Testimony of
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Chairman Kyl, Chairman Thomas, and Members of the Committee, I welcome this opportunity to testify on international trade and U.S. pharmaceutical policy and to explain how our trade initiatives are promoting innovation and ensuring access to lifesaving medicines. I value the close cooperation I have had on trade issues with you and other Members of Congress and appreciate your leadership on this important and complex topic.

Trade Promotes Innovation

Innovation is vital to the success of many U.S. industry sectors – from pharmaceuticals and medical devices to telecommunications and information technology. Innovation within and across these and other sectors brings life-saving medicines and other revolutionary products to market, puts existing products to creative new uses, and even launches entirely novel industries. It means higher productivity, faster economic growth, and better living standards for American families.

Developing groundbreaking medicines and other innovative products depends largely on two factors – regulatory regimes that encourage the introduction of new products, and strong and effective intellectual property rights (IPR) protections and enforcement. Innovation thrives in the United States because of our fertile economic environment – an environment that encourages the flow of capital to the most productive uses and ensures that novel ideas are granted strong IPR protections. American pharmaceutical companies produce an estimated two -thirds of the world's innovative medicines.

America's trade policy is promoting innovation and creating new opportunities for innovative U.S. industries. The Office of the U.S. Trade Representative (USTR) has successfully led efforts to build a worldwide legal infrastructure that supports and rewards innovation. And we are working globally, regionally and bilaterally to counter barriers that restrict access to innovative health care products and discourage research and development (R&D) that can improve quality of life and, in many cases, save lives.

Building the Infrastructure for Innovation

Strong intellectual property rights (IPR) protections are the foundation for innovative R&D. These protections – including patents, copyrights or trademarks – provide vital incentives to invest in innovation. They ensure that pharmaceutical companies and other knowledge-based firms are rewarded for their unique ideas and achievements.

USTR has been instrumental in bringing the strong IPR protections we enjoy at home to the trading nations of the world – fostering a global climate for groundbreaking innovation and research in the development of lifesaving medicines. IPR had been on the international economic agenda for decades when the United States joined other members of the General Agreement on Tariffs and Trade (GATT) to launch the Uruguay Round of global trade negotiations. By the time negotiations commenced on a multilateral Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in 1986, a large and growing consensus had emerged within the international community on the importance of IPR protection to economic growth and on fundamental rules for protecting new ideas and innovations. USTR seized the opportunity of those negotiations to harvest and bring together rules that had been negotiated in a number of intellectual property treaties – clarifying and improving them where necessary and making them subject to binding dispute settlement.

A decade after the conclusion of the Uruguay Round, TRIPS remains the basis for our ongoing efforts to improve the legal protection and enforcement of IPR around the world. USTR is vigilant in ensuring that our trading partners around the world live up to their TRIPS commitments – using our annual Special 301 Reports to identify and resolve the IPR concerns of U.S. pharmaceutical companies and many others in markets worldwide. We are instrumental in fighting the counterfeiting of patented drugs around the globe. These illegal copies not only steal protected patents, but prey on unsuspecting consumers with fake and often unsafe versions of critical medicines. Most recently, we have secured an agreement from China to crack down on such counterfeit trade and to introduce deterrent criminal penalties for violators. And we are raising the bar through our free trade agreements (FTAs) by crafting groundbreaking IPR provisions that build and improve on the TRIPS foundation.

Securing Access to Lifesaving Medicines

Through global, regional and bilateral trade negotiations, USTR is also knocking down barriers our pharmaceutical and other companies face in particular overseas markets – enabling them to access new customers, seek additional economic rewards of their innovations and deliver life-saving new medicines to the world. We are successfully opening new markets and resolving trade-related concerns regarding access to medicines.

Through the World Trade Organization (WTO), we are working globally to deliver expanded market access to U.S. pharmaceutical firms and other innovative industries. In successive rounds of multilateral trade negotiations, we have sharply lowered tariffs and non-tariff barriers around the world, to the benefit of U.S. companies, workers and consumers.

During the Uruguay Round, for example, the United States and 21 other major trading nations agreed to the reciprocal, immediate (from January 1, 1995) elimination of tariffs on existing pharmaceutical products and committed not to impose duties on new pharmaceutical products as they are developed. This initiative covered finished pharmaceutical products and chemical intermediates used in the production of those products – giving consumers around the world better access to innovative drugs. We have already begun work on the third review of this agreement to ensure that duty-free treatment

is guaranteed to new medicines – a top priority for U.S. industry.

