Testimony of
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"International Trade and Pharmaceuticals"

Thank you, Chairman Kyl, Chairman Thomas, and Members of the Committee, for holding this important hearing and for inviting me to testify before a joint session of the Subcommittees on Health and Trade. I welcome the opportunity to discuss trade issues pertaining to the pharmaceutical industry and how our efforts on the trade front intersect with global health care issues.

In the developed world, the pharmaceutical industry can make an enormous contribution not only to the quality of life, but also in reducing the cost of healthcare. In the developing world, new and innovative medicines can make a significant contribution to eradicating the root causes of poverty. In both cases, the demand for improved healthcare plays to one of our great strengths as a society and as an economy – applying American ingenuity to solve the problems confronting society and sharing our solutions through free and open trade.

The United States has been, and remains, the world leader in innovative medicine. Indeed, healthcare in general represents a growing export market for both U.S. goods and services. What holds true for the healthcare sector as a whole applies with particular force in the case of the U.S. pharmaceutical industry. While the industry serves the American public as its most important market, most of its potential customers live abroad. The latest trade figures reflect that trend – global pharmaceutical sales grew 9 percent in 2003 for a total of $491.8 billion.

The key to opening foreign markets to U.S. goods and services in healthcare lies on the negotiating table. Trade negotiations on pharmaceuticals have, in the past, focused on market access in the traditional sense (i.e., lowering tariffs or eliminating quantitative restraints). More recently, they have focused on reinforcing a global system of intellectual property protection, particularly in the area of patent rights. Going forward, however, those negotiations will have to reach beyond the traditional forms of trade barriers to confront the distortions created by foreign pricing practices and the lack of transparency in foreign government health care systems.

I. Economic Context

As context for today's discussion, I want to emphasize the importance of a healthy research-based pharmaceutical industry to the U.S. economy. The U.S. pharmaceutical industry is, most importantly, a key investor and employer in manufacturing in the United States. In 2002, total U.S. pharmaceutical industry sales grew by 12 percent to reach $219.2 billion or roughly 2 percent of gross domestic product (GDP). That same year, the industry employed 293,000 workers in the United States, up from 283,000 in 2001.

More broadly, the pharmaceutical industry has a tremendous multiplier effect as one of the key innovators in the manufacturing sector and the U.S. economy as a whole. In 2003 alone, the U.S. Patent and Trademark Office (USPTO) granted 3,803 patents for drugs to U.S. firms. Indeed, the industry represents a model of the direction toward which manufacturers in the United States are turning to succeed in an increasingly global economy. That model is one based on a heavy investment in innovation, the creation of a brand that signifies both safety and quality, and a commitment to after-sales services as a means both of meeting its customers' needs and maintaining the quality and safety associated with American pharmaceutical brands.

The industry also has the ability to help lower medical costs through the development of new and innovative medicines and improvements in their delivery. As I noted above, those innovations, particularly in the area of preventive care, will be needed to reduce costs to an aging population, not only in the United States, but elsewhere in the developed world. Such innovations will also be needed to reduce the incidence of diseases that take a huge toll on the developing world.

That said, the U.S. pharmaceutical industry's ability to provide those benefits depends on its ability to gain access to new markets and earn a remunerative rate of return on the sale of its products. By increasing access to foreign markets, American drug companies can spread the heavy cost of new research and development across a broader number of consumers, thereby reducing the cost to the individual and the cost to taxpayers, who ultimately pay for the medical assistance that is a part of our social safety net. On the other hand, where American firms are denied market access or are denied a market rate of return on their sales, they are forced to raise prices to recapture their research and development costs.

Moreover, limits on market access or price control, deny U.S. pharmaceutical firms the full benefit of their patent rights. The grant of a patent monopoly is designed to foster innovation in two ways. The first is by ensuring that the patent holder has a prescribed period – 20 years under both U.S. law and international norms – to recover the outlays that led to the invention. The second is to provide information on the patented product to the marketplace in order to encourage further innovation. By limiting market access or capping prices, foreign governments effectively undercut the value of the patent protection, limit the incentive patents provide for further innovation, and, ultimately, reduce the investment in research and development needed to improve upon the prior.

As holds true in other areas of the economy, if you tax an activity, you get less of it. The barriers to market access and caps on prices abroad impose an implicit tax on the introduction of new and innovative medicines worldwide. Perversely, such constraints not only limit the benefits that new and innovative medicines could provide, but also limit the expansion of the generic pharmaceutical industry, competition from which is the surest way to keep drug prices down across the board on all but new and innovative medicines.

