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May 10, 2001

Ms. Gloria Blue
Executive Secretary
Trade Policy Staff Committee
Office of the U.S. Trade Representative
600 17th Street, NW, Room 122
Washington, DC 20508

Re: Request for Public Comments: Mandated Multilateral Trade Negotiations on Agriculture and Services in the World Trade Organization (WTO) and Priorities for Future Market Access Negotiations on Non-Agricultural Goods, (March 28, 2001)

Dear Ms. Blue:

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies, I am pleased to submit our comments identifying negotiating priorities in the areas of agriculture, services and market access for future negotiations under the auspices of the World Trade Organization (WTO).

PhRMA is a trade organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, happier, healthier and more productive lives. This year, PhRMA members expect to invest more than $ 30.5 billion in research and development efforts to identify and bring to market new drugs. Our members employ almost a quarter of a million Americans in a variety of high-skill, high-wage jobs. The industry's annual worldwide sales in 2001 are expected to exceed $160 billion. One third of this revenue comes from sales of our products in foreign markets. It goes without saying that our ability to compete effectively in foreign markets is dependent on effective, non-discriminatory trade rules that protect our technology and products. Access to world markets has been, and will continue to be, essential to helping these companies maintain their preeminent position in the world.

PhRMA welcomes this opportunity to provide comments on U.S. objectives for negotiations under the built-in agenda for agriculture and services. We also applaud the decision to accept comments on the U.S. objectives during a new round of WTO negotiations, should such a new round be launched. These negotiations provide a tremendous opportunity for opening global markets and strengthening international trade rules, and PhRMA stands ready to support USTR's efforts. At the same time, it is crucial that the negotiations not be used to reopen negotiations on existing commitments. The United States must guard against any weakening of the protections that were negotiated during the Uruguay Round, particularly in the area of intellectual property rights. With these goals in mind, we provide below our comments on U.S.

Given the significant burden that these types of limitations place on services related to the distribution and sale of pharmaceuticals, the U.S. Government should work to ensure that regulations concerning the distribution, sale, and advertising of pharmaceutical products are not prepared, adopted or applied with a view to or with the effect of creating unnecessary barriers to trade.

MARKET ACCESS

NON-MARKET-BASED GOVERNMENT INTERVENTIONS

Non-market-based government interventions that regulate prices, profits, or sales volumes of pharmaceutical products penalize consumers and threaten to undermine the ability of the pharmaceutical industry to develop new innovative products. As a result, the quality of health care around the world is diminished. Governments often justify these market interventions as cost-containment measures that are necessary to ensure the availability of cheap medicines to their citizens. While the industry recognizes and supports the need for governments and consumers to contain costs, the approaches used by governments to do so often distort free trade in these products and threaten to undermine the competitiveness of the U.S. research-based pharmaceutical industry and its innovative products. Furthermore, they actually reduce the availability of new medicines over the long term.

The success of the U.S. pharmaceutical industry depends upon its ability to continue to fund the enormous research and development costs necessary to continue to develop high-quality innovative medicines. It costs approximately $500 million to develop and test a new pharmaceutical product. Investment in new platform technologies such as high-throughput screening, combinatorial chemistry and genomics must be considered as well. The industry is most willing to undertake this level of investment risk when producers can operate in an environment where the market determines the price for their products. Price controls and other government interventions in the market upset the balance of supply and demand and threaten to undermine the future development of innovative medicines. A more immediate impact of such measures is that they often deprive health care providers of effective treatment options that are already available in other healthcare systems around the globe.

The impact on U.S. industry and consumers is significant. Because U.S. pharmaceutical companies are the world leaders in the development of innovative pharmaceutical products, they are inevitably the hardest hit by government imposed price controls and similar market interventions. These measures operate to undermine the value of the intellectual property rights of U.S. companies and U.S. patents while protecting generic producers and inefficient foreign companies that cannot compete with U.S. companies in a free and fair market. Furthermore, government market interventions create conditions for free-riding on U.S. privately and publicly-funded research which is not sustainable in the long-run.

Price and cost control measures can take several forms. Several countries employ reference pricing systems in which prices are restricted based, for example, on the prices in other markets, which may themselves be subject to price controls. Prices may also be based on the prices of other products in the same or similar therapeutic class, a system that often ignores significant therapeutic differences among products, such as side effect profiles, contraindications, and dosing regimens. Frequently, patented and non-patented products are grouped together and priced in the same manner, thus significantly undercutting the value of the patent holder's rights. Some government measures, like those that have been proposed in China, directly discriminate between domestically produced products and foreign products.