The United States also led a successful effort in the WTO to resolve the crucial issue of drug patents and access to medicines, especially for pandemic diseases like HIV/AIDS, malaria and tuberculosis – striking a delicate balance between addressing the needs of the poorest countries while ensuring the strong IPR protections necessary to foster the future development of lifesaving drugs.

Regionally, the United States successfully removed barriers to trade with Canada and Mexico through the North American Free Trade Agreement (NAFTA). The NAFTA eliminated tariffs among the three countries on nearly all products, including pharmaceuticals.

Through completed and ongoing bilateral FTAs – including our recent agreement with Australia – the United States is:

- Advancing transparency provisions that provide for greater openness for government decision-making on drug approvals and reimbursements.

- Pursuing state-of-the-art IPR provisions that afford better protection for test data, extend patent terms to compensate for delays in granting the original patent, and help to prevent arbitrary patent revocation and the marketing of drugs that violate patents.

- Opening new markets to U.S. services and investment – giving American firms opportunities to provide supplemental health insurance and promote awareness of new medicines to consumers abroad.

- Eliminating costly customs duties on U.S. medicines exports worth hundreds of millions of dollars a year. Nearly all duties on U.S. pharmaceutical products were or will be eliminated immediately through our FTAs with Jordan, Chile, Australia and the Dominican Republic. Most pharmaceutical products will be duty-free immediately on implementation of FTAs with Morocco and Central America, with the remainder removed over a phase-in period.

These commitments are already bearing fruit in Singapore, where USTR and other agencies have successfully pressed that government to publish draft IPR legislation on patent linkage and parallel imports for public comment, citing FTA transparency provisions. Singapore posted the draft laws on the Internet on March 30, and U.S. agencies and other interested parties – including pharmaceutical companies – are currently reviewing them. We are seeking similar significant results in ongoing and planned negotiations with the Southern African Customs Union, Bahrain, Thailand, Panama and the Andean countries.

We are also advancing bilaterally through government-to-government consultations aimed at reducing barriers and improving market access for American medicines. Where we see trade problems, we move to resolve them. And where we see trade barriers, we seek to eliminate them – from negotiations spanning the last ten years to our most recent work with China. For example:

- Over the past decade, USTR has pursued greater market access for U.S. and other foreign pharmaceuticals in Korea, which up until the late 1990s were not allowed to be marketed or sold under the Korean national healthcare system. In 1999, after consultations with the United States, Korea agreed to place foreign drugs on its national health insurance reimbursement list for the first time and to take a more market-based approach to drug pricing. Largely as a result, U.S. and other foreign firms have been able to grow their business in Korea significantly and now hold about 30 percent of the market.

- Pharmaceutical issues have been a centerpiece of our ongoing Regulatory Reform Initiative with Japan. Under this initiative, which I chair with Japan's Deputy Foreign Minister Fujisaki, we have worked with Japan on a range of pharmaceutical matters to uphold the principle of innovation, promote transparency, expedite product approvals, and take a fairer approach to drug pricing. Under the 1998 U.S.-Japan Enhanced Initiative on Deregulation and Competition Policy, for example, Japan committed to two important principles: ensuring transparency by allowing foreign drug and devices manufacturers meaningful opportunities to input into the development of Japan's healthcare policies; and further speeding the introduction of innovative new pharmaceuticals by significantly shortening approval times. We have also pushed back discriminatory pricing initiatives in Japan that targeted U.S. medical devices.

- I have been actively engaged in efforts to urge China to end the rampant counterfeiting of U.S. pharmaceuticals and many other products that harm American manufacturers and put health and safety at risk, to price innovative drugs fairly, and to add new drugs to its national formulary, which controls access to medicines for China's nearly 1.3 billion people and currently contains no medicines produced after 1998. In discussions last week between U.S. Trade Representative Robert Zoellick and China's new Commerce Minister Bo Xilai, China agreed to delay onerous new pricing decisions planned for certain innovative drugs and to update its national formulary. At a subsequent meeting of the U.S.-China Joint Commission on Commerce and Trade (JCCT), China also committed to a range of improvements to its IPR enforcement regime aimed at substantially reducing IPR infringement levels. Those commitments included: applying criminal sanctions to a greater range of IPR violations – from on-line piracy to the import, export, storage and distribution of pirated and counterfeit goods; conducting nation-wide enforcement actions against piracy and counterfeiting; launching a national campaign to educate its citizens about the importance of IPR protection; and establishing a U.S.-China IPR working to consult and cooperate on IPR matters. These commitments are significant and should pave the way for successful high-level discussions on the economic aspects of healthcare delivery in Beijing at the end of next month.