The barriers our industry faces reach well beyond the conventional tariff and non-tariff measures facing U.S. exports in other sectors. For U.S. producers of patented pharmaceuticals,

concerns tend to center on foreign price and drug management regimes, which can push prices below what producers understand as fair market prices. Such regimes tend to limit the drugs that can be sold and reimbursed, and consumers tend to have only limited information about mainstream drugs and possible alternatives.

With respect to foreign drug pricing practices, our industry has raised the impact such practices have not only on their access to foreign markets, on research and development (R&D), and innovation as well. For that reason, Congress has directed the Department of Commerce to analyze a number of inter-related issues affecting the industry and consumers. That analysis will be complex, in large part because the pharmaceutical industry operates at the intersection of research, patents and innovation, drug regulation, and the health and wellbeing of individual American and citizens worldwide.

II. Industry Overview and Market Conditions

The American pharmaceutical industry is robust, diversified, and globally oriented. It exemplifies the innovation and creativity that power the U.S. economy. According to the IMS Market Prognosis International 2002-2006 Report, the domestic market for pharmaceuticals is expected to reach $330 billion by 2006.[1] The U.S. pharmaceutical market is expected to show annual growth of nearly 12 percent, for the period 2000-2005. Generic drug makers' share of the prescription drug industry has itself grown from 19 percent to 47 percent since 1984. Economists predict that by 2005 generics will account for 57 percent of the drug market, by volume.

The United States is expected to spur worldwide growth in the pharmaceutical market, for the period 2002-2005. Global sales of prescription drugs (including both branded and generics) and over-the-counter (OTC) remedies already exceed $300 billion annually. Domestic industry's cutting-edge practices are expected to increase American dominance of the global pharmaceutical market to 60.5 percent next year, according to IMS health reports. Innovative medicines remain a small share of health care spending in the United States**,** in spite of medicines' growing role in medical treatment.

The international marketplace offers great opportunities for expanded sales by U.S. drug companies. An aging population, the rising standard of living in developing nations, and intensified global R&D activity should generate a steady flow of new therapeutic products. During the next five years, the high-growth markets are expected to be in North America, the Middle East, and Asia, especially China, India, and Korea. Aging populations, increased wealth and large populations are the main drivers of expected growth in demand for pharmaceuticals.

At the same time, growth is not assured. The structure of the industry, particularly when combined with the heavy overlay of government regulation, can inhibit the full play of market forces. Patent protection provides R&D based producers with periods of exclusivity, but that is dependent on the receipt of a patent in each country and the companies' ability to effectively

[1] IMS Health is largest and most comprehensive private source of data and information on world pharmaceutical markets.

enforce it's rights under that patent; pricing policy that affect both wholesale and retail pricing and the health and efficacy review that occurs in most countries also have an effect on the market and individual countries. In that environment together with significant restrictions on trade outside normal distributions channels, prices in one market can be relatively independent of prices in another market. Indeed, that would likely hold true even in the absence of restrictions at the border.

Government intervention varies by country, but it exists everywhere in one form or another. Governments employ a number of mechanisms and procedures to control prices, the most important of which include – comparisons with prices in other countries, reference prices to drugs with similar therapeutic characteristics, negotiated prices, and ceilings on expenditures. In addition, information on both drug choices and drug alternatives can be limited, which prevents consumers from making an informed choice.

Most industrialized countries, with the exception of the United States, have imposed a variety of regulations at the national level that deal with prices and availability. A good example is France. The French government administers the National Health System, which covers virtually every Frenchman. It is supported by the national Social Security Program, which is itself funded by contributions from employers and employees. Social Security contributions cover approximately three quarters of health expenditures. Supplemental private insurance helps patients pay incurred costs not covered by the government system.

The French government closely monitors and controls prices for drugs that are eligible for national reimbursement, making drugs relatively cheap in France, by EU standards. The current price control system was established in 1994, via a framework agreement between government and industry. The government negotiates prices with drug companies using a number of factors to determine what they will pay. The negotiated prices are based on an expected level of sales. Should sales exceed these limits, the government can require that prices be adjusted downward.

Pharmaceutical companies may set prices as they wish for name brand and generic drugs, which are not officially reimbursable, but they must limit promotional activities. Lack of reimbursement, of course, greatly limits sales. Reimbursable drugs account for approximately 83 percent of sales.[2] They have also imposed various other restrictions to limit the variety of drugs available in markets as well information about new drugs.

By contrast, in the United States, we rely more heavily on the interplay of market forces to determine drug prices, rather than imposing price controls or enforcing cost-containment programs. At the national level, for example, the United States has promoted the use of generic drugs, which necessarily puts downward pressure on prices, to set an economic boundary on the price of most medicines. In relying on direct governmental controls, most other industrial countries forego the benefits of competition that generics create and prices are higher in the absence of effective competition from the generic sector of the market.