Some of the more egregious government interventions are as follows:

- *Canada*: The Patented Medicine Prices Review Board imposes price controls on patented pharmaceutical products based on the average price for the same medicine in the same or comparable dosage forms; international price comparisons; or the prices of other products in the same therapeutic class.

- *Canada*: In the province of British Columbia, reimbursement of a pharmaceutical product by the health care system is based on a reference price, which is the price of the least costly drug in the product's therapeutic category.

- *New Zealand*: The Pharmaceutical Management Agency (PHARMAC) groups together patented and generic products, or products with significant therapeutic differences, for reference pricing purposes; denies reimbursement for a product when it subjectively determines that "sufficient" products are available; denies or conditions reimbursement based on the manufacturer's acceptance of a reimbursement level that is less than or equal to the current PHARMAC-imposed reimbursement level of existing medicines; and uses sole supply tendering for certain products, which effectively precludes more than one supplier from entering the market.

- *Australia*: Australia applies Therapeutic Group Premiums (TGP), a form of reference pricing, to four classes of drugs. The TGP system groups certain classes of drugs that have a "similar clinical activity." The Government sets a single base or benchmark price for products in each group, and provides reimbursement at that price level. Patients must pay a premium for drugs that are priced above the base or benchmark price.

Government interventions of this sort undermine the protections afforded by, *inter alia*, the TRIPS Agreement, the Agreement on Government Procurement, the TRIMS Agreement and GATT Article III. However, existing rules are not always sufficient to address the specific problems resulting from the various measures employed by WTO members. Therefore, the U.S. Government should encourage the WTO to take note of the negative impact that government market interventions may have on international trade and investment, examine the use of such measures, and assess their impact on the benefits of trade, competition and investment in innovative products and technology. It should also seek to negotiate new rules, either within or

outside the framework of existing WTO agreements, to address the problems raised by government interventions.

GOVERNMENT PROCUREMENT

Existing international trade rules do not adequately address situations in which governments control their pharmaceutical markets through reimbursement of health care costs and other indirect means. As explained above, governments often abuse this power by imposing strict price controls or similar measures on the sale of pharmaceutical products. In some cases, there is notable lack of transparency. These measures have the effect of distorting the market and undermining the ability of research-based pharmaceutical companies to continue to develop innovative products. Consequently, the United States should explore the expansion of WTO rules, and the creation of new rules, to ensure that these measures do not curtail the global competitiveness of the U.S. research-based pharmaceutical industry.

One way to do this would be to pursue expanded coverage of the plurilateral Agreement on Government Procurement. In particular, the United States should ensure through negotiations the coverage of governmental and quasi-governmental entities responsible for the direct or indirect procurement of and/or payment for pharmaceutical products. Although the Ministries of Health of many Parties to the Agreement are currently listed in Appendix 1 to their respective schedules, the entities that actually procure pharmaceutical products are not listed and apparently do not adhere to the rules set forth in the Agreement. Members should be encouraged to bring these entities within the scope of the Agreement. Those countries that are not currently signatories to the Agreement should be encouraged to sign the Agreement and ensure that the relevant health and/or procurement authorities are subject to the Agreement's disciplines. The expanded coverage of the Agreement would help ensure fair competition and transparency.

PhRMA member companies also fully support U.S. efforts to conclude a WTO Agreement on Transparency in Government Procurement. Such an agreement would help ensure that government procurements are conducted in a fair, equitable and non-discriminatory manner.

GOVERNMENT CORRUPTION

In Singapore in 1996, the Ministerial Conference established a working group to conduct a study on transparency in government procurement practices, taking into account national policies. The Ministerial Conference agreed that, based on this study, Members would develop elements for inclusion in an appropriate agreement.

PhRMA urges the United States to ensure that WTO Members broaden this inquiry to encompass the impact of government corruption on trade. In addition, PhRMA believes that the United States should encourage WTO Members to include elements of the Anti-Bribery Convention completed under the auspices of the Organization for Economic Cooperation and Development within their national statutes.

CUSTOMS AND TARIFF ISSUES

A. Tariff Elimination

The pharmaceutical tariff elimination agreement, while beneficial for consumers and the industry alike, is limited in the scope of its coverage of products and countries. The number of countries participating in the "zero-for-zero" tariff elimination agreement on pharmaceuticals remains limited, allowing for many free rider countries whose products are not assessed duties upon importation into the U.S., but who do not reciprocate with respect to U.S. exports to those countries. In addition, the coverage of products is not comprehensive. Although there is a schedule for periodic updates, such negotiations have not kept pace with rapid developments in the industry, creating unproductive administrative costs.

