shown that tort costs are actually substantially at risk. About a third of the price difference according to this economist is explainable by our tort system here. To give you an example, if you have a product liability case in Europe or Germany

for example, $100,000 would be a big settlement. This is a cost to the system that is in there.

Even if we take out the rebates and even if we do this, yes, prices are higher in the United States. That does mean that some countries are getting a free ride in terms of R&D because it is paid for here. But we are also getting the benefit of having the R&D here.

Mr. GUTKNECHT. But you are getting the benefit too. I want to come back to this because I am also the vice chairman of the Science Committee. We will spend this year, American taxpayers, over $29 billion on basic research, about $24 billion of which companies like yours will benefit. For example Tomoxaphen, and there are a number of examples, we can argue which examples are which but I have a Senate report from a couple of years ago that essentially says, the National Cancer Institute, part of the NIH, sponsored 140 clinical trials of Tomoxaphen. The story we have is a big chunk of the research was paid for by the taxpayers on Tomoxaphen. Are we wrong in that?

Mr. BRENNAN. I don't know the specifics of how much was spent by the Government or by the company, but the company spent a lot of money discovering and developing Tomoxaphen along with the Government as we do with other cancer products and the NCI.

Mr. GUTKNECHT. We don't begrudge that but let me come back to the point. Would you be willing to allow us to audit your books to find out exactly how much you do spend on research?

Mr. BRENNAN. No. I don't think it is appropriate. I think we can provide you with the information we have for Tomoxaphen.

Mr. GUTKNECHT. Let me say this. We contract with defense contractors but in every defense contract we put in there that we have the right to audit them. Last week you may have seen that one of the defense contractors, we are going after them for $191 million in what we believe are excess profits.

Mr. BRENNAN. I just want to say that I think the arrangements we have entered with the National Cancer Institute by way of example are cooperative arrangements that advance science and they want to be very actively involved and we want them involved. We spend a lot more money on research in our company than we get from the Government to develop products.

Mr. GUTKNECHT. I have with you guys on tort reform and I am with you on research. I am glad we spend as much on research as we do but I don't know if we can continue to go back to our constituents and say we need to continue to subsidize the starving Swiss. It is time for them to pay their fair share. My solution may not be the best solution, but at least it is an answer.

If I could, Mr. Chairman, I want to put in the record, I don't know if you are familiar with some of the new technology coming out but in my hand I have a little vial and we will put it on the screen so you can see and in this little vial there are 150 computer chips. This is the new UPC code. This is going to change everything in terms of distribution of products. This combined with counterfeit proof, bubble pack packages is going to make it virtually impossible for imposters because we will be able to pass this through a detecting door and it will tell us exactly what that prod-

uct is, where it was made, when it was made, everything you need to know.

You said earlier you didn't think technology was going to be able to deal with the potential problems of reimportation. Are you folks working with counterfeit proof packaging and are you familiar with these new computer chips that replace the UPCs?

Mr. VIEHBACHER. First, I fully agree with you that counterfeiting is a major problem and we try to spend a lot of time figuring out these new technologies. It is a particular problem for us in some international areas. Thus far, we have not found any technology that actually works. The counterfeiters always manage to stay just right behind us.

Mr. BURTON. This product, and the gentleman's time has expired, this is the same technology we use on the $20 bill which works pretty well as far as counterfeiting is concerned.

We have two people left. Mr. Janklow.

Mr. CANNON. Mr. Chairman, I am willing to forego my time because I don't think we have time before the vote to get both of us in.

Mr. BURTON. Mr. Janklow, go ahead.

Mr. JANKLOW. I appreciate it and I will try and be brief.

You gave examples of other companies' rate of return, Microsoft, Coca Cola and yours. The fact of the matter is you are not aware of much taxpayers' money that has gone into research for Coca Cola, are you?

Mr. VIEHBACHER. I am not aware we are getting any more government money than Microsoft.

Mr. JANKLOW. You probably misunderstood me. Even though it is late, I will try and repeat it. Are you aware of any Government money that has gone into research at Coca Cola?

Mr. VIEHBACHER. No, sir.

Mr. JANKLOW. I want you to understand, I have gotten no money from the AFL–CIO nor either of your two companies and I love profit, I think it is a clean word. I am not accusing you of profiteering, I think most of your problems have been Government created. You are both aware of the Hatch, Waxman laws, aren't you?

Mr. VIEHBACHER. Yes.

Mr. BRENNAN. Yes.

Mr. JANKLOW. You are aware there have been a lot of accusations where people have figured out how to legally game the Hatch, Waxman laws, isn't that correct? Haven't those allegations been made?

Mr. VIEHBACHER. There have been allegations made.

Mr. JANKLOW. As a matter of fact, on some subsequent patents files, there have been attempts to protect for 30 additional months, there has actually been litigation with respect to some of those, hasn't there?

Mr. VIEHBACHER. There may be some. I am not aware.

Mr. JANKLOW. Are there any with your company?

Mr. VIEHBACHER. Specific litigation on which patents?

Mr. JANKLOW. On any patents where you sought a 30-month extension under the Hatch-Waxman law?

Mr. VIEHBACHER. Yes, we have sought a 30-month extension under Hatch-Waxman.

Mr. JANKLOW. Has there been any litigation with respect to your company where they have actually litigated the 30-month extension?

Mr. VIEHBACHER. Yes.

Mr. JANKLOW. Was your company successful or unsuccessful in that litigation?

Mr. BRENNAN. I believe we demonstrated the validity of our patents with four of the five companies that we were involved with.