[2] EFPIA, "The Pharmaceutical Industry in Figures." EFPIA is essentially Europe's pharmaceutical association, the equivalent of PhRMA in the United States.

Insurance companies, health maintenance organizations (HMOs) and other market participants attempt to use their market power to negotiate lower prices. They also try, to varying degrees, to limit choices or curtail use of more expensive drugs. As a result, even in the United States, the market is not pure in a technical economic sense.

There are federal and state government sponsored buying programs that involve reimbursement limits, rebates, discounts, price caps, and limits on price increases. Such programs reportedly account for only about 13 percent of sales. Public sector plans include Medicaid and programs administered by the Departments of Defense and Veterans Affairs.[3]

Yet, even with our departures from a perfect free market, the United States market is far different from a system such as that administered by the French and other Organization for Economic Cooperation and Development (OECD) governments. In terms of market conditions, many studies indicate that prices for prescription drug products in the United States tend to be higher than in other OECD countries. That said, the magnitude of the gap is often difficult to measure. The most significant variation is the different consumption patterns among countries, which complicates any assessment of a market basket of drugs. Other factors that make cross-border comparisons particularly complex include variations in dosages, concentrations, dosage strengths, units of measurement, and types of treatments and therapies.

Actions by the United States and other members of the OECD have resulted in a variety of government policies with regard to health care overall, and drug pricing in particular. The segmentation of the global drug market promotes wide variations in drug prices, accessibility, and prescription rates. Studies also indicate that in markets with lower prices – and lower company revenues – research, development, and drug innovation suffer.

Nations approach overall health care differently, and likewise with drug pricing policies.[4] For example, in 2000, the United States' health care spending was 13.6 percent of total GDP. In Japan, the figure was 7.4 percent; in Canada, 9.3 percent; and in France, it was 9.6 percent. The United States simultaneously has comparatively low medicinal expenditures, as a percentage of total health care costs – only 7.3 percent, compared to 10.8 percent in Canada, 13.9 percent in France, and 15.3 percent in Japan. However, the per capita expenditure on prescription pharmaceuticals was $293 in the United States, $203 in Canada, $321 in France, and $378 in Japan. Some of the discrepancy is due to the substantially smaller population over the age of 65, 12.5 percent of Americans versus 15.7 percent of the French. Also, new drugs enter some markets more quickly than others, and such drugs tend to be more costly than existing alternatives.

[3] PhRMA 2000
[4] All of the data in the following paragraph are drawn from OECD 2000.

III. Addressing Industry Concerns Through Trade Negotiations

Rules governing the healthcare sector abroad can have a significant effect on export opportunities for U.S. pharmaceutical and other healthcare suppliers. We work closely with our industry in tackling pharmaceutical trade problems that arise within the existing framework of the WTO in cases against India, Argentina and Brazil, among others, and under other trade agreements whenever possible. That said, the current architecture of the international trading system does not address a number of our industry's concerns.

For that reason, Congress directed U.S. negotiators, in the Trade Act of 2002, to seek "the elimination of government measures such as price controls and reference pricing which deny full market access for United States products" in markets abroad. The over-arching objective is to ensure that foreign governments do not use government regulation to provide a competitive advantage to their domestic producers.

A. Basic Objectives

In pursuing the objective set out by Congress, the Administration has focused on the following six core elements.

1. Eliminating Tariffs and Non-Tariff Barriers

The first and most obvious way in which trade negotiations can create export opportunities for U.S. pharmaceutical firms is by removing the direct obstacles to market access, such as tariffs and non-tariff barriers in the form of any outright restraints on importation abroad. Removing foreign tariffs on U.S. drugs, for example, can significantly improve the availability of a wider range of healthcare options for consumers in the foreign market by eliminating what is the most regressive form of taxation on healthcare for consumers. Removing those tariff barriers also has the effect of stimulating stronger competition for local suppliers, which often provides a further spur to innovation and can lead to new entrants in the generic market which helps set an outward bound on pricing in many instances.

2. Opening Markets for U.S. Investment and Healthcare Service Providers

Market access negotiations can help expand the market for U.S. pharmaceutical products in other ways as well. For example, improving access for U.S. investment and the establishment of U.S. healthcare service providers can ensure that foreign markets are aware of and have access to the latest in healthcare options. Those advances in medicine commonly include new and innovative pharmaceuticals produced by U.S. firms. In addition, expanding the availability of supplemental health insurance that reimburses for non-regulated drugs can help in financing the cost and improving the availability of American medicines. Similarly, opening the market for new advertising and marketing services can expand the market for U.S. pharmaceuticals by informing the public of the benefits of innovation and promoting the awareness of new

medicines among consumers. Non-discrimination in these areas can increase public demand for choice.

