United States Senate
Republican Policy Committee
Jon Kyl, Chairman

November 6, 2003

There is a Better Way to Help U.S. Consumers

Pharmaceutical Price Controls Abroad: An Unfair Trade Policy

– Executive Summary–

- According to the U.S. International Trade Commission (ITC), prices for pharmaceutical products are higher in the United States than those in most other countries. The Associated Press today is running a story with the results from its own survey, revealing that Canadian prices for 10 popular prescription drugs were 33 percent to 80 percent cheaper.

- Many of today's industrialized countries impose strict price controls on pharmaceuticals despite their developed economies. These price-control policies inhibit fair and equal market access between the United States and its trading partners, causing U.S. consumers to shoulder a disproportionate share of the increased worldwide spending on pharmaceuticals.

- The imposition of price controls harms society by reducing the amount of trade in the economy. Moreover, in the case of pharmaceuticals, the most damaging area is likely to be the reduction of innovation, which will harm all future generations of patients.

- Pharmaceutical spending is at an all-time high. If U.S. consumers are to continue to rely on such important forms of medical treatment, then it is incumbent upon the United States Trade Representative (USTR) to begin a dialogue with our trading partners in order to obtain more open, equitable, and reciprocal market access for pharmaceuticals.

- Current trade laws provide a compelling rationale for including pharmaceutical access and pricing in trade negotiations. The USTR must aggressively pursue these pricing disputes. The result will be fairer pricing for U.S. consumers and greater access to new, innovative drug therapies for all the world's citizens.

Introduction

Constituents are urging their representatives in Congress to provide them relief from the skyrocketing prices of prescription drugs. U.S. prescription drug spending now accounts for 10 cents of every health care dollar spent, as compared to 6 cents in 1990. This trend likely will continue, with expenditures projected to account for 14 cents of every health care dollar by 2010.[1] The increase in spending primarily is due to a greater reliance on pharmaceuticals as the population ages and drug therapies increasingly replace inpatient hospital treatment.

The growth in pharmaceutical use is a worldwide phenomenon. According to a June 2003 study by the Organisation for Economic Co-operation and Development (OECD), pharmaceutical spending rose significantly between 1990 and 2001 in nearly all OECD countries.[2] People everywhere rely more on pharmaceuticals with the creation of newer and better drugs – most of which (in recent years) have been developed and brought to the market by U.S. manufacturers.[3]

It makes sense that the introduction of new and more expensive drugs results in increased spending on pharmaceuticals. However, due to the widespread use of foreign price controls, this increased spending is not shared equally by all consumers. This paper will demonstrate that U.S. consumers pay a disproportionate share of worldwide drug expenses. This occurs in the form of a higher price for the very same pharmaceuticals prescribed elsewhere.

Some U.S. policymakers and presidential contenders have proposed "importing" pharmaceuticals from other nations to ameliorate the difference in pricing. However, there are two dangerous side effects to this approach: first, manufacturers would have less incentive to pursue promising, but also expensive, pharmaceutical R&D that results in drug innovations; and second, consumers would be at risk due to mislabeling or adulteration as a result of inadequate oversight by exporting countries.

Clearly, we need to find a better way to address this problem. One avenue to explore is trade policy. The current trade laws provide a compelling rationale for including pharmaceutical access and pricing questions in trade negotiations. And, because the use of price controls by foreign governments carries long-term implications for the world's drug supply, it is certainly appropriate for the United States

---

[1]U.S. Centers for Medicare and Medicaid Services, "Market Update: Pharmaceuticals," 2003.

[2]Organisation for Economic Co-operation and Development, "OECD Data Show Health Expenditures at an All-time High," June 23, 2003.

[3]U.S. manufacturers now account for 7 of the top 10 worldwide best-selling medicines, and 15 of the top 20. (Source: John E. Calfee, Ph.D., "Free Markets vs Canadian Drug Reimportation," American Enterprise Institute, July 9, 2003.)

Trade Representative (USTR) to begin a dialogue with our trading partners that strives to obtain more open, equitable, and reciprocal market access for pharmaceuticals. The result will be fairer pricing for U.S. consumers and greater access to new, innovative drug therapies for all the world's citizens.

