Congress of the United States
Washington, DC 20515

December 5, 2005

The Honorable Rob Portman
United States Trade Representative
600 17th Street, N.W.
Washington, DC 20508

Dear Ambassador Portman:

We are writing to request immediate clarification of the U.S. Government's stance on access to generic medications at the forthcoming World Trade Organization Ministerial in Hong Kong. The positions reportedly taken by the United States threaten access to affordable generics, both for developing nations and for the United States itself.

At issue is the ability of countries to import generic versions of a patented drug. The United States has stated that it will not take advantage of a process that would allow it to import generics under a compulsory license, even if the public health requires it. In addition, it has reportedly pushed for provisions that could make it harder for all countries, including the poorest, to access generics in this manner.

Our concerns are detailed below.

Background on Intellectual Property and Importation of Generic Drugs

The TRIPS agreement on Trade-Related Aspects of Intellectual Property Rights took effect in 1995.[1] The 2001 Doha Declaration states that "the TRIPS agreement does not and should not prevent Members from taking measures to protect public health."[2] According to the Declaration, "the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' rights to protect public health, and in particular, to promote access to medicines for all."[3] In August 2002, the U.S. Congress passed legislation that directs adherence to the Doha Declaration in U.S. trade negotiations.[4]

The Doha Declaration affirmed the right of countries to issue compulsory licenses to domestic manufacturers to make a generic version of a patented drug when the country deems necessary.[5] However, the Declaration did not resolve how countries could access such generics if they lack sufficient manufacturing capacity.

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

[2] Paragraph 4, 'Declaration on the TRIPS Agreement and Public Health', WTO Ministerial Conference — Fourth Session, WT/MIN(01)/DEC/2, adopted 14 November 2001. (Doha Declaration).

[3] *Id.*

[4] Trade Promotion Authority Act, Pub. L. No. 107-210; 19 U.S.C. §3802(b)(4)(C).

[5] Doha Declaration, Paragraph 5.

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Compulsory Licenses for Importation of Generics

In August 2003, WTO members established a temporary mechanism by which countries could issue compulsory licenses to manufacturers in other nations and then import the drugs.[6] While this addressed an important gap in the Doha Declaration, the mechanism has been criticized by public health organizations and experts as placing undue burdens on countries' abilities to issue such licenses.[7]

Specifically, the protocol involves a separate process for every country and every drug, diminishing economy of scale and reducing the incentive of generic manufacturers to produce for other governments. Furthermore, the procedure has not yet been employed, and there is therefore no evidence yet of whether it can work to provide effective and speedy access to generic drugs. The high prices of the current generation of HIV/AIDS drugs — which will be on patent for years — make these concerns even more pressing.[8]

In addition, a Statement from the General Council Chairperson read aloud at the 2003 meeting, though of unclear legal status, calls into further question the feasibility and usefulness of the mechanism.[9] According to the WTO, the Statement was "designed to provide comfort to those who feared that the decision might be abused and undermine patent protection."[10] One problematic provision would place the responsibility of preventing diversion of drugs on both exporting and importing countries, which may not have the enforcement capacity.[11]

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[6] World Trade Organization, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,* Decision of the General Council of 30 August 2003 (WT/L/540)(Sept. 1, 2003)(online at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm#asterisk).

[7] *Joint Statement by NGOS on TRIPS and Public Health: WTO Members Should Reject Bad Deal on Medicines* (Dec. 4, 2005)(online at http://lists.essential.org/pipermail/ip-health/2005-December/008767.html).

[8] Doctors Without Borders/Médecins Sans Frontières (MSF) Campaign for Access to Essential Medicines, *The Second Wave of the Access Crisis: Unaffordable AIDS Drug Prices ... Again* (Dec. 2005).

[9] *The General Council Chairperson's statement* (Aug. 30, 2003)(online at http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm).

[10] World Trade Organization, *Press Release: Decision removes final patent obstacle to cheap drug imports* (Aug. 30, 2003)(online at http://www.wto.org/english/news_e/pres03_e/pr350_e.htm).

[11] *The General Council Chairperson's Statement, supra* note 9.