3. Improving Intellectual Property Protection

One of the central aspects of market access in the pharmaceutical industry is the extent of intellectual property protection available in the potential market. The lack of sound intellectual property protection can interpose as significant a barrier to U.S. drugs, particularly new and innovative medicines, as any tariff or non-tariff measure. The first step is, of course, ensuring that our trading partners are abiding by their obligations under the WTO's Agreement on Trade-Related Aspects of Intellectual Property (TRIPs). There are, however, a number of steps beyond that baseline that are important and relevant to the pharmaceutical industry as the recent negotiations with our Central American trading partners reflect. The objective is to ensure that our trading partners are implementing state-of-the-art intellectual property protections, even where those protections are "TRIPs plus."

4. Transparency

Ensuring transparency represents a fundamental tenet of American agreements, from government procurement to standards-making processes to other regulatory practices. Rules on transparency generally require governments to ensure that rules-setting process is open and accessible to all interested parties and guard against discriminatory practices. In the case of pharmaceuticals, government systems that define which products are eligible for coverage and those that fix prices are all too often non-transparent. Trade negotiations can help open up the decision-making process in these areas, with positive benefits for further system-wide improvement. Industry's ability to inform decision makers about research and development costs, and the benefits of continuous pharmaceutical innovation, can help elected officials and the public to reach better decisions. Increasing transparency requires public officials to be more responsive to citizens' needs rather than selectively issuing reimbursement applications to hold drug budgets down.

5. Promoting Competition

By adopting rules that encourage competition in both the private and public sectors for healthcare, trade agreements can help expand the market for our pharmaceutical industry abroad. By ensuring non-discriminatory, science-based determinations in the development of product standards and in the course of approvals of products by the foreign equivalent of the U.S. Food and Drug Administration, such agreements can ensure that foreign markets are not artificially closed to U.S. drugs in ways that limit healthcare options for consumers at the expense of U.S. firms and for the benefit of their local competition. Trade agreements can also shape the market for government procurement of pharmaceuticals by eliminating "buy national" requirements that afford a preference for locally produced drugs, even when U.S. firms' products might offer a new and innovative treatment not offered by their local competition.

6. Establishing Cooperative Working Groups

Trade agreements can also establish a cooperative forum for addressing systemic problems, expanding on market access not already covered by the agreement as it goes into effect, and ameliorating specific market access problems as they arise. The goal is to help both sides gain insight and develop mutually beneficial solutions that avoid trade disputes, rather than allowing what may be a technical disagreement fester into a more intractable trade problem.

B. Recent Trade Agreements and Upcoming Negotiations

Best understood, market access negotiations and the trade agreements that follow can become proving grounds, allowing trust to build as foreign markets transform and become more open and competitive. What follows is a summary of recent negotiations with Australia and our Central American trading partners as they affect U.S. pharmaceutical interests. The summary also highlights the sorts of issues that will become the focus of upcoming talks with Thailand.

1. Australia

The recently concluded free trade agreement with Australia represents a first step toward that goal. It represents an important breakthrough that should lead, in the first instance to more transparent pricing procedures in Australia. Australia represents a $5.4 billion pharmaceutical market; about 60 percent of the drugs sold are imported.[5] U.S. pharmaceutical exports to Australia totaled $539 million in 2003, a 19 percent increase over 2002. U.S. companies have invested substantially in this sector, which is highly restricted by the government's management of the national health care system.

In the case of Australia, U.S. industry has long complained that the system for being listed and priced by Australia's Pharmaceutical Benefits Scheme (PBS), the agency that reimburses pharmaceutical manufacturers for drugs prescribed by health care providers, fails to reward innovation, lacks transparency, and is plagued by delays. According to the Australian governments own study, Australia's prices for innovative drugs are among the lowest in the OECD.[6]

The recently concluded FTA contained commitments on pharmaceuticals of two sorts. First, the United States and Australia agreed to common principles for facilitating high quality health care and continued improvements in public health. Agreement on these principles will provide a common basis for future discussions on pharmaceutical issues. The two sides affirmed

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[5]Domestic demand defined as turnover plus imports less exports, "Industry Sector Analysis for Pharmaceutical Industry," Dept. of Commerce, U.S. Commercial Service, Sept. 29, 2003.

[6]"International Pharmaceutical Price Differences," Australia Productivity Commission, July 2001

a shared commitment to a number of principles, including the important role played by innovative pharmaceuticals and the need to promote pharmaceutical research and development.

Second, the two sides subsequently agreed to establish a Medicines Working Group, which will foster discussion about emerging health policy issues. They also agreed to have the U.S. Food and Drug Administration and its sister agency, the Australia Therapeutic Goods Administration, work together to make innovative medical products quickly available. Australia also committed to specific steps to increase transparency and accountability of the PBS procedures. The Australian government, for example, agreed to an independent review of listing decisions, obligations to explain proposed decisions, allowing applicants to comment and memorialize reasons for decisions. Furthermore, they agreed to give meaning to these provisions by opening them to independent review.