Our industry works diligently to make our products available worldwide, yet we are frustrated to find that countries with the largest population of medically underserved people often have high tariffs on medicines. Tariffs on pharmaceuticals overburden and distort healthcare costs and should be opposed outright by all trading nations.

PhRMA requests that the US continue to press trading partners to complete scheduled updates of the tariff elimination agreement covering newly developed products, as committed to in the Uruguay Round and without regard to the timing of initiation of a new round. Furthermore, the U.S. should call upon all WTO members to immediately reduce tariffs on medicines and sole-use inputs to zero. In addition, PhRMA supports improvements to the pharmaceutical tariff elimination agreement by revising the tariff nomenclature to permit coverage of new products without the cumbersome process of negotiating update agreements every three years. PhRMA also seeks to include the free-rider countries, either through direct inclusion in the agreement, or through full participation in the Accelerated Tariff Liberalization initiative. All additional countries acceding to the WTO should be required to become signatories to the pharmaceutical tariff elimination agreement.

B. Rules of Origin

The completion of the harmonization work program under the Agreement on Rules of Origin is of great importance to global trade in pharmaceutical products. The work in the Technical Committee on Rules of Origin, under the auspices of the World Customs Organization, and the WTO Committee on Rules of Origin must be completed within a reasonable period of time so that realistic origin-conferring processes are incorporated in the resulting non-preferential rules of origin.

To this end, PhRMA urges the United States and other WTO Members to:

1. Adopt rules of origin for pharmaceutical goods based upon chemical reactions, normal dosage formulation, and activities resulting in a change in tariff classification;

2. Make sufficient resources available so that the work program in the WCO and WTO may be completed as soon as possible, or else consider possible early-harvests of those sectors where agreement has been reached.

C. Customs Valuation

Many developing country Members of the WTO invoked the five-year transitional provisions of Article 20 of the Customs Valuation Agreement. In addition, these Members are eligible to delay for an additional three years the application of some of the technical rules on customs valuation. Unfortunately, several Members have failed to meet the January 1, 2000 deadline, and some have requested additional waivers for several years. As with tariffs and local taxes, customs place additional burden on the cost of medicines and biological products, costs which must be passed along to consumers. These customs duties are most burdensome on consumers in poorest countries.

It is in the interest of all WTO Members to ensure the faithful compliance with the Agreement as soon as possible. Accordingly, PhRMA recommends that, consistent with paragraph 3 of Article 20 of the Agreement, WTO Members assign sufficient technical resources to assist developing country Members to meet their obligations without delay and to limit the approval of waivers to those countries that have shown actual, significant progress on implementing the Agreement.

INTELLECTUAL PROPERTY RIGHTS

1. Preservation of Existing TRIPS Commitments

Given the status of implementation of the patent, trademark, data exclusivity and procedural obligations of TRIPS, PhRMA believes the United States should place a priority on pursuing improvements to global intellectual property standards through bilateral and regional efforts, and through norm-setting efforts in the World Intellectual Property Organization focused on improving patent granting systems. Indeed, until full implementation of current TRIPS obligations is substantially complete, PhRMA believes that it would be ill-advised and premature to open the TRIPS agreement in a new round of WTO negotiations.

It is imperative for the United States to dispel any notion that TRIPS implementation and reviews or any new negotiations provide opportunities to reduce, dilute or delay implementation of the obligations mandated by the current text of the TRIPS Agreement. The minimum international obligations undertaken in the Uruguay Round on intellectual property must be respected and met by all WTO Members, including developing countries and countries seeking to join the WTO. Accordingly, the United States Government must preclude any deliberations that would call into question the *existing* obligations of the Agreement and should seek to forestall any efforts to pursue such an end through a reopening of the Agreement. In particular, the U.S. Government should seek to preserve existing rules on the following matters:

a. Scope of Patent Obligations

PhRMA members urge the U.S. Government to oppose all proposals that could raise the possibility of diminishing the patent obligations of the Agreement by, for example, narrowing the obligations concerning patent eligibility for plant and animal inventions, or by loosening the restrictions on use of patented inventions without the permission of the patent owner. .

b. The Moratorium on Use of Non-Violation Grounds in WTO Dispute Settlement Proceedings Involving the TRIPS Agreement

