



**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.

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.

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.

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.”

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 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.

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.

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 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.

We also pioneered the pharmaceutical industry's patient-savings card programs with the Orange CardSM, 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 CardTM 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.

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.

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.