While some worried that the U.S. might pressure the Australian government to raise domestic pharmaceutical prices, that did not happen. Under the PBS, Australians pay a small co-payment for prescriptions, and the government subsidizes the remainder. The FTA will not alter the prescriptions-framework for Australians or Americans.

2. CAFTA

The focus of our efforts on behalf of the American pharmaceutical industry in trade negotiations will necessarily vary with the agreement. In that sense, the Central American Free Trade Agreement (CAFTA) offers a contrasting example to that of Australia. The five countries involved in the negotiations represent different levels of development than Australia and the market access issues of importance to the U.S. pharmaceutical industry differ accordingly.

In strict market access terms, CAFTA reflects the importance of trade agreements in eliminating many of the traditional barriers to trade that inhibit our firms' entry into the healthcare sector in Central America. Under CAFTA, 83 percent of U.S. pharmaceutical exports will become duty-free immediately upon implementation of the agreement; tariffs on the remaining 17 percent of pharmaceutical exports will be eliminated over five years.

In addition, intellectual property protection represented a higher level of concern in Central America than in the Australian market. In the event, the five Central American countries proved willing to adopt state-of-the-art intellectual property protections that reach beyond the minimum standard required under the TRIPs agreement. The CAFTA will strengthen patent protection by (1) specifying that test data and trade secrets submitted to a government for the purpose of product approval will be protected against unfair commercial use for a period of 5 years for pharmaceuticals (and 10 years for agricultural chemicals), which sealed potential loopholes in these provisions; (2) extending patent terms to compensate for delays in granting the original patent, consistent with U.S. practice; (3) limiting the grounds for revoking a patent, thus preventing arbitrary revocation; and (4) requiring a system that prevents marketing pharmaceutical products that violate patents.

The willingness of the five Central American countries to broaden the existing

protections under their law represents a significant breakthrough. In effect, the five countries agree to adopt standards better than TRIPS-level protections, which, when fully implemented, should significantly improve the level of intellectual property protection for U.S. pharmaceutical products in Central America. The later inclusion of the Dominican Republic within that structure and subject to the same commitments will simply expand the reach of those protections.

3. Thailand

The upcoming FTA negotiations with Thailand provide an opportunity to address market access issues in the pharmaceutical area again. As required by TRIPS, the existing Thai Trade Secret Act includes a provision barring unfair commercial use of proprietary data. However, regulations for implementation are still pending, and American industry remains concerned that those regulations will not provide sufficient protection. The proposed regulations have been discussed with Thai officials under the Trade and Investment Framework Agreement (TIFA), and if needed, can also be addressed during FTA talks in late June. U.S. officials have already broached the topics of counterfeit pharmaceuticals and patent examinations, which can suffer delays of up to five years under the current Thai system. Our negotiations offer the chance to resolve these issues for the benefit of both the U.S. pharmaceutical industry and the consumer of healthcare in Thailand.

IV. Advocacy to Address Specific Impediments

In addition to trade agreements, our bilateral commissions, working groups and bilateral contacts facilitate problem solving and the elimination of specific impediments to trade in U.S. pharmaceutical products and other healthcare goods and services. Through these with straightforward aggressive advocacy and dialogue, Commerce has the opportunity to make the case that certain government policies inhibit long-term innovation and cost saving measures. In many instances, these help reduce or eliminate market access barriers for our pharmaceutical and medical device industries.

What follows is a series of examples in significant foreign markets where aggressive advocacy on our industry's behalf is contributing to the elimination of barriers to trade in U.S. pharmaceutical products or healthcare goods and services in general. The lesson to draw from these examples is that focusing on the underlying needs of our industry and the obstacles they face, while remaining flexible as to the best approach to achieve our aims, can contribute to a successful outcome in many instances.

A. China: Poor Enforcement of IPR/US-China Healthcare Forum

Innovative U.S. medicines currently account for about [25] percent of China's pharmaceutical market, which is estimated at approximately $6 billion per year. Despite China's potential, intellectual property violations, price controls and lack of transparency remain major obstacles to U.S. medicines. Industry concerns are addressed through bilateral meetings between U.S. and Chinese government officials in Beijing and Washington, through written correspondence

and in bilateral forums designed to support US companies' interest in engaging the Chinese government on issues that ultimately will influence their ability to access the Chinese market.