Mr. JANKLOW. Are you familiar with the FTC study of 2002 called "The Generic Drug Entry Prior to Patent Expiration," July 2002, the FTC report? Are you gentlemen aware of that?

Mr. BRENNAN. Yes, I have heard of it. I am aware of some of the facts. I don't know if I know them all.

Mr. JANKLOW. That study reports of the four cases that actually went to court on the 30-month extension, the drug companies were unsuccessful in all four of those pieces of litigation. Would that be incorrect, sir?

Mr. BRENNAN. I am not sure I know the specific answer.

Mr. JANKLOW. With respect to the pricing, the fact of the matter is, you are both aware, aren't you, that nonprofit corporations in the United States cannot be held in violation of the Robinson-Patman price fixing laws, correct?

Mr. BRENNAN. Nonprofit companies?

Mr. JANKLOW. Yes.

Mr. BRENNAN. I take your word for it.

Mr. JANKLOW. Let me ask it this way. When your companies sell to hospitals through wholesalers, they get the cheapest price of all, don't they?

Mr. BRENNAN. No, that is not the case.

Mr. JANKLOW. Can you tell me who gets a cheaper price than a hospital?

Mr. BRENNAN. The Government through FFS pricing and through Medicaid.

Mr. JANKLOW. THS and the Indian Health Service.

Mr. VIEHBACHER. Medicaid by law gets the lowest price.

Mr. JANKLOW. Medicaid is matching. Don't you give a rebate to the States on Title 19 Medicaid based on the lowest price you sell someplace else. That is the way Medicaid works, isn't it?

Mr. VIEHBACHER. We have to provide Medicaid with our best possible price, so no one can get a lower price than Medicaid.

Mr. JANKLOW. The only reason a Medicaid price is set is because it is set at what you sold to somebody else at a price?

Mr. BRENNAN. Not necessarily.

Mr. JANKLOW. I believe the law says when it comes to Medicaid reimbursement by State and local governments, you have to rebate to the State and local governments, whoever is the Medicaid provider, the equivalent of the lowest price that you sell to someone else. That is where the rebate program comes in.

Mr. BRENNAN. Or a minimum of 15 percent, so if we are selling it to everyone else at a rate that is above the 15 percent discount, Medicaid gets the difference.

Mr. JANKLOW. With respect to the sales you make to hospitals, am I incorrect that say in South Dakota a wholesaler sells a drug they would sell at a particular price to a drug company and at the

end of a month they would send a billing to your company who would give them their mark up plus the difference between the price they are supposed to charge the hospital and the price they charge others?

Mr. BRENNAN. I am not familiar with any products we have where the hospitals operate that way.

Mr. JANKLOW. Are you sure with respect to Glaxo?

Mr. VIEHBACHER. I am not aware of those either.

Mr. JANKLOW. Do you know whether or not your companies do it? You both may not be aware and I realize you are senior executives, but are you aware whether or not your companies do that?

Mr. BRENNAN. We work through group purchasing organizations who sell to hospitals but the prices are strictly controlled. We are audited for Medicaid and we know our Medicaid best prices and I am certain that best price is offered to Medicaid even if the hospital is getting a better price.

Mr. JANKLOW. Quickly, if I could. With respect to the pricing for your products, based on negotiation you sell to a national chain pharmaceutical house, like Walgrens which gets a better price than a sole proprietor druggist in Timbuktu, America, don't you?

Mr. BRENNAN. In the case of AstraZeneca, the small pharmacies in those places in America buy from wholesalers, so we sell through wholesalers primarily.

Mr. JANKLOW. They can't buy from your direct, can they?

Mr. BRENNAN. We have a minimum amount of purchase.

Mr. JANKLOW. Walgrens meets it and they don't?

Mr. BRENNAN. That is correct.

Mr. JANKLOW. Is that also the way it is with Glaxo?

Mr. VIEHBACHER. That is my understanding.

Mr. JANKLOW. The teldrugs, the giant mail order operations, operate the same way, don't they?

Mr. VIEHBACHER. I couldn't say, sir.

Mr. BRENNAN. I don't know.

Mr. JANKLOW. Neither one of you know?

Mr. BRENNAN. Mail order operations.

Mr. JANKLOW. Large purchasers of drugs sent in mail order get preferential pricing based on the volume, as you said?

Mr. BRENNAN. Pharmacy benefit managing companies?

Mr. JANKLOW. No, just a plain mail order pharmacy like Teldrug, for example?

Mr. BRENNAN. I believe if they didn't meet our minimum purchasing requirements, they would get their product from the wholesaler and the wholesaler position price.

Mr. JANKLOW. The price you charge in America to the various purchasers is not based upon the cost of doing the individual sales transaction, there is more to it than that? The savings you have by selling 100,000 to a Walgrens as opposed to 5,000 to an individual pharmacy or to a wholesaler based on 5,000, the break is more than just the incremental savings there is in volume purchasing, isn't it?

Mr. BURTON. We have 4 minutes on the clock on the floor. Thank you, Mr. Janklow.

Mr. JANKLOW. Thank you, Mr. Chairman, for your indulgence.

Mr. BURTON. One thing I would like to point out is GlaxoSmithKline agreed to pay $87.6 million to settle civil charges it had overcharged the Medicaid Program for Paxil, an antidepressant and Flonase, an allergy spray. The deal also involved relabeling medicines for Kaiser. Let me ask one question because we have to run.

"GlaxoSmithKline will stop providing our products to those pharmacies and other wholesalers who distribute the products to them if they continue selling to other countries." That is correct? You have said that, right?