The Danger of Foreign Price Controls on Pharmaceuticals

Despite their developed status, many of today's industrialized countries impose price controls on pharmaceuticals. Unfortunately, these controls limit a drug manufacturer from recouping its fixed costs associated with researching and developing expensive and new breakthrough pharmaceutical therapies. A study issued by Fiona Scott Morton, associate professor of economics and strategy at Yale University, confirms this adverse impact. Ms. Morton concludes: "The imposition of price controls harms society by reducing the amount of trade in the economy. . . . Moreover, in the case of pharmaceuticals, the most damaging area is likely to be the reduction of innovation, which will harm all future generations of patients."[4]

The market demands innovation, but manufacturers will not risk investment if they cannot cover the high fixed costs of R&D associated with bringing new products to the market. Over the past decade, the bulk of pharmaceutical R&D has transferred from European countries to the United States as manufacturers have been forced to look to other markets with less government intrusion. Prior to 1990, European pharmaceutical firms spent 75 percent more on R&D than did American firms. By 2000, American firms spent more than a third more than European manufacturers.[5] Much of this transfer is a result of growing price control policies worldwide.

The Relative Free Market of the United States vs. Foreign Price Controls

The U.S. pharmaceutical industry is highly regulated to ensure drugs meet rigorous safety standards. But when it comes to pricing, companies generally are allowed to price their products without significant intrusion by the Federal Government. Prices are determined by several factors. One is the cost of government regulation. Second is the cost of R&D, marketing, and distribution. Other factors that affect pricing decisions include demand for the product, potential profit, and perceived therapeutic outcome.[6]

---

[4]Fiona M. Scott Morton, "The Problems of Price Controls," *Health and Medicine*, Yale University, Spring 2001.

[5]Mark B. McClellan, M.D., Ph.D., Food and Drug Administration Commissioner, speech before the First International Colloquium on Generic Medicine, Cancun, Mexico, September 25, 2003.

[6]In addition, prices somewhat are influenced by certain Federal and State purchasing programs that require rebates and discounts (e.g., Medicaid, Department of Defense, and the Veterans Affairs Administration). However, these programs account for only 13 percent of U.S. health expenditures, and as a result, do not have a significant impact on prices. See, U.S. International Trade Commission,

In addition, U.S. consumers have relatively unfettered access to pharmaceuticals, including access to newly released innovative drugs. However, they also pay a high price for these drugs. After an accounting for differences in exchange rates, the U.S. International Trade Commission (ITC) confirmed that "U.S. prices for prescription products generally tend to be higher than those in most other countries, though the magnitude of the gap varies [from country-to-country]."[7] The following examples illustrate a few of the price differentials that are common among industrialized nations. Lipitor, the world's top-selling anti-cholesterol drug, costs Canadians an average of $174.50 for 90 tablets (20 mg) as compared to $287.97 for Americans purchasing the same dosage and amount.[8] That is, Canadians pay 39 percent less for Lipitor than their American neighbors. Canada is not the only country where pharmaceuticals are less expensive. In Germany, 30 tablets of Zocor (10mg), another anti-cholesterol drug, cost on average $41.20 as compared to $89.95 in the United States for the same dosage – that is, Germans are getting a 54-percent discount on their prescriptions.[9]

Why the Same Drugs Cost Less Abroad

Most foreign governments finance the bulk of (if not all of) health care services, and so employ a variety of direct and indirect pricing schemes as a way to contain their costs. In the case of pharmaceuticals, the following is a list and description of these methods.[10]

"Pricing of Prescription Drugs," Investigation No. 332-419, Publication 3333, December 2000.

[7]The U.S. International Trade Commission was requested to conduct an investigation under section 332(g) of the Tariff Act of 1930 for the purpose of reviewing pharmaceutical pricing structures of the other G-8 countries or other countries that are signatories to the North American Free Trade Agreement. The investigation highlighted four specific areas: 1) the process by which prescription drug prices are established; 2) the role of compulsory licensing in setting prices; 3) a description of the costs associated with the development of prescription drugs, and a comparison of the authorized prices in the specified countries; and 4) whether and to what extent price control systems utilized by such countries impact pricing for comparable drugs in the United States. U.S. International Trade Commission, "Pricing of Prescription Drugs," Investigation No. 332-419, Publication 3333, December 2000, p. 2-2.