Although there has been little recent discussion among WTO Members of a revival and extension of the now-expired moratorium on invoking non-violation grounds in WTO dispute settlement proceedings involving the TRIPS Agreement, we expect renewed debate close to Doha. PhRMA believes that any further foreclosure of use of non-violation grounds in dispute settlement proceedings will deprive intellectual property owners of the full protections afforded by the Agreement. Given the resistance of certain WTO Members to substantive intellectual property reform, it is crucial that the U.S. Government preserve all of its options in the dispute settlement process to remove direct and indirect impediments to TRIPS compliance. The U.S. Government should accordingly strongly oppose any effort to re-institute the moratorium specified in Article 64.2.

c. Transition Periods for Compliance

Many developing country WTO Members have used their transition period to establish the necessary reforms to bring their regimes into compliance with TRIPS standards. However, a far larger number of developing country WTO Members have not made these legislative reforms. More distressing is the fact that few developing countries have undertaken reforms in the areas of enforcement or in development of improved registration systems (e.g., procedures for granting patents and registering trademarks) that are critical to giving effect to the obligations of the Agreement. Of particular concern is the disregard many countries have shown for data protection, still not fully-implemented in many countries, such as Egypt, which continues to allow local companies to register copycat products based on data owned by the originator U.S. company.

The U.S. Government should oppose any effort to extend transition periods for compliance with the obligations of the Agreement for developing countries. The five years provided to developing countries to date should have been more than adequate to enable these countries to undertake the legislative and regulatory reform needed to bring their systems into compliance with TRIPS standards. Countries that have chosen to delay implementation with the hope that the transition periods will be extended should not be rewarded. PhRMA members strongly urge the United States to oppose any effort to dilute any of the obligations of the Agreement including transition periods or to obtain transition-type waivers of obligations to implement or enforce the TRIPS Agreement.

2. Ensuring Compliance with Existing TRIPS Obligations

PhRMA encourages the United States to continue use of the dispute settlement procedures of the WTO to promote compliance and to confirm the nature of the existing obligations of the Agreement. We applaud that the US has requested a panel in the Brazil case and urge the US to move quickly to the panel phase in the Argentine disputes. Further, we are pleased that USTR has indicated that India, Israel, Hungary and the Dominican Republic among others are candidates for potential dispute settlement proceedings. PhRMA believes the United States should complement these and other WTO-based enforcement efforts with bilateral discussions with WTO Members that fail to implement their obligations under the TRIPS Agreement or otherwise undermine the intellectual property of innovative U.S industries.

PhRMA also encourages the U.S. to include within the WTO dialogue new capacity building/technical assistance initiatives that will assist Member States that seek to comply with the existing obligations of the Agreement.

3. Future Negotiations

Work planned under the built-in agenda will include reviews specified in Article 71 of the Agreement, including the limited review in 2000 and the more comprehensive review of the Agreement starting in 2002. These reviews will provide an opportunity for the United States to elaborate its views on a number of the provisions of the Agreement, and will provide other WTO Members a similar opportunity to indicate how they view the Agreement.

PhRMA recommends that the United States Government seek assurances that developments arising out of work on the built-in agenda are framed so as to ensure that the existing agreement is not weakened.

Under the built-in agenda, the TRIPS Council has begun its review of the protection required by the Agreement for plant and animal innovation and on the issue of expiration of the moratorium on use of non-violation grounds in dispute settlement proceedings involving the TRIPS Agreement. The United States Government should make it a priority to ensure that these reviews produce favorable outcomes that will strengthen the obligations of the Agreement.

4. Technical Assistance

PhRMA and its members applaud the efforts of the United States – directly and through its support of WIPO and other relevant multilateral organizations – to provide technical assistance to developing country officials focused on legislative reform. PhRMA believes that these efforts must be complemented by additional programs and activities that will help developing country industrial property officials establish efficient and cost-effective procedures for granting rights. This assistance should include training of officials responsible for review and granting of patents and development of relationships between the United States Patent and Trademark Office and other major industrial property offices that would enable these developing country industrial property offices to expedite the application review and granting process. PhRMA also believes the United States should expand its efforts to provide training and other

forms of assistance to courts, customs authorities and law enforcement officials in developing countries to help those countries develop effective enforcement measures.

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PhRMA member companies encourage the United States to take advantage of opportunities under the auspices of the World Trade Organization to strengthen international trade rules and eliminate remaining barriers to trade in innovative products. The tearing down of trade barriers and the opening of global markets will help maintain the competitiveness and strength of U.S. industry and boost the U.S. economy. PhRMA fully supports the U.S. Government's efforts to assume a leading role in this effort.

Sincerely,

Shannon S.S. Herzfeld

Shannon S.S. Herzfeld
Senior Vice President, International