U.S. pharmaceutical companies note that China's failure to protect intellectual property rights poses a serious public health risk and undermines the competitive advantage innovative companies gain from their substantial investments in research and development. The industry estimates that it loses between 10-15 percent of its annual revenue in China to counterfeit products. American pharmaceutical companies have taken an active and cooperative approach in trying to reduce the production and distribution of counterfeit pharmaceuticals in China. Many companies have joined the Quality Brands Protection Committee, in which participant companies conduct market sampling and surveillance, as well as raids on suspected counterfeit manufacturers and distributors. U.S. pharmaceutical companies seek to work with the U.S. and Chinese governments to eliminate counterfeit pharmaceuticals and urge both countries to make this a high priority. The Commerce Department has held numerous technical assistance seminars on IPR enforcement throughout China and has raised the issue with senior Chinese government officials.

As a result of these efforts, at the Joint Commission on Commerce and Trade meeting on April 21, chaired by Secretary Evans and Ambassador Zoellick on the U.S. side and China's Vice Premier Wu Yi, China announced a series of significant steps to strengthen its protection of intellectual property rights, including for pharmaceutical products. These include a commitment to achieve a substantial reduction in IPR infringement through increased enforcement efforts and a reduction in the thresholds for criminal prosecutions of IPR violators. We will continue to monitor progress on these commitments and work with China to ensure their implementation. We have established a bilateral IPR working group to maintain a focus on these efforts. Through the working group we will also seek to address individual IPR cases brought to us by our companies and develop additional avenues to strengthen China's protection for pharmaceutical and other intellectual property.

The US-China Healthcare Forum is being developed by the Department of Commerce and its Chinese counterparts to enhance cooperation in the areas of healthcare policy; to improve China's ability to provide effective, sustainable, high quality healthcare services to its people; and to support US companies' interest in engaging the Chinese government on issues that ultimately will influence their ability to access the Chinese market.

For much of the last decade, China has been wrestling with the problem of reforming its centrally planned healthcare system. Following the onset of SARS, the White House announced enhanced cooperation with China in battling this and other infectious diseases. However, most of these efforts have focused on the medical/technical aspects of the problem, for example, increased training of medical workers, cooperative research programs and donations of medical equipment.

Though important, these steps represent only a part of the puzzle. High tech equipment and innovative pharmaceuticals are of limited value unless China has a comprehensive system for efficiently delivering healthcare services to its vast population. Developing such a system will require a much larger private healthcare sector.

In response to these issues, Secretary Evans and Secretary Thompson (HHS) jointly proposed in a letter to China's Vice Premier Wu Yi that the U.S. and China develop a high-level dialogue to focus on the economic aspects of healthcare delivery. China accepted, and together with industry, we have planned a two-day program in Beijing (May 27 and 28) that will feature senior government officials and industry representatives from China and the United States. The discussion will focus on ways of making the provision of healthcare sustainable and efficient, methods for developing a transparent, objective and science-based approach to regulation of healthcare products and services, and how to foster a system that rewards innovation and promotes the continuous upgrading and modernization of the healthcare system.

We hope this forum will provide U.S. industry an opportunity to engage Chinese policy makers on issues that impact their ability to access the Chinese market as well as expand the dialogue between healthcare providers in the U.S. and China.

B. Japan: Pharmaceuticals/Medical Equipment

The United States Government (USG) has been using an advocacy approach to encourage Japan to adopt policies that reward American firms' intensive research and development, which prompts production of the world's most innovative medical devices and pharmaceuticals. Japan's population is rapidly aging, which is draining financial resources from the national health insurance system and creating pressure for spending cuts. This pressure is particularly strong in the medical device and pharmaceutical sectors.

The USG meets several times a year with Japan's Ministry of Health, Labor and Welfare in the U.S.-Japan Working Group on Medical Devices and Pharmaceuticals and has raised concerns about Japanese reimbursement policies. This Working Group is part of two bilateral mechanisms – the 1986 bilateral agreement known as Market-Oriented, Sector-Selective (MOSS) and the Regulatory Reform and Competition Policy Initiative, which is part of the Economic Partnership for Growth ("Partnership") created by President Bush and Prime Minister Koizumi in 2001.

USG's advocacy in this Working Group has contributed to reimbursement pricing reforms in Japan that have been gradually leveling the playing field for U.S. companies. U.S. efforts to date have resulted in substantial savings for American medical device and drug firms, which previously faced unfair reimbursement price cuts. Japanese patients have also benefited by gaining access to innovative products that save money in the long run and can reduce the length of hospital stays.

C. South Korea: Establishment of a Health Care Working Group

The South Korean government has traditionally prevented foreign drug companies and other key health care stakeholders from providing input before policies are adopted. Such actions have adversely affected U.S. pharmaceutical companies. The U.S. government has responded, focusing on increasing transparency in government pricing and regulatory policies.