[8]These prices were advertised on-line by Canuck Drugs for a 90-day supply of pharmaceuticals purchased via the internet. Canuck Drugs is a Canadian pharmacy licensed in the province of Manitoba, Canada, http://www.webmeds.ca/. Web search conducted September 6, 2003. Additionally, according to IMS Health, which supplies market research and business analysis concerning the global pharmaceutical market, Lipitor was the top-selling drug prescribed throughout the world for the past year. "IMS Health Retail Drug Monitor: Tracking 13 Key Global Pharma Markets," IMS Health, June 2003.

[9]Representative Gil Gutknecht (R-MN), "Pharmaceutical Drug Price Comparison," comparing the price of pharmaceuticals purchased at the Metropolitan Pharmacy (Munich Airport) to pharmaceuticals purchased at various pharmacies in the United States.

[10]Each identified example is documented in "Health System Reform Principles: Cost Containment Issues," Pharmaceutical Research and Manufacturers of America, September 2001.

- **Global budgets**, most often used by France, Italy, Portugal, and Austria, provide fixed amounts of money to pay for health care services. In the case of pharmaceutical spending, budgets usually are linked to sales volume. If drug sales exceed the government's allocated budget, then manufacturers must return any payments either in the form of a cash rebate or accept a price freeze on existing drug products.

- **Reference pricing** is another method growing in support among Canadian, German, Australian, and other governments. It uses local or international price comparisons of drugs classified in the same therapeutic group to determine a single price. The therapeutic class of drugs can encompass old and new drugs, including brand name or generic drugs. The lowest priced drug then establishes the maximum reimbursement rate for the entire class of pharmaceuticals.

- **Cost-utility evaluation** is often used by Australia, Canada, the Netherlands, Portugal, and the United Kingdom (UK). This method, also referred to as pharmacoeconomics, is meant to compare drug prices to therapeutic outcome as a basis for coverage decisions. However, the complexity of the system often fails to keep pace with the most recent and relevant scientific data that is necessary to make the most accurate coverage decisions.

These methods grossly distort a pharmaceutical's price by comparing one product to the price of another less expensive, and in some cases, much older drug. Additionally, many governments restrict manufacturers from appealing certain coverage or price decisions as a way to further tighten their price controls on pharmaceuticals. Unfortunately, it is this type of government intrusion that has caused many pharmaceutical R&D sectors to flee from foreign countries. When governments restrict manufacturers from recouping their fixed costs, then they will look elsewhere and, effectively shift to markets with less regulation like that of the United States.[11] As a result, U.S. consumers are shouldering a greater price burden for today's pharmaceuticals. Furthermore, consumers who reside in the price-controlled markets receive less access to newer pharmaceuticals. For instance, in areas where governments link the price of a new drug to an off-patent medicine through reference pricing, recent research finds that manufacturers may choose to delay the launching of a new product rather than accept a low price.[12]

---

[11]Patricia M. Danzon, "Pharmaceutical Price Regulation: National Policies Versus Global Interests," American Enterprise Institute, 1997.

[12]Patricia M. Danzon, Y. Richard Wang, and Liang Wang, "The Impact of Price Regulation on the Launch Delay of New Drugs – Evidence from Twenty-Five Major Markets in the 1990s," National Bureau of Economic Research, July 2003.

