Congress of the United States
Washington, DC 20515

**FOR IMMEDIATE RELEASE**
October 13, 2006

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# SEN. KENNEDY AND REP. WAXMAN CALL FOR INVESTIGATION OF U.S. TRADE AGREEMENTS AND INTERNATIONAL HEALTH

**WASHINGTON, DC** — Senator Edward Kennedy and Representative Henry Waxman have requested that the Government Accountability Office investigate the Administration's trade negotiations and their negative effects on developing countries' access to medicines. According to the Trade Act of 2002, the Administration is obligated to promote access to healthcare for all countries in their trade practices, and Sen. Kennedy and Rep. Waxman want to ensure those obligations are fulfilled.

Senator Kennedy said, "We've requested this investigation to help understand how the Administration has balanced commercial drug interests with the health needs of poor people living in developing countries. In this era of HIV epidemics, avian flu outbreaks, and other public health threats, it is essential that we promote good health and access to medicines in every nation."

Rep. Waxman said, "Administration trade agreements have numerous provisions that threaten access to affordable medicine. We have to recognize that the Bush Administration's single-minded pursuit of intellectual property protections for drug companies can have potentially devastating consequences for the public health in developing countries."

Senator Kennedy and Representative Waxman have also requested the Administration retract its demand that the World Health Organization withdraw a report on trade and health. The report criticizes the trade practices of some developed countries — including the U.S. — as interfering with developing countries' rights to promote public health.

In response to the Administration's letter, Kennedy said, "The World Health Organization's study, and others like it, suggests that our trade policies have hampered access to life-saving medicines, such as HIV therapies and treatments for avian flu. If this is the case, we need to know — and we need to change our policies."

Rep. Waxman said, "Most of our trade policy takes shape far from the public spotlight. We need more analysis of the implications of our policies — not less. The Bush Administration should assess its own obligations to public health rather than seeking to quash any criticism."

The letters sent from Senator Kennedy and Representative Waxman to Comptroller General Walker on September 27, 2006, and to Sec. Leavitt on October 13, 2006, are below. (PDF available upon request)

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October 13, 2006

The Honorable Michael O. Leavitt
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Leavitt:

We are writing with regard to an August 18, 2006, letter from William R. Steiger, HHS Special Assistant for International Affairs, to the Acting Director General of the World Health Organization. In this letter, Mr. Steiger insisted that the World Health Organization withdraw a study critical of the impact of U.S. trade policy on international health.

The report Mr. Steiger found objectionable is titled "The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?" Commissioned by WHO, it identified barriers to public health resulting from the trade policies and free trade negotiations of several developed nations, including the United States.

In his letter, Mr. Steiger demanded that WHO "withdraw" the report and remove its emblem from the publication. Mr. Steiger stated that he has "raised similar concerns with the WHO Secretariat in the past about trade agreements," and he requested that the Executive Board of the WHO conduct a full review of WHO's publication policy.

As a signatory to the Doha Declaration, a trade agreement recognizing the right of member countries to protect public health, the United States is obligated to respect the public health initiatives of other countries. Yet in the past, we have expressed concerns that the Administration has sought intellectual property provisions in bilateral trade agreements that contradict our obligations under the Doha Declaration. These concerns have never received a satisfactory response from the Administration, and it seems that the problems raised by the WHO report are being similarly dismissed rather than addressed.

In this era of AIDS epidemics, pandemic flu threats, and drug-resistant tuberculosis outbreaks, we need more—not less—analysis of the factors affecting global public health. Attempting to suppress a report because it is critical of U.S. trade policy is unacceptable. Instead, the United States should seriously assess the impact of our trade policies on access to medicines and public health.

We request that you forward to our offices any additional letters or communications sent by Mr. Steiger or other members of the Administration requesting that a World Health Organization publication, official, or representative be recalled for criticizing U.S. policies. Specifically, we request that these include copies of the past correspondence described by Mr. Steiger and the further correspondence mentioned by Mr. Steiger when he wrote, "I intend to address these specific issues in a subsequent letter to you."

We also ask that you cooperate fully with the Government Accountability Office as it responds to our request last week for an investigation into the effect of the U.S. Trade Representative's activities on public health. Specifically, we have asked GAO to assess whether the formal and informal mechanisms of U.S. trade policy conform to the Congressional directive to respect the Doha commitment to public health.

We would appreciate receiving these documents by October 28, 2006. If you have any questions, please let us know, or contact David Bowen at (202) 224-7675.