Mr. VIEHBACHER. Our Canadian affiliate will not provide product to Internet pharmacies.

Mr. BURTON. Are either one of your companies going to cut sales to Canadian pharmacies if they continue to sell to other countries?

Mr. VIEHBACHER. That is our intention.

Mr. BURTON. Is that your intention as well?

Mr. BRENNAN. We distribute through wholesales there and we are on an allotment program, so the wholesalers make the decision about who gets product but we are allocating the product within Canada.

Mr. BURTON. So if they sell to America or any other country, you are going to cut back on production of supply you send there which would be a burden on the Canadian people?

Mr. BRENNAN. We are not knowingly going to facilitate the violation of U.S. law if we think the products are going out.

Mr. BURTON. So the FDA is saying it is illegal to sell to the United States because of safety reasons and you are backing them?

Mr. BRENNAN. The law is in place to ensure the safety of our products here.

Mr. BURTON. And that is the only reason? It is not because of the excessive prices you are charging in America? It has nothing to do with these prices?

Mr. VIEHBACHER. The amount of product coming across the border from Canada is less than 1 day's sales in the United States. It is an unsafe practice. Products are not the same. Here is one.

Mr. BURTON. I understand but the long-term concerns you have is there might be a flood of people, not just a million buying up there, but tens or hundreds of millions of people that might start buying from Canada instead of through the U.S. system.

Thank you very much for being here. We stand adjourned.

[Whereupon, at 6:37 p.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]

[The prepared statement of Hon. Chris Cannon and additional information submitted for the hearing record follows:]

June 12, 2003
Statement of Congressman Chris Cannon
Subcommittee on Wellness and Human Rights
Government Reform Committee
"Canadian Prescription Drug Importation: Is There A Safety Issue?"

Thank you Mr. Chairman for calling today's hearing. I share your interest in and desire to improve our nation's healthcare system while ensuring that all Americans have access to affordable and safe prescription drugs.

The third district of Utah may not resemble the Chairman's district in regard to the environment and topography, but I suspect the two are very similar in regard to the need for affordable medicines for our constituents. It is important to find affordable solutions for the growing number of uninsured and ensure that Medicare beneficiaries can afford life-saving medicines without sacrificing other basic needs.

The statistics are well known; of the current 40 million Medicare beneficiaries there are tens of millions without prescription drug coverage. With an additional 80 million from the baby boom generation entering into the Medicare system in the next few years the current system will fail, it is just not designed to accommodate such large numbers of beneficiaries. Congress has held countless hearings on the need to include prescription drugs in the Medicare program and we have all heard stories of families and individuals devastated by the physical and financial burden of chronic diseases and illnesses. It is not surprising that our inability to pass a Medicare drug provisions has led many in Congress to pursue other means of providing prescription drugs for those in need. While the intentions of these piecemeal approaches have been honorable, I am concerned that they are not sustainable in the long run and often expose seniors to unnecessary risks.

The idea of opening U.S. borders to allow the re-importation of drugs from Canada seems benign, but as is often the case, the devil is in the details. A recent report from Health Canada, their version of the FDA, made clear that Canada can not, and will not, vouch for the safety of medicines exported to the U.S. Furthermore, there is a legitimate concern that allowing importation from Canada would establish a pipeline for adulterated and counterfeit drugs to make their way into our country. As a member of the Congressional Diabetes Caucus, I found it particularly troubling to learn that insulin has been found in counterfeit form in several countries. Some of the fake products were simply vials filled with sugar water, other instances were far more insidious, the counterfeits contained compounds capable of inducing heart failure in patients. While the Untied States currently enjoys the most safe and effective drug regulatory system in the world, the idea of overturning the Prescription Drug Marketing Act, which is intended to protect consumers, or stretching our already over-burdened regulatory agencies even more broadly causes me great concern. It speaks volumes that eleven former FDA

Commissioners from both Republican and Democratic Administrations have stated that re-importation is dangerous for patients.

So where does that leave us, and more importantly where does it leave the millions of Medicare beneficiaries without prescription drug coverage? In spite of the program's shortcomings, I believe that Medicare can be modernized and is the correct means by which to provide America's seniors safe and affordable medicine. President Bush, working with our conference and leaders from both Houses of Congress, has given this task high priority on his domestic agenda and he has thus far proven very effective in accomplishing that which he sets out to do. I understand that enactment of a prescription drug provision will probably be neither easy nor particularly fast, but that is no reason to risk the safety of the very people we are trying to help. I have seen statistics and charts comparing drug discount cards to the cost savings data from Canada and I have been impressed and encouraged with the comparable savings these readily available cards provide to needy seniors without the risks associated with re-importation.

I look forward to learning more about this issue today and I am ready to work with my colleagues toward our shared goal of providing safe, affordable, cutting-edge medicines to our most deserving citizens. Thank you.

Congress of the United States

Washington, DC 20515

June 2, 2003

David M. Walker
Comptroller General
General Accounting Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Walker,

Prices for prescription drugs in the United States are astronomical. In some cases, they are ten times higher than prices for the same drugs in other developed countries. The pharmaceutical industry, citing safety concerns, has opposed legislation that would enable American consumers to obtain prescription drugs at prices available elsewhere on the world market. As a result of the high cost of prescription drugs, many Americans without adequate prescription drug coverage, particularly seniors, are forced to choose between buying prescribed medications and buying other essential commodities, including food.