U.S. Consumers "Cover Most of [the] Costs of Developing a New Drug"

Pharmaceuticals offer worldwide benefits. Thus, the costs of developing new breakthrough drug therapies ought to be shared equally across nations. This point recently was emphasized in a speech before international drug executives by Food and Drug Administration (FDA) Commissioner Mark McClellan, M.D., Ph.D. Dr. McClellan announced:

> If we do not find better ways to share the burden of developing new drugs and biologics, all of us will suffer. The benefits of these treatments are global, and so if we think only of the short-term interest of our own country, we all lose the opportunity for a healthier world. The heart of the problem is that we are not all paying our fair share of the costs of bringing new treatments to the world. And the problem is getting worse. . . . The United States is now covering most of these costs of developing a new drug to the point where it can be used by the population of the world.[13]

Drug development is time-consuming and capital-intensive. One new drug can take 12 to 15 years – and almost $500 million – to research and develop.[14] If foreign governments continue to shift costs to U.S. consumers by imposing strict price controls, then manufacturers either will be unable to recoup these R&D expenses or U.S. consumers will continue to bear most of the burden. Because neither result is politically sustainable, U.S. policy makers increasingly will be compelled to push for domestic price controls of some sort – such as importation of pharmaceuticals from countries that control the prices.

A Closer Look at the Importation of Drugs

Some U.S. policymakers and presidential contenders have proposed to import pharmaceuticals from other nations as a way to reduce the price of today's pharmaceuticals for consumers. The problem with this approach is that it would indirectly impose the very same price controls on U.S. pharmaceuticals that are implemented elsewhere. Importation allows wholesalers to purchase pharmaceuticals in other countries at a lower price – due to price controls – and then import those drugs into the United States.

Importation of pharmaceuticals only treats the symptom, not the cause – it may reduce drug prices temporarily, but it can lead to two devastating scenarios: first, it would be difficult to impossible for the United States to assure the safety and efficacy of the imported drugs;[15] and second, indirectly

---

[13]Mark B. McClellan, M.D., Ph.D., Food and Drug Administration Commissioner, speech before the First International Colloquium on Generic Medicine, Cancun, Mexico, September 25, 2003.

[14]Pharmaceutical Research and Manufacturers Association, "Publications/Quick Facts," January 1, 2001. (www.pharma.org)

[15]See, for example a press release issued by the Food and Drug Administration entitled, "CanaRX Illegally Supplying Prescription Drugs; Company Violates U.S. Law, Puts Americans at Risk," November

imposing pharmaceutical price controls in the United States eventually will lead to reduced spending on R&D and fewer new drugs coming into the market.[16] That would hurt all consumers, at home and abroad. Policymakers should reject the importation option and, instead, carefully weigh Dr. McClellan's words.

Solution: Fairer Trade Will Lead to More Equitable Drug Prices

In order to obtain more open pharmaceutical markets in other industrialized countries, the United States needs to begin a new dialogue with our trading partners in trade negotiations. According to Article 7 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology [that] mutually advantages producers and users of technological knowledge."[17] When used in the correct way, pharmaceuticals provide medical science the tools to treat today's and tomorrow's diseases, often in a less expensive and, certainly, in a more productive way than in years past. As a result, it is in the United States's best interest to ensure that our pharmaceutical innovations are appropriately protected; and the TRIPS Agreement offers a way to do that.

A second compelling rationale for including pharmaceuticals in trade negotiations is found in Section 301 of the Trade Act of 1974 as amended (US Code 19 Sec. 2411). The statute states that unreasonable trade policies include those which deny fair and equitable "protection of intellectual property rights. . . ; and market access opportunities for United States persons that rely upon intellectual property protection even if the foreign country is in compliance with the WTO Agreement on Trade-Related Aspects of Intellectual Property (TRIPS)."

The Trade Act makes clear that *even if a policy or practice is not necessarily in violation of, or inconsistent with, the international legal rights of the United States, it can still be deemed unreasonable* as long as the policy is unfair and inequitable. This provides a clear legal avenue for the inclusion of pricing and access-related pharmaceutical issues in trade negotiations and invites revisions of existing trade relationships.

Moreover, there is a current understanding of unfair trade practices domestically as established in the 1914 Federal Trade Commission Act. According to that statute, "unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby

---

6, 2003; http://www.fda.gov/bbs/topics/NEWS/2003/NEW00973.html.

[16]John E. Calfee, Ph.D., "Free Markets vs Canadian Drug Reimportation," American Enterprise Institute, July 9, 2003.