In pursuing this goal, the U.S. government proposed – and South Korea's government agreed to – establishing a bilateral health care reform working-group in January 2002. The group provides a forum for foreign drug companies to discuss South Korean governmental proposals and health care reform. The U.S. has urged Korea to keep using the Working Group, whose work is ongoing, as a way to disseminate information.

D. Taiwan: Lack of Data Exclusivity Regime for Pharmaceuticals (IPR)

Taiwan was required to put into place a TRIPS-level intellectual property protection regime, as a condition of WTO membership. Taiwan, unfortunately, still has not revised its legislation to meet the data protection obligation of TRIPS Article 39.3, the provision that directly affects the pharmaceutical industry.

Under Article 39.3, WTO member governments are required to: (1) protect against "unfair commercial use," and (2) not disclose the data that the pharmaceutical manufacturers give governments in order to gain market approval for their innovative drugs. This article is understood worldwide to mean that governments must prevent regulators or third parties from relying on data provided for market approval to market later versions of the drug during a period of exclusivity – unless the originator grants consent.

The U.S. government is working with Taiwanese officials to ensure full compliance with this Article. Discussions are continuing through regular bilateral trade talks.

E. Hungary: Pharmaceutical Pricing Regime

The Department of Commerce is currently working with the American pharmaceutical industry to reverse a Hungarian government policy that unilaterally cut the price for pharmaceuticals by 15 percent. Secretary Evans received a commitment from the Hungarian government to establish a working group with the U.S. pharmaceutical industry that will examine the situation. This working group would help the Hungarian Government develop a pricing policy that provides adequate medical coverage for the public and supports innovation in the pharmaceutical sector. We have commitments from the Hungarian government that the working group will meet soon.

This is important because, on March 8, 2004, the Hungarian Ministry of Health informed both Hungarian and foreign pharmaceutical companies, that individual companies had four days to agree to return 15 percent of total turnover from reimbursed products to Hungary's government. If companies did not agree, the Ministry of Health would cut drug prices by 15 percent on April 1, 2004. Since only five percent of companies active in Hungary's pharmaceutical market signed the agreement, the remaining 95 percent have received 15 percent cuts that began April 1. The domestic and foreign pharmaceutical companies in Hungary have appealed to the Constitutional Court in hopes of obtaining a reversal.

In September 2003, the Hungarian government issued a similar order, threatening to cut prices by 20 percent if companies did not return partial turnover from reimbursed products. This price cut was avoided through a negotiated settlement. The staff of the local U.S. embassy fears that the Minister of Health believes this forced repayment system is a viable, enduring solution to Hungary's budgetary woes and could use such tactics annually. Secretary Evans and Department staff members have encouraged the Hungarian government to resolve this problem through a working group with the pharmaceutical industry.

F. Brazil: Patent Approval Delays

Commerce is leading an interagency effort to provide technical assistance to patent examiners at the Brazilian Patent Institute (INPI) and my colleague, Jon Dudas, Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the U.S. Patent and Trademark Office, can describe how the PTO is helping provide technical assistance to Brazil's National Patent Institute to resolve the backlog of pending trademark applications.

Brazil's difficulties in granting patents and trademarks continue to worsen, as INPI lacks much needed resources and the involvement of the Ministry of Health's Sanitary Surveillance Agency (ANVISA) in pharmaceutical patents has become more pronounced. The Lula Administration's industrial policy goals focus on improving the technological base of Brazilian industry with special emphasis on software and pharmaceutical industries, has spotlighted INPI. The 2004-2007 Pluriannual Plan announces the objective of reducing patent processing time from seven years to four, and from four years to one for trademarks.

There appears to be recognition within the government of Brazil that the INPI/ANVISA joint review has negatively affected approval for pharmaceutical products or processes, but no remedies have been offered. INPI's staffing woes should be ameliorated somewhat this year, with 108 new patent examiner positions available to qualified civil servants, and Ministry officials expect a permanent president of INPI to be named shortly.

I intend to travel to Brazil during the last week of May on a trade policy mission. During this trip, I will meet with the regulatory agencies that oversee pharmaceutical patents and trademarks and convey USG concern about problems encountered during the approval process and to press for the resolution of those issues.

G. Mexico: Protection of Pharmaceutical Patents

Commerce was instrumental in helping to achieve protection of pharmaceutical patents in Mexico. The U.S. pharmaceutical industry reported that Mexico's Ministry of Health was granting marketing approval of pharmaceutical products without checking with the Intellectual Property Institute (IMPI) for valid patents on the products. The lack of coordination between the Ministry of Health and IMPI had the potential to inflict losses of approximately $10 million for U.S. firms who owned the Mexican patents. Following significant U.S. government advocacy, President Fox signed a decree that requires the Ministry of Health to check with IMPI for valid patents before granting marketing approval.