According to the Kaiser Family Foundation, almost twenty-five percent of seniors in eight states surveyed did not fill or skipped doses of their prescription drugs to make their medicines last longer, regardless of prescription drug coverage. More than thirty-three percent of seniors without drug coverage did not fill or skipped doses, a rate twice as high as for those with coverage. As startling as these findings are, they tell us little definitively about the adverse outcomes suffered by those who cannot afford to take their prescription medications as prescribed or at all. Unfortunately, there is very little documentation of the nature and scope of adverse outcomes caused by patients skipping doses or forgoing their medications altogether because they cannot afford them.

While Congress debates various aspects of the prescription drug crisis in the United States, we believe information regarding the toll that unaffordable prescription drug prices are having on Americans' health is desperately needed. Therefore, we would like to request that the General Accounting Office conduct an investigation to address the following questions:

1. To what extent are elderly Americans failing to obtain medications (including refills) that have been prescribed for them by a physician?
2. What are the primary types of medications that elderly Americans are failing to obtain?
3. What are the primary types of medical conditions for which these medications are prescribed?
4. To what extent are elderly Americans seeking emergency treatment for the medical conditions most frequently associated with unfilled prescriptions?
5. To what extent are elderly Americans dying due to medical conditions most frequently associated with unfilled prescriptions?

PRINTED ON RECYCLED PAPER

Thank you very much for your attention to this request.

Sincerely,

Dan Burton
Chairman
Subcommittee on Wellness and Human Rights

Diane Watson
Ranking Member
Subcommittee on Wellness and Human Rights

Bernard Sanders
Member of Congress
Subcommittee on Wellness and Human Rights

FDA SAFETY CONCERNS

Assertion:

William K. Hubbard, Associate Commissioner for Policy and Planning, FDA

- The FDA cannot assure the American public that drugs imported from foreign countries are the same as products approved by the FDA.

Rebuttal:

FDA Week - June 2, 2003 – "FDA Commissioner McClellan Says 'Reimportation' Possible Once Tracking System in Place"

- "They keep drugs safe within Canada, and I think they do a very good job of that," FDA Commissioner McClellan told *FDA Week*. "But they stopped short of saying they can assure the safety of drugs exported to the United States. But since we can only assure the safety of drugs within our own regulatory system, there is a risky gap there."

FDA Week - June 2, 2003 – "FDA Commissioner McClellan Says 'Reimportation' Possible Once Tracking System in Place"

- "There are some steps that we can potentially take to improve the technology used in monitoring the distribution of drugs in the entire distribution chain," McClellan said. "If we can work that out, then maybe there's a way to work beyond the borders in that effort as well."

Congressional Research Service Memorandum – May 28, 2003
Subject: Questions Concerning the U.S. and Canadian Regulatory Systems for Approving and Distributing Prescription Drugs

- "Canadian health officials said there is little evidence of a counterfeit drug problem in their country at this time. As for the United States, the FDA has anecdotal evidence, but little quantitative data, on the number of counterfeit drugs being produced or imported into this country."

Assertion:

William K. Hubbard. Associate Commissioner for Policy and Planning, FDA

- "When purchasing drugs on the Internet, American consumers cannot be certain that the drugs that the drugs they receive are actually dispensed by the person from whom they are ordered."

Rebuttal:

Testimony of Mr. Andy Troszok, Vice President of Standards, CIPA, before the Subcommittee on Human Rights & Wellness, April 3, 2003

- "So what we did was mirrored our CIPA (Canadian International Pharmacy Association) certification behind the VIPPS (Verified Internet Pharmacy Practice Sites, which issues a non-governmental seal of approval for U.S. Internet pharmacy sites) certification."

Testimony of Dr. Elizabeth A. Wennar, President & CEO United Health Alliance, before the Subcommittee on Human Rights & Wellness, April 3, 2003

- "IMPAC is {the} Internet and Mail Order Pharmacy Accreditation Commission … made up of pharmacists and physicians from Canada, the United States, and Mexico… IMPAC is an accreditation process that is much like the Joint Commission on Accreditation of Health Care Organizations."

Assertion:

William K. Hubbard, Associate Commissioner for Policy and Planning, FDA

- "Consumers who buy prescription drugs from foreign countries are at risk of suffering adverse events, some of which can be life threatening."

Rebuttal:

FDA Commissioner McClellan speech before the Commonwealth Club. San Francisco, California. June 9, 2003

- "These approved products, while safe and effective to the best of our knowledge when used as intended, are involved too often in costly and potentially preventable adverse events …"

FDA Commissioner McClellan speech before the Commonwealth Club, San Francisco, California, June 9, 2003

- "… This includes medical errors as many as 20% of Americans have experienced some kind of significant medical error. Preventable errors and complications involving prescription drugs alone are responsible for thousands of deaths, millions of emergency room visits and hospitalizations, and billions of dollars in additional health care costs each year, in addition to all of the unnecessary suffering …"

FDA Commissioner McClellan speech before the Commonwealth Club, San Francisco, California, June 9, 2003

- "… There's too much wasted money that would be better spent on care that actually made people healthier."

Institute of Medicine Press Release, November 29, 1999
Subject: Preventing Death and Injury From Medical Errors Requires Dramatic, System-Wide Changes

- "The human cost of medical errors is high. Based on the findings of one major study, medical errors kill some 44,000 people in U.S. hospitals each year. Another study puts the number much higher, at 98,000 …"

Institute of Medicine Press Release, November 29, 1999
Subject: Preventing Death and Injury From Medical Errors Requires Dramatic, System-Wide Changes

- "… Even using the lower estimate, more people die from medical mistakes each year than from highway accidents, breast cancer, or AIDS."

