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SENIOR VICE PRESIDENT
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PhRMA

November 27, 2000

Ms. Gloria Blue
Executive Secretary
Trade Policy Staff Committee
Office of the United States Trade Representative
600 17th Street, N.W., Room 122
Washington, D.C. 20508

Re: Request for Public Comment With Respect to the Annual National Trade Estimate Report on Foreign Trade Barriers, Federal Register (Volume 65, Number 211)

Dear Ms. Blue:

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), I am writing in response to USTR's October 31, 2000 request for comments on foreign trade barriers facing the U.S. research-based pharmaceutical industry. As in previous years, we understand that these comments will be used in preparing the National Trade Estimate Report (NTE) as required by Section 303 of the Trade and Tariff Act of 1984, as amended. We estimate conservatively that the lost revenues attributable to the trade barriers identified in this submission total more than $11 billion per year.

Intellectual Property Protection

While the U.S. research-based pharmaceutical industry is faced with an array of foreign trade barriers, the fundamental impediment to our industry globally remains inadequate and ineffective intellectual property protection. Flagrant violations occur in countries such as Argentina, China, Egypt, India, Israel, Thailand and Turkey, but as our attached submission demonstrates, intellectual property rights are under threat to varying degrees around the world. Our industry invests more than any other on research and development and relies heavily on patent protection and the safeguarding of proprietary data against unfair commercial use. Our continued ability to improve the health and prolong the lives of the world's citizens is directly linked to adequate intellectual property protection. Regrettably, as we describe in the attached document, continued failures in legal systems and enforcement constitute onerous barriers to trade.

More than ever before, our strong economy relies on knowledge-based exports. In the United States and in many of our major trading partners, strong intellectual property protection for all fields of technology enjoys broad public and government support and must remain a cornerstone of U.S. trade policy.

As described in detail in this submission, we often face adamant opposition, particularly from vested interests abroad which profit handsomely from the production of

medicines based on stolen American ideas. These patent pirates do no innovative research and divert resources from efforts to find tomorrow's cures. In most cases, they do not pass their "savings" on to their fellow citizens. International patent piracy means that U.S. and foreign patients lose, as do U.S. industry and labor, while only the local pirate industry wins. Thus, the absence of adequate patent protection imposes heavy net social as well as economic costs both at home and abroad.

While our industry highlights a number of countries where intellectual property protection remains the most daunting challenge, we also have witnessed genuine improvements in that protection in several key countries, most notably, the Czech Republic. We appreciate the efforts of the Executive Branch and Congress in attaining that success.

We remain concerned that the TRIPS agreement is not enforced government-wide in many countries. While patent offices are generally aware of TRIPS' provisions, health regulatory authorities frequently fail to protect confidential information and test data. Article 39 of TRIPS calls on WTO member states to provide meaningful protection against unfair commercial use for undisclosed information - "trade secrets" and "test data." We believe that if a WTO member requires the submission of test data to obtain marketing approval for pharmaceutical or agricultural products, it must protect such data against disclosure and unfair commercial use. Test data must be protected against disclosure to the public (or even within government) unless such disclosure is necessary for public safety, or unless

requirements that undercut the effectiveness of TRIPS trademark protections; illicit business

Agreement. There is reason for optimism, with the recent signing of the U.S./Jordan Free Trade Agreement. We are encouraged that Israel is considering legislative action to provide data protection. Progress in Egypt towards meeting WTO TRIPS obligations appears to have slowed in recent months. In addition, the U.S. research-based pharmaceutical industry faces discriminatory policies and price controls, as well as the absence of data exclusivity in this region.

The Western Hemisphere. There have been positive changes in several countries during the past several years, including the provision of pipeline protection in Brazil, Chile and Mexico, as well as discussions on regulatory harmonization throughout the region. However, significant problems persist, notably inadequate intellectual property protection in numerous countries (with Argentina providing the most egregious example), price controls, and discriminatory requirements for registering innovative pharmaceutical products.

The attached submission outlines the principal trade barriers that our industry faces in 46 countries or areas worldwide. These are organized into four regional groups: Asia-Pacific, Europe, Middle East-Africa, and the Western Hemisphere. Individual discussions are provided on: the Andean Community, Argentina, Australia, Belgium, Brazil, Canada, Central America, Chile, China, Czech Republic, Dominican Republic, Egypt, Estonia, European Union, Hong Kong, Hungary, India, Indonesia, Israel, Japan, Korea, Lithuania, Mexico, Morocco, New Zealand, Pakistan, Philippines, Poland, Russia, Saudi Arabia, Singapore, Slovenia, South Africa, Taiwan, Thailand, Turkey, the United Arab Emirates, Uruguay and Vietnam. The challenges are many but vigilance and perseverance are the only options for one of America's strongest industries.

PhRMA appreciates the opportunity to contribute to the 2001 National Trade Estimate Report. We are hopeful that the efforts of the U.S. Trade Representative and Departments of State and Commerce will lead to continued success in achieving both bilateral and multilateral agreements on intellectual property protection and in eliminating other pernicious barriers to U.S. trade. Please do not hesitate to contact my staff or me if you have any questions regarding the content of PhRMA's submission.

Sincerely,

Shannon S.S. Herzfeld

Attachment