[17]World Intellectual Property Organization. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (1994). Geneva, World Intellectual Property Organization, 1997.

declared unlawful. . . [This standard] shall apply to unfair methods of competition involving commerce with foreign countries [if] such methods of competition have a direct, substantial, and reasonably foreseeable effect."[18] Because foreign pharmaceutical price controls directly affect U.S. consumers and U.S. drug manufacturers, we can no longer turn a blind eye to cost-shifting and the ability to conduct fair trade.

Therefore, in the context of the Trade Act, TRIPS Agreement, and the Federal Trade Commission Act, drug price controls are arguably "unreasonable or discriminatory burdens" that restrict U.S. commerce by forcing U.S. consumers to pay a disproportionate share of the costs.

The Trade Promotion Authority Act and Unfair Trade Practices

Given the unfair R&D burden that U.S. consumers shoulder, it is incumbent upon the USTR to aggressively pursue discussions with our trading partners when entering into bilateral or multilateral negotiations. The 2002 Trade Promotion Authority Act (TPA) can help in this effort. Specifically, the TPA acknowledges the trade-distorting barriers posed by price controls and reference pricing on pharmaceuticals. In the report language that was written to accompany the law, Congress stated that the problem of such laws and regulations act as "disguised trade barriers," which can be problematic if they are not available for the public to view provide input.[19]

The TPA gives the President the authority to negotiate trade deals that open markets, increase choices, and lower costs for American consumers and businesses. While the President serves as the nation's voice in foreign trade matters, the TPA represents a means of accommodating Congress' authority to regulate foreign trade by requiring consultation during the course of trade talks both on the conduct of the respective trade negotiations and on the implementation of any final agreement. This preserves the Senate's ultimate role, which is to vote to ratify any such treaty.

Congress gave the President this special trade authority, *but with proviso that he strive to eliminate unfair trade practices* – that is, "barriers and distortions that are directly related to trade and that decrease market opportunities for United States exports or otherwise distort United States trade."[20] This includes the assurance of "regulatory transparency," which is a specific standard used in trade negotiations to determine whether a foreign government's rules and regulations are applied consistently and equitably in an open manner. As the United States enters into free trade negotiations with

[18]The Federal Trade Commission Act 1914, section 45 (Title 15 U.S.C. section 41-51).

[19]Senate Report 107-139, pg. 23.

[20]The Trade Promotion Authority Act, Public Law No. 107-210, section 2102, 19 U.S.C. section 3801 (2002).

industrialized countries, one of its goals should be to address such issues as pharmaceutical price control policies to ensure balance between today's medical needs and tomorrow's requirement for medical innovation.

Another Tool: the "Special 301" Annual Report

Another opportunity for the USTR that can help maintain open access for pharmaceuticals is the "Special 301" annual report. In 1988, Congress passed legislation requiring the USTR to identify "those foreign countries that deny adequate and effective protection of intellectual property rights, *or* deny fair and equitable market access to United States persons that rely upon intellectual property protection."[21] Historically, the USTR has focused on identifying foreign countries with inadequate intellectual property protections.[22] It now should consider turning its attention to the issue of fair and equitable market access and the impact on drug innovation.

Gathering Empirical Evidence of the Effect of Price Controls

To help augment the USTR's efforts in these areas, the Senate recently passed legislation that directs the Comptroller General of the United States to study pharmaceutical price control policies among the other G-8 countries and their impact on consumers and R&D.[23] The study, which is included in S. 1, the Medicare prescription drug bill (now in a House-Senate conference), will help provide the additional evidence that illustrates the disproportionate share of R&D expenses borne by U.S. consumers. The report is due one year after the date of enactment of the Medicare prescription drug bill. There is no reason to believe that a similar provision will not be a part of the Medicare conference report.

With the growing interest in free trade agreements, Congress has been clear in outlining its goals and objectives as the United States engages in these discussions. It has provided the USTR with a set of tools like the TPA and "Special 301" reporting authority in order to eliminate current cost-shifting and achieve more equitable pharmaceutical trading opportunities. Now the Administration must focus its attention on this issue as it negotiates on behalf of U.S. consumers.