Assertion:

William K. Hubbard, Associate Commissioner for Policy and Planning, FDA

- "It is illegal under the Federal Food, Drug, & Cosmetic Act, to import unapproved, misbranded, and adulterated drugs into the U.S. This includes foreign versions of U.S. approved medications."

Rebuttal:

MEDS Act (Medicine Equity and Drug Safety Act – Public Law 106-387)

- Section (1) Conditions:

  This section shall become effective only if the Secretary (of Health and Human Services) demonstrates to the Congress that the implementation of this section will -

MEDS Act (Medicine Equity and Drug Safety Act – Public Law 106-387)

- (1) pose no additional risk to the public's health and safety;

and

- (2) result in a significant reduction in the cost of covered products to the American consumer

U.S. Government Subsidies

Written testimony of Christopher Viehbacher, President, US Pharmaceuticals, GlaxoSmithKline, June 12, 2003

- "… Yet Americans subsidize the rest of the world in many ways: from the $15 Billion we will spend to help address the epidemic of AIDS in developing countries, to the $15 – $20 Billion we send to other countries in direct foreign aid."

April 30, 2003, written response from Janie A. Kinney, Vice President, Federal Government Affairs & Public Policy, GlaxoSmithKline, to Chairman Dan Burton's letter of inquiry.

- DB: "Why should American consumers, and only American consumers, bear the cost of the Pharmaceutical industry's research and development?"
- JK: "The fact is that the U.S. is one of the few relatively free markets in the world, and Americans do subsidize the discovery and development of new medicines for the rest …"

April 30, 2003, written response from Janie A. Kinney, Vice President, Federal Government Affairs & Public Policy, GlaxoSmithKline to Chairman Dan Burton's letter of inquiry.

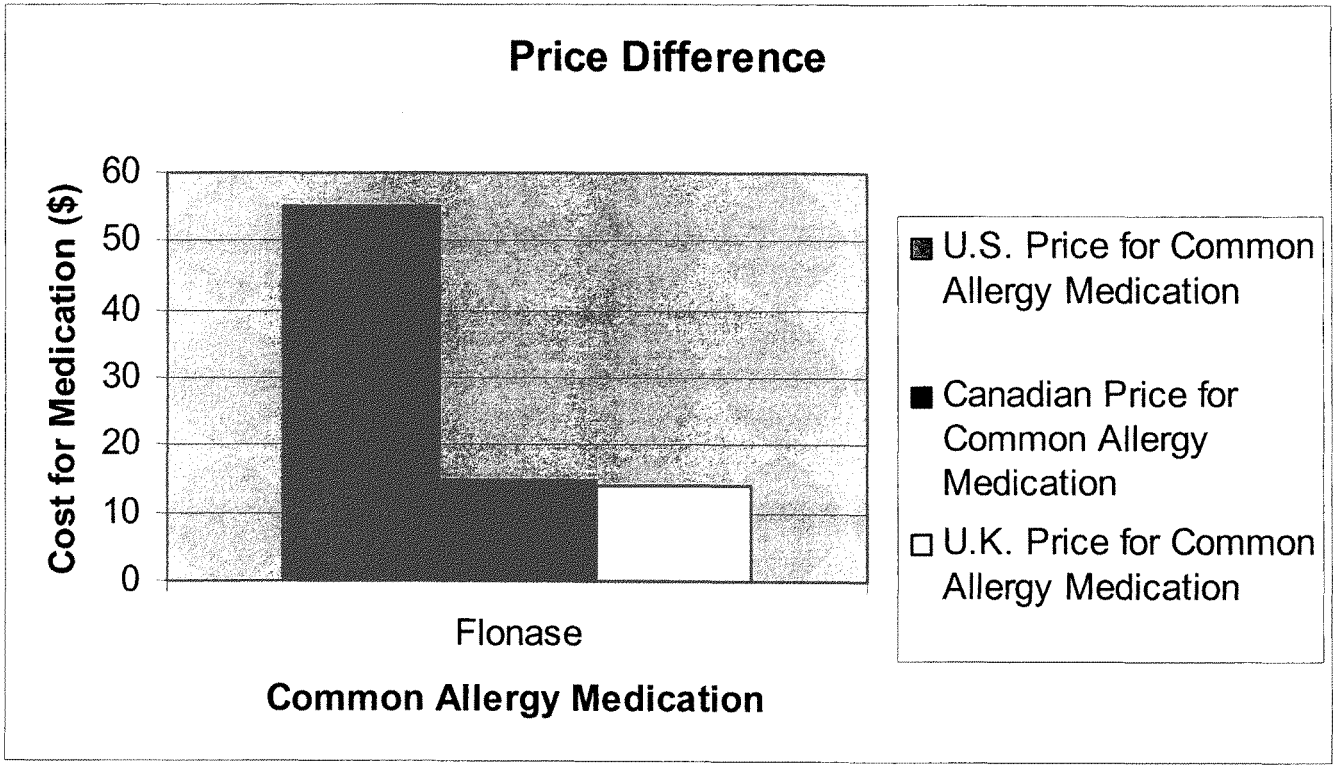
- JK (cont.): "… It's not fair and we are making efforts to change it."