The United States, along with European nations, declared in the August 2003 agreement that it would not avail itself of the importation option.[12] Certain other countries, including Hong Kong, China, Israel, and Korea, stated that they would only use the system in cases of emergencies or extremely urgent situations, but the U.S. "opt-out" inexplicably rejected any such safety net.[13]

In the recent Gaborone Declaration, African Health Ministers questioned the August 2003 decision, calling for "the Ministers of Trade to seek a more appropriate permanent solution at the WTO that revises the TRIPS agreement and removes all constraints, including procedural requirements, relating to the export and import of generic medicines."[14] However, this proposal has not gained traction.

The Current U.S. Position

Despite the August 2003 proposal's apparently unwarranted complexity, the lack of evidence that it will be effective, and the concern of developing nations most directly affected, United States and European negotiators have reportedly insisted that it be incorporated into the TRIPS agreement as a permanent amendment.[15] They also reportedly urged that the Chairman's Statement from 2003 be incorporated into the agreement. Though they appear to have relented on this demand, they have reportedly insisted that the statement be read again at the upcoming Hong Kong Ministerial.[16]

Furthermore, we understand that the USTR maintains the position that the U.S. will not avail itself of the opportunity to issue a compulsory license for importation even in the event of a crisis.[17] We believe this is an untenable position, especially in light of the current threat of an avian flu pandemic. Although the U.S. Government has been working with Roche, the sole producer of Tamiflu, to stockpile supplies for 2007, there remains concern that the company will not be able to manufacture enough of the antiviral drug to fill orders for the United States (or

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[12] World Trade Organization, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, supra* note 6 at footnote 3.

[13] *Id.*

[14] *Sustainable Access to Treatment and Care For the Achievement of the Millennium Development Goals*, 2nd Ordinary Session of the Conference of African Ministers of Health (CAMH2) Gaborone, Botswana, 10 – 14 October 2005 CAMH/Decl.1(II)(online at http://www.phrusa.org/campaigns/aids/pdf/gabarone_declaration.pdf).

[15] *Status of TRIPS and Public Health Negotiations* (Dec. 2, 2005)(online http://lists.essential.org/pipermail/ip-health/2005-December/008764.html).

[16] *Id.*

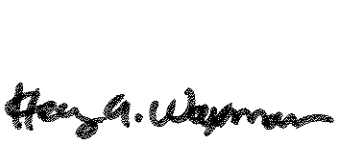
[17] *Id.*

other countries).[18] Despite Roche's intention to issue voluntary licenses to generic manufacturers to fulfill unmet need, an imported generic could theoretically be necessary if, for example, another drug is found to be more effective or the pandemic progresses more rapidly. In addition, Roche's issuance of voluntary licenses was neither inevitable nor precedent-setting. For this and future public health problems, the U.S. "opt-out" from compulsory licensing for importation could leave our government — and citizens — dangerously vulnerable.

Because of the potential threats to public health preparedness in developing countries and at home, we request clarification of the U.S. Government's position on compulsory licensing for importation. Specifically, we would like to know why the U.S. reportedly wishes to make permanent a system that has been criticized as overly burdensome and has not yet been shown to be effective. In addition, we request an explanation of why the United States should foreclose the possibility of using the importation mechanism. We would like to know if it is the belief of the U.S. Trade Representative that the United States will be able to "opt back in" to the compulsory licensing for importation system if public health requires. If yes, we request a detailed explanation of the procedures that would have to be employed to permit the United States to do so.

We request an immediate response.

Sincerely,


Henry A. Waxman
Member of Congress

Sherrod Brown
Member of Congress

Thomas H. Allen
Member of Congress

[18] Secretary of Health and Human Services Michael Leavitt testified at a recent hearing, "Unfortunately, current capacity for domestic manufacture of influenza vaccine and antiviral drugs can meet only a small fraction of the need projected for a pandemic response." Testimony of HHS Secretary Michael O. Leavitt (Nov. 8, 2005)(online at http://energycommerce.house.gov/108/Hearings/11082005hearing1704/Leavitt.pdf).