---

[21]Section 182 of the Trade Act of 1974 as amended in 1988 [Public Law No. 100-418, section 1303 (b)].

[22]The 2003 Special 301 Report issued by the United States Trade Representative concentrated solely on intellectual property protections in approximately 74 countries. (Issued May 1, 2003.)

[23]The other G-7 countries, besides the United States, are France, Germany, Italy, Japan, the United Kingdom, and Canada.

The Australia Free Trade Agreement: A Model for Fairer Trade

Currently, there is an opportunity to address unfair pharmaceutical trading practices as a part of the United States/Australia Free Trade Agreement (FTA). In March, the United States entered into the first round of free trade negotiations with Australia. Additional rounds of discussions are scheduled for later this year.[24]

Australia is a developed nation with an economy similar to that of the United States. Since 1948, however, the Commonwealth Government has administered the Pharmaceutical Benefit Scheme (PBS), which is based on an arcane set of reference pricing and cost-utility methods to determine how and when medicines are prescribed.[25] The Australian PBS results in some of the lowest pharmaceutical prices among all OECD member countries.[26] These low prices further compound the cost-shifting effect to U.S. consumers. Equally troubling, the PBS discriminates against U.S. manufacturers by offering little chance to appeal pricing decisions and present scientific data to accompany new breakthrough therapies.

This week, Australian Health Minister Tony Abbott stated that the "design of the PBS was not a trade issue and should not even be a part of the FTA negotiations."[27] This position should be unacceptable to the U.S. negotiators.

It is critical that the USTR advance Congress' will for open and reciprocal markets. This includes adding pharmaceuticals to the U.S. trade agenda during these negotiations. The ongoing trade negotiations with Australia present an opportunity to begin confronting the problem of pharmaceutical price controls. Australia is a good friend of the United States. Its commitment to a free market economy should include the removal of trade barriers like reference pricing and cost-utility evaluations. If negotiations are completed, the Senate likely will vote next year on the Australian FTA. If the USTR delivers an agreement that improves access and greater transparency in the pharmaceutical market, this will be a win-win for both U.S. and Australian consumers.

---

[24]U.S. Trade Representative News Release, "USTR Zoellick Notifies Congress of Intent To Initiate Free Trade Negotiations with Australia," November 13, 2002. The negotiations started 90 days after the announcement.

[25]The Australian Pharmaceutical Benefit Scheme finances almost 96 percent of all prescriptions. It creates a government-approved list of eligible drugs. Those manufacturers requesting approval for new drugs often must provide extensive proof that the drug is necessary to prevent or treat significant medical conditions not already covered by existing listed drugs, and that it is at least as therapeutically beneficial, safe, and cost-effective as other listed drugs. This process often can take 3 to 6 years off the patent life of a new drug.

[26]Productivity Commission 2001, *International Pharmaceutical Price Differences*, Research Report, AusInfo, Canberra.

[27]Tim Colebatch, Economics Editor with Aap, "Drugs Deal Isn't on Free Trade Agenda, Aboot Tell US," interview with Channel 7's Sunday Sunrise, 3 November 2003.

Conclusion

With the increased attention being given to rising pharmaceutical drug prices, Congress must give careful thought as to how it can assist U.S. consumers. It should keep its focus on clear trading objectives – not on concepts like importation, which could endanger U.S. consumers and further restrict critical R&D efforts. Given the promise of pharmaceuticals, it is vital that all industrialized nations do their part to assure a worldwide market environment that is fair and that promotes the arrival of new, improved, and more cost-effective medical treatments. Everyone benefits from scientific breakthroughs that improve health; so everyone should help pay the costs. The answer to rising prescription drug prices is not price controls, but, rather, open markets that allow competition to work across borders. Innovation in the pharmaceutical industry will languish if foreign governments continue to artificially control prices; it could disappear if the United States joins these governments in their negative policy. The answer is a positive market approach for all developed countries, and the United States should lead the way in trade discussions with our trading partners. The USTR already has the tools in hand. It should use them. The first step can begin with the free trade negotiations currently underway with Australia.