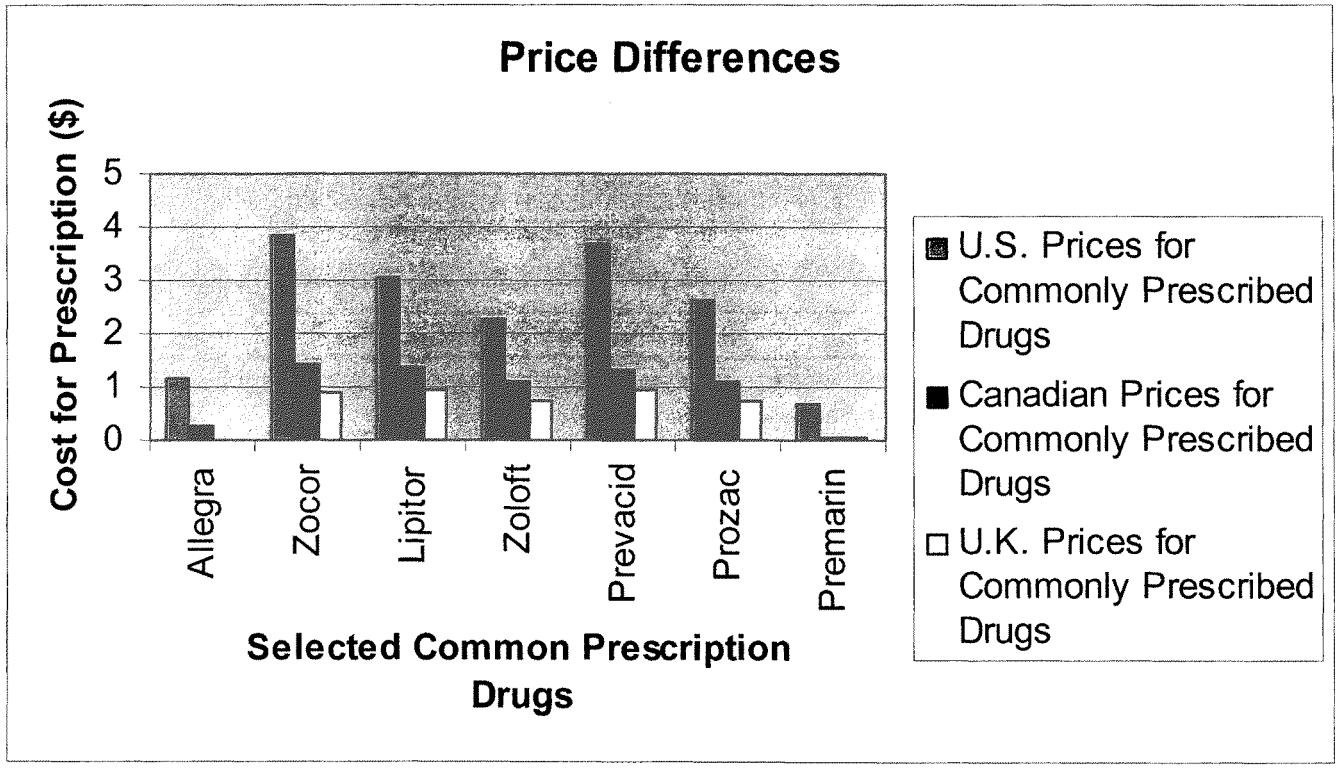
Canadian Pharmacies Cut Off

- "We have found that a number of pharmacies are selling our products for export outside the country through the Internet or direct export, and we are now in communication with them to cease exportation," say Executives of GlaxoSmithKline…

- "… GSK (GlaxoSmithKline) will stop providing our products to those pharmacies and to the wholesalers who distribute our products to them, if they continue selling to other countries."

- "It was reported that AstraZeneca became the second major drug company to limit sales of its products to Canadian pharmacies and wholesalers. In April, AstraZeneca sent a letter to Canadian pharmacies and wholesalers advising that some orders would be reduced due to a new allotment program initiated because of unexpected sales increases."


Price Difference
Cost for Medication ($)
60
50
40
30
20
10
0
Flonase
Common Allergy Medication
U.S. Price for Common Allergy Medication
Canadian Price for Common Allergy Medication
U.K. Price for Common Allergy Medication


Price Differences
Cost for Prescription ($)
5
4
3
2
1
0
Allegra
Zocor
Lipitor
Zoloft
Prevacid
Prozac
Premarin
Selected Common Prescription Drugs
U.S. Prices for Commonly Prescribed Drugs
Canadian Prices for Commonly Prescribed Drugs
U.K. Prices for Commonly Prescribed Drugs

Common Drugs Bought in Canada

TOP SELLING DRUGS: EXAMPLES OF PRICE DISCREPENCIES		U.S.	Canada	U.K.
Drug Names	Company	Internet Discount Price Per Dosage	Internet Discount Price Per Dosage	UK Price Per Dosage
Flonase	GlaxoSmithKline	$ 55.010	$ 14.660	$ 14.100
Lipitor	Pfizer	$ 3.035	$ 1.348	$ 0.930
Zoloft	Pfizer	$ 2.247	$ 1.081	$ 0.713
Prozac	Various	$ 2.627	$ 1.098	$ 0.730

Janie A. Kinney
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April 30, 2003

The Honorable Dan Burton
Chairman
Subcommittee on Human Rights and Wellness
U.S. House of Representatives
2185 Rayburn House Office Building
Washington, DC 20515-1405

Dear Chairman Burton:

JP Garnier has asked me to respond to your letter of April 17.

We understand and share your concerns about assuring access to prescription medicines for patients in the U.S. We do not want a lack of insurance coverage or financial means to put a patient at risk by either not filling a prescription or filling it through illegal, potentially unsafe means. Accordingly, we do not believe that having patients rely on illegal cross-border Internet sales is a viable "solution" to providing safe and affordable access. Our actions reflect this belief. Secretary Thompson, the Food and Drug Administration (FDA), and the US Customs Service agree, and have made statements to Congress, that prescription medicines dispensed to US patients from foreign pharmacies are illegal and pose significant risks.