H. Other Monitoring and Enforcement Approaches

Beyond these advocacy efforts we also have the opportunity through the annual "Special 301" review led by USTR to identify countries that deny effective protection of intellectual property rights or equitable market access for Americans dependent on intellectual property protection. Pharmaceutical Research and Manufacturers of America (PhRMA) member companies are important contributors to the Special 301 process. This annual review of countries' actions, or lack thereof, to protect IPR is often an effective means to get results. Many trading partners are motivated by their potential placement on our lists to take action and resolve our concerns such as protection of data and enforcement against counterfeit drugs.

And of course, on a daily basis, Commerce Department staff are monitoring foreign countries' compliance with trade agreements, including TRIPs, and ensuring that these issues are raised with foreign counterparts in every opportunity from travel to foreign capitals or in our bilateral meetings here in Washington.

V. Getting Policy Climate Right to Promote Innovation

Mr. Chairmen, I have described our efforts to promote and protect U.S. intellectual property rights around the world, but we do not do this just because our innovative industries deserve that support. We recognize in the United States that solid protection of intellectual property is essential to our ability to maintain a research-based pharmaceutical industry that promotes innovation, inspires creativity, achieves breakthroughs in life-saving medicines and enhances quality of life. A positive climate that fosters innovation has spillover effects well beyond pharmaceuticals.

Americans benefit from the fact that foreign firms recognize and value this climate in the United States. Swiss drug development giant Novartis announced plans to establish the Novartis Institute for Biomedical Research Inc. (NIBRI) in Cambridge, Massachusetts, in 2002. The project, which is valued at $250 million and brought 400 jobs to Cambridge, created a new center for its worldwide research activities. Novartis CEO Daniel Vasella also announced that NIBRI would hire an additional 1,000 researchers and scientists over the next five years. According to press reports, Novartis chose Cambridge for its scientific talent pool, high-quality academic base, and comparative proximity to Europe. Like many other foreign-based firms, Novartis has found American universities, policy, and markets as highly conducive to drug development.

Let me give you a few examples of what can happen when governments fail to take these considerations into account in setting policy. In 2004, Pfizer announced it planned to close its facility in Freiburg, Germany. Pfizer's decision was largely due to Germany's plans to limit market access for innovative drugs. The new reimbursement and pricing policies would categorize innovative drugs identically to twenty-year-old generic drugs, for pricing and reimbursement purposes.

A November 2000 report prepared for the Directorate General Enterprise of the European Commission found that European industry has been losing its competitive edge, when compared to the United States. Although there are differences across various European countries, Europe as a whole lags behind in its ability to generate, organize, and sustain innovation processes that are increasingly expensive and organizationally complex.[7]

The need to get the policy environment right means encouraging the use of market-based mechanisms to set prices and relying on the market both to reward real innovation and to expand the market for generic products that set the outward bounds on pricing. Nowhere is that more important than in the case of Canada. Unlike many other countries, Canada uses a system of international price comparisons that disregards valid reasons for cross-border price differences.

On behalf of our pharmaceutical industry, we have consistently argued that using international price comparisons and price ceilings on patented medicines is inappropriate and does not bolster quality health care. Plainly, addressing the issues our industry confronts under the Canadian system is an essential step in ensuring that both prices in the North American market reflect the risk our firms take on in developing new and innovative medicines and the true cost to the consumer of providing those benefits to the market.

One way to improve our advocacy of changes in the policy environment, particularly among OECD countries, is to gain a clearer understanding of the facts. That is one reason I welcome the opportunity provided by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 to examine the drug pricing practices of other OECD countries, including Canada, Europe, and Japan. The report has been undertaken in consultation with the Department of Health and Human Services, the Food and Drug Administration, the International Trade Commission, and USTR. We have coordinated closely with the FDA on our data needs, focusing our efforts on a comparison of pricing between the United States and 9 other OECD countries.

I am hopeful that our findings will provide further elaboration on the issues and will point out gaps in our collective knowledge while providing additional information in order to understand better the economics of this complex market. We intend to present the final report to Congress within the congressionally mandated deadline.

In looking at this issue, the OECD itself has begun work aimed at finding ways to improve health care system performance. In my view, the OECD efforts create yet another avenue for our advocacy. We will look to the OECD to help in rounding out our understanding of the impact that pharmaceutical pricing systems have on innovation and ultimately on the availability of quality healthcare at the lowest possible cost to all Americans and the citizens of our trading partners abroad.

[7] Alfonso Gambardella, Global Competitiveness in Pharmaceuticals – a European Perspective.

Mr. Chairman, that concludes my remarks. Thank you again for the opportunity to testify before you today. I would be pleased to answer any questions you may have.