- Closer to home, we secured a commitment from Canada to phase out its "compulsory licensing" system that required U.S. companies to license their proprietary medicines to Canadian firms. Laws implementing that commitment took effect in February 1993.

- And in Mexico, we resolved U.S. pharmaceutical company concerns over government procurement of generic versions of patented pharmaceuticals and decisions by the Mexican Ministry of Health to grant health registrations to generic products without verifying whether a patent already exists for those products.

Meeting New Objectives

Trade Promotion Authority (TPA) granted by Congress in the Trade Act of 2002 introduced a new trade negotiating objective – requiring the Administration to seek to address price controls and referencing pricing systems maintained by foreign governments that discriminate against American products, including pharmaceuticals.

USTR pursued that objective in trade negotiations with Australia, and I and others at USTR worked closely with this Committee to make the U.S.-Australia FTA the first to include special provisions addressing market access for pharmaceuticals. In the agreement, the United States and Australia committed to common principles on facilitating high quality health care and continued improvements in public health for their nationals. These principles include recognition of:

- The important role innovative pharmaceuticals play in delivering high quality health care;

- The importance of research and development in the pharmaceutical industry, and of government support for R&D – including through IPR protection;

- The need to promote timely and affordable access to innovative pharmaceuticals through transparent, expeditious and accountable procedures; and

- The need to recognize the value of innovative pharmaceuticals through adopting and maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical.

To address these principles, Australia will make a number of improvements to its Pharmaceuticals Benefits Scheme (PBS) procedures that will enhance transparency and accountability in the operation of the PBS – including establishing an independent process to review available determinations for product listings. Crucially, the FTA also establishes a Medicines Working Group that will provide a forum for ongoing dialogue on Australia's system of comparing generics to innovative medicines and other emerging health care policy issues. In addition, the U.S. Food and Drug Administration and the Australia Therapeutic Goods Administration will work together to make innovative medical products available more quickly. We urge Congress to act quickly to approve the U.S.-Australia FTA, so that we may begin implementing agreed provisions and working toward further reform.

Our negotiations with Australia and our ongoing consultations with this Committee and others in Congress following the granting of Trade Promotion Authority have placed new barriers to innovation and access to medicines squarely on our agenda, and we are acting to gather the

information we need to understand how these barriers operate in different markets around the world and to effectively organize our trade negotiating team to address them.

The study on drug pricing practices required under the Medicare Prescription Drug Improvement and Modernization Act of 2003 will aid in our understanding. In this study, Congress asked the Department of Commerce – in consultation with USTR, the U.S. International Trade Commission and the Department of Health and Human Services – to report on drug pricing practices of countries that are members of the Organization for Economic Cooperation and Development (OECD) and whether those practices utilize non-tariff barriers with respect to trade in pharmaceuticals.

To bring greater focus to our work in this important area, Ambassador Zoellick also recently announced the creation of a new Assistant USTR for Pharmaceutical Policy. Ralph Ives – the Assistant USTR for Southeast Asia who served as lead negotiator for our FTA with Australia – will serve in this capacity, bringing 30 years of trade policy expertise to the job. He will be assisted by Deputy Assistant USTR for Southeast Asia Barbara Weisel, who also gained experience through the U.S.-Australia FTA negotiations. This announcement recognizes that the trade challenges facing pharmaceuticals firms – like so many others – cut across a number of key functional and geographic areas – from tariffs and non-tariff barriers to IPR and services, and from Asia and Australia to Europe and North America.

Conclusion

Mr. Chairman, promoting innovation in the pharmaceuticals sector and ensuring access to lifesaving medicines has been on the U.S. trade agenda for many years. And we have established a solid track record of delivering results for this important sector and for the workers and consumers who contribute to and benefit from its achievements.

But we are here today to consider new concerns and new objectives. I believe the U.S.-Australia FTA developed core principles that may serve as useful guideposts as we consider the best opportunities and methods to address barriers to trade in pharmaceuticals and the objectives that will steer us in ongoing and future global, regional and bilateral negotiations – including upcoming FTA negotiations and consultations with Canada and other major trading partners bilaterally and in international fora like the OECD. Our experience with Australia has also taught us that we need to take a customized approach to tackling these barriers – recognizing that healthcare systems and restrictions on trade in medicines differ significantly from country to country.

As we move forward, we welcome the continued guidance and leadership of this Committee and others in Congress.

Thank you.