GlaxoSmithKline (GSK) and its heritage companies have provided patient assistance programs for years to low-income patients without drug coverage. GSK's patient assistance programs helped more than 400,000 patients last year by giving away products worth $168 million. We are in the process of enhancing and expanding the programs, including expanding the eligibility requirement to $25,000 (single) or 250% of the federal poverty level (multi-person household). For our oncology products, the income eligibility ceiling is even higher -- up to 350% of the federal poverty level.

More recently, we pioneered a consumer-savings program, the Orange Card℠, for Medicare beneficiaries of modest means without prescription drug coverage. Subsequent to its introduction in 2001, we joined with six other companies to offer the Together Rx Card™. More than 711,000 beneficiaries have enrolled and have saved an estimated $87 million since the programs began. Incidentally, patients using either card are able to realize a net price on GSK medicines that can be comparable to prices advertised by Canadian Internet companies, and still have the protection and peace of mind that come with filling prescriptions at a trusted, accountable local pharmacy.

While I know you are primarily concerned about American patients, GSK's efforts to assure access to our medicines are not limited to the U.S. In fact, last year GSK invested more than $350 million in global community outreach programs, including product donations and charitable contributions.

As a percentage of pre-tax profits, that amounts to more than four times the average given by the top 250 companies in the U.S. Our global programs include donating treatments to protect people at risk for Lymphatic Filariasis, also known as elephantiasis, a disease affecting 120 million people in 80 countries; and providing access to HIV/AIDS medications at preferential prices through extensive programs in developing countries.

In response to your specific questions, we provide answers below.

Question: Why did you decide not to appear at the Subcommittee hearing on April 3, 2003?

We have clearly and publicly stated our position on the cross-border sale of prescription medicines over the Internet and the reasons for our actions to curtail the illegal practice. In our judgment, our appearance at the hearing would have been a diversion from the more important issue -- developing solutions for assuring safe access to medicines while preserving the incentives to develop new ones.

We are continuing to work toward viable solutions for providing safe and affordable access to medicines to Medicare beneficiaries and low-income, uninsured patients that assure them access without putting them at risk.

In spite of the lower prices in Canada, does your company still make a profit from your Canadian pharmaceutical sales? What is your profit margin in Canada?

Because the extensive cost of pharmaceutical research and development is largely "sunk" by the time a medicine is marketed, we are able to sell our medicines in Canada for a profit. However, that perspective overlooks something quite crucial: artificially constrained prices, such as those prevailing in Canada, are not sufficient to fund the robust investment in research upon which we and the patients we serve depend. Last year, for example, GSK alone invested more than $4 billion in the search for new medicines -- that is four times more than was invested in Canada on research and development by the entire pharmaceutical industry. (Canada Rx&D). We could not make this level of investment if we relied solely on markets like Canada. Not surprisingly, the U.S. is the worldwide leader in the development of new medicines. In 2001, eight out of ten new medicines were developed in the U.S. (Scrip Magazine Jan. 22, 2003).

GSK does not report profitability on a country-by-country basis. As reported in ValueLine Investment Surveys, GSK's global net profit was 18.5 percent in 2002. That's slightly more than half of Microsoft's net profit (36.6%), and is comparable to Coca-Cola (22.5%) and Weight Watchers (18.1%).

How do your Canadian pharmaceutical prices compare to your prices in European Union countries?

In Canada, a Canadian government body, the Patented Medicines Prices Review Board, reviews the prices of patented medicines to establish a national "maximum". To establish a maximum price, the Board takes the median price from a list that includes prices from the U.S. and six countries in Europe -- France, Germany, Italy, Sweden, Switzerland, and the UK. The US price

used is a straight average of the wholesale acquisition cost, (i.e., the "list price" to wholesale customers), and the price set under the Federal Supply Schedule. Most of the other countries in the comparison are price controlled, single-payor systems.

Since the Canadian "maximum" price is the median of the benchmark prices, by definition, the Canadian price will always be lower than half of the benchmark prices and higher than the other half.

The table below provides a few examples (wholesale prices are provided in US dollars at current exchange rates).

Drug Name & Dosage	**Canada**	**UK**	**France**	**Germany**
Advair/Seretide diskus (50/250 mcg) – 60 doses	$59.20	$54.82	$43.65	$51.03
Avandia (4 mg)	$133.17/100 tablets	$148.03/112 tablets	$117.39/112 tablets	$116.52/112 tablets
Paxil/Seroxat (20 mg) per tablet	$1.07	$0.83	$0.64	$1.02

Please let us know if you want information on specific countries.

For generic medicines, however, which account for almost 50 percent of all prescriptions in the U.S., prices in the U.S. tend to be lower than in Canada and other price-controlled markets – a market aberration of price controls. (Patricia M. Danzon, "Making Sense of Drug Prices," Regulation, Vol 23, No. 1:56-63 (2000)).

Canada's price control system, however, does not mean patients have better access to medicines. Under the Canadian system, seniors (aged 65 and older) and low-income patients on welfare receive prescription drug coverage under Canada's Medicare system. Many breakthrough medicines are not covered for patients under Canada's Medicare system. For example, though our breakthrough treatment for diabetes, Avandia®, was approved in Canada more than three years ago, it still is not covered under Canada's Medicare system in most provinces. Fosamax®, a leading treatment for osteoporosis, and Vioxx®, a leading treatment for arthritis, are only available on a limited basis in several provinces (neither of these is marketed by GSK). Three new treatments for Alzheimer's disease, Aricept®, Reminyl®, and Exelon℠, available in the U.S. and approved in Canada, are only available to Medicare patients in Canada on an extremely restricted basis in several provinces. (None of these medicines are marketed by GSK.)