With respect and appreciation,

Sincerely,

Senator Edward M. Kennedy
Ranking Member
Committee on Health, Education,
Labor and Pensions
U.S. Senate

Representative Henry A. Waxman
Ranking Member
Committee on Government Reform
U.S. House of Representatives

September 27, 2006

The Honorable David M. Walker
Comptroller General
United States Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Walker,

We are writing to request a study of the U.S. Trade Representative's interpretation and implementation of the principle trade objectives relating to intellectual property, as established by Congress in the Trade Act of 2002.

The Act elaborated three objectives relating to intellectual property: "to further promote adequate and effective protection of intellectual property rights"; "to secure fair, equitable, and nondiscriminatory market access opportunities for United States persons that rely upon intellectual property protection"; and "to respect the Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization at the Fourth Ministerial Conference at Doha, Qatar on November 14, 2001."

Taken together, these three objectives identify priorities and articulate a clear vision for trade negotiations related to intellectual property. By Congressional mandate, the Administration has an obligation to advance this vision through its formal and informal trade promotion activities. We are interested in how these objectives have been interpreted, pursued, and implemented by the Administration since Trade Promotion Authority was granted by Congress in 2002.

In particular, we would like to learn to what extent the third objective, to respect the Doha Declaration on TRIPS and Public Health, has been pursued. In relevant part, the Doha Declaration states that no country should be prevented from exercising its rights to protect public health and promote access to medicines for all. Subsequent elaborations, in 2003 and 2006, have specified mechanisms intended to facilitate such access to medicines. We are interested in understanding how the rights and priorities identified by the Doha objective have been incorporated into trade-related policies, agreements, and practices of the Administration. In your study, please consider the following questions:

- Has the U.S.T.R., through trade agreement provisions, negotiations, preference programs, trade-capacity building, and other efforts, pursued objectives and principles established under the Doha Declaration and TRIPS Agreement? Have these efforts been successful?

- How has the U.S.T.R. balanced efforts to pursue the Doha objective with the two other intellectual property negotiating objectives outlined by Congress in 2002? How many, if

any, provisions negotiated since 2002 expand the Doha protections for access to medicines? How many, if any, provisions of such agreements narrow these protections? What has been the relative impact of each set of provisions?

- If any instruction included in the Trade Act of 2002 has been found to be in conflict with the Doha objective in practice, how has the Administration acted?

- How has the U.S.T.R. promoted the obligations of developed countries as articulated in the Doha Declaration? For example, the Doha Declaration reaffirms "the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members." Has the U.S.T.R. facilitated such transfer through or in connection with bilateral trade agreements or other mechanisms?

- Have demands of the U.S.T.R., through bilateral trade agreements and other mechanisms, expanded or limited the rights of developing countries as articulated in the Doha Declaration? For example:

    - Has the U.S.T.R. expanded or constrained developing countries' freedom to independently interpret the TRIPS Agreement according to the Agreement's objectives and principles under Articles 7 and 8?
    - Have the U.S.T.R.'s activities affected developing nations' use of compulsory licensing, Bolar provisions, and other provisions endorsed by the World Trade Organization for the protection of public health and the promotion of access to life-saving medicines?

- Which government agencies and private sector groups provide input into and exert influence over the U.S.T.R.'s policies and activities related to intellectual property rights? How does the U.S.T.R. balance and incorporate the concerns of these agencies and private sector groups in its policies and activities, and how have such concerns, once incorporated, affected pursuit of the Doha objective?

- As GAO found in 2002, the U.S.T.R.'s Industry Trade Advisory Committee system has consistently failed to incorporate adequate input from global public health interests. To what extent has this failure been addressed, and has the failure affected implementation of the Doha objective? Does the U.S.T.R. use other mechanisms to assure that input is incorporated from groups advocating the rights and obligations established under the Doha Declaration?

- Has the U.S.T.R. used mechanisms outside formal trade agreements to pursue, implement, and monitor the negotiating objectives related to intellectual property rights, and the Doha objective in particular? Please consider the General System of Preferences, the Special 301 process, trade capacity building activities, the Industry Trade Advisory Committee system, side letters, accessions, and diplomacy. For example:

- Have provisions in "public health side letters" achieved or failed to achieve the Doha policy goal of facilitating access to affordable medicines, including the Doha right to implement compulsory licensing? In practice, have the authorities articulated in these side letters been invoked? If so, to what effect?
- How has advice offered through trade capacity building balanced protection of intellectual property rights with preservation of developing countries' rights under the Doha Declaration?

We look forward to your response to this request. If you have any questions, please contact David Bowen of Senator Kennedy's staff at (202) 224-7675 or Naomi Seiler of Representative Waxman's staff at (202) 225-5420.

With great respect and appreciation, and we look forward to the study.

Sincerely,

Senator Edward M. Kennedy
Ranking Member
Committee on Health,
Education, Labor, and Pensions

Representative Henry A. Waxman
Ranking Member
Committee on Government Reform

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