

Congress of the United States

Washington, DC 20510

June 14, 2006

Susan Schwab
U.S. Trade Representative
600 17th Street, N.W.
Washington, D.C. 20508

Dear Trade Representative Schwab,

We congratulate you on your recent nomination to the office of U.S. Trade Representative. The work of this office is vital to the interests of Americans and people throughout the world. We are writing to share our hopes for your upcoming term, and to urge you to include public health in your priorities and goals for future trade negotiations.

Your predecessor, Ambassador Portman, deserves great credit for his efforts to include public health representatives on three trade advisory committees—those addressing intellectual property rights, health and science products and services, and tobacco and other agricultural goods. This was an important step, and we hope that you will take prompt action to fill these positions and continue to expand public health and consumer input.

We feel that a public health representative should be appointed to the Advisory Committee for Trade Policy and Negotiations, which provides high-level counsel on overall trade policy. We also urge you to create a new tier-2 advisory committee, specifically addressing public health, to provide advice, technical information, and guidance on policies affecting health care, global health, environmental health, and other important issues.

We understand that several public health organizations have brought a lawsuit against your office, seeking representation on six Industry Trade Advisory Committees. We urge you to voluntarily comply with these requests, by appointing public health representatives to the advisory committees on consumer goods (ITAC 4); distribution services (ITAC 5); information and communications technologies (ITAC 8); services and finance industries (ITAC 10); customs matters and trade facilitation (ITAC 14); and standards and technical trade barriers (ITAC 16).

Advisory committees of the federal government are established to provide policy-makers with expert, independent counsel on important technical issues. The viewpoints represented should be balanced and diverse, in order to fulfill the requirements of the Federal Advisory Committees Act and also ensure the high quality and integrity of the advice provided. A 2002 report by GAO suggested that the trade advisory system has

excluded public health and consumer interest organizations—particularly when issues like intellectual property, food and health standards, and environmental regulations are considered. Because the impacts of U.S. trade policy are felt by our own citizens and by people throughout the world, the advisory system should provide guidance across a wide range of professional expertise, including global public health and environmental health.

Another priority is ensuring access to affordable, high quality generic drugs, both at home and abroad. We support laws that promote innovation and encourage wealthy nations to fairly share the costs of drug research and development. It is important to balance measures that promote innovation and cost-sharing with measures that protect access to affordable medicines for those in need.

We are especially concerned by reports that the Trade Representative has sought intellectual property provisions in bilateral trade agreements that contradict commitments made by the United States in the Doha Declaration. Our government should defend and uphold the letter and the spirit of the Doha Declaration in all current and future negotiations. Trade policy that ignores the urgent health needs of our trading partners is short-sighted. It slows economic development by undermining the health and productivity of our trading partners' workforces. It can also jeopardize health in neighboring nations and the world and may well increase the risks of pandemics, which could threaten our own nation.

Several examples demonstrate how U.S. trade negotiations have threatened or undermined the Doha Declaration. One such example is the Administration's position on clinical trial data and marketing exclusivity. In all free trade agreements negotiated under Trade Promotion Authority, the Administration has introduced rules to protect test data, even though such rules are not included in the World Trade Organization's Trade-Related Aspects of Intellectual Property agreement. In practice, these rules could stretch drug company monopolies beyond the bounded 5-year window offered under United States law, by starting the 5-year clock only after a pharmaceutical product is considered for marketing approval in a new country. If the drug is first registered in the U.S. or another nation, which is usually the case, generic alternatives could be delayed by 10 years or more.

By preventing generic drug manufacturers from timely registration of their products with local drug regulation agencies, the Administration's bilateral trade agreements have directly contradicted the Doha Declaration, which affirms that member countries have the right to protect public health and promote access to medicines for all. The Administration's restrictive rules delay the introduction of low cost alternatives and effectively extend the monopoly rights of brand medicines. If incorporated into future trade agreements, this approach could particularly undermine access to life-saving drugs for poor people living in developing countries.

Another problematic U.S. strategy has been the inclusion of vaguely-worded provisions, such as those in the Central American Free Trade Agreement, requiring broad patent extensions for delays in trade partners' regulatory approval processes. Provisions

in these agreements enable drug companies to enjoy terms of patent protection well beyond those available in our own country, by failing to include limitations on extensions contained in current U.S. law—including a five year cap and a fourteen year limit on the total length of a patent restoration period, as well as a requirement that only ‘new chemical entities’ be eligible for patent extensions. We feel that patent term extensions in free trade agreements should be subject to the same limitations found in U.S. statutory and corresponding case law.

We are concerned that by going beyond the protections required by the World Trade Organization’s agreement on Trade-Related Aspects of Intellectual Property, our bilateral trade agreements will harm developing countries, where alternative approaches to incentives for innovation may be more effective than patent rights. A recent report by the World Health Organization’s Commission on Intellectual Property, Innovation, and Public Health found that some intellectual property rights can block the ability of developing countries to attain the knowledge and technology needed to discover and develop products necessary for public health. In today’s global economy, improving public health in developing countries is important for the health and safety of Americans. Increasing access to drugs in the developing world can reduce the spread of dangerous infectious diseases and improve public