Medicines under patent are not the only treatments that may be cheaper in Canada. Though US Medicare pays more than three times more for a hip replacement than the cost in Canada, the reason people aren't crossing the border to have a hip replaced in Canada is that US Medicare covers these procedures for US patients.

Is there any country in the world where your prices equal or exceed your U.S. prices?

We supply products to 191 markets around the world, including 28,000 different finished packs a year. Different regulations and market conditions mean different labeling, manufacturing, and packaging standards. Because of these differences among the products sold in different countries, making pricing comparisons is extremely difficult. Straightforward apple-to-apple comparisons are not possible. However, there is no question that prevailing prices in the U.S., where the market is relatively free of artificial constraints, tend to be higher than in many countries.

Price comparisons are also significantly complicated by differences in the healthcare systems around the world and how they pay for medicines. For example, frequently the price comparisons that are reported often ignore the widespread variations in rebates and discounts available. For the U.S. free-market system, competition drives prices down through discounts, rebates, and bargained-for contractual terms. Accordingly, published "list price" in the U.S. will overstate the actual price that GSK is paid by insurers, hospitals, the government, and other payors. In countries that set prices, the "list price" is the actual price or very close to the actual price that the government pays GSK. Thus, a comparison between those two prices may reflect a greater difference than actually exists.

Just looking at GSK's "list prices" in the U.S. and other countries shows that though the U.S. often has higher list prices for medicines, this is not always the case. The table below provides some examples.

Drug Name & Dosage	US	Canada	Japan	UK	Germany
ReQuip (2 mg) – per tablet	$1.06	$0.75	N/a	$1.53	$1.70
Agenerase (150 mg) – per tablet	$1.22	$1.26	N/a	$1.30	$1.00
Valtrex (500 mg) – per tablet	$3.21	$1.97	$4.26	$3.26	$2.51

Is your company acting alone in blocking drug shipments to Canada, or are you serving as a stalking horse for the rest of the industry?

GSK did not block shipments to Canada. In fact, GSK continues to supply medicines to the Canadian market for the legal sale to patients in Canada. We acted in the best interest of patients based upon our understanding of the safety risks and legal/business concerns to curtail the illegal sale of medicines from Canada to patients in the U.S. We acted completely independently of other pharmaceutical firms. We do not know, nor would it be appropriate for us to discuss, the plans of other pharmaceutical companies with respect to cross-border pharmaceutical sales from Canada.

How much does your company spend annually on drug promotion and advertising (all kinds) compared to expenditures for research and development?

Last year, GSK invested more than $4.3 billion in the search for new medicines. In contrast, we spent $2.9 billion promoting our products in the U.S. The promotion figure includes free samples we provide to healthcare providers, direct-to-consumer and other advertising, and the salaries and expenses associated with our professional field representatives who call upon healthcare providers.

Some media accounts have erroneously reported the "Sales, General & Administrative Expenses" line in a company's financial statement or annual report as promotional spending. Promotional spending is only a part of that figure. For GSK, "Sales, General & Administrative Expenses" includes promotional spending and a wide array of other expenses ranging from salaries and benefits of employees in our Human Resources, IT, Legal, and Finance departments to basic operational expenses like utility bills, computers, and office supplies.

How much does your company spend to promote Together Rx, the program designed to help low income consumers?

Over the two-year period 2002-2003, the seven pharmaceutical companies who participate in the Together Rx will spend about $24 million promoting the card. This amount does not include the cost of having 35,000 sales representatives, including approximately 10,000 GSK representatives, promote the program.

In addition to working with doctors, nurses, and pharmacists to help identify and inform eligible patients, we are involved in several innovative outreach activities. For example, we recently have partnered with Meals on Wheels to include copies of applications on meal trays. We also continue to work with Members of Congress in reaching out to constituents who can benefit from the Together Rx program, including staffing senior health fairs sponsored by Members in districts across the U.S. Currently, more than 20,000 Indiana residents are Together Rx cardholders; more than 2800 live in your district. We will be glad to work with you, as we have with other Members of Congress, to make certain that all of your constituents who can benefit get an application and enroll.

Also, of the more than 400,000 low-income, uninsured patients helped by the GSK patient-assistance programs last year, greater than 11,000 live in Indiana.

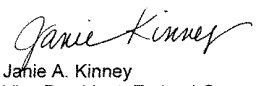
Why should American consumers, and only American consumers, bear the cost of the pharmaceutical industry's research and development?

The fact is that the U.S. is one of the few relatively free markets in the world, and Americans do subsidize the discovery and development of new medicines for the rest. It's not fair, and we are making efforts to change it.

In the meantime, the fact remains that the sales from medicines today are what fund our efforts to find tomorrow's medicines. Including GSK's $4.3 billion contribution, pharmaceutical companies

invested $30 billion last year in the search for new medicines. Because of the free market environment in the U.S., the vast majority of pharmaceutical research and development is done here. Other countries anxious to attract this type of investment look to the U.S. as the gold standard for pharmaceutical research and development. Without such a robust investment, US patients will continue to wait, potentially in vain, for better treatments for Alzheimer's disease, cancer, and the many other diseases for which answers are currently limited.

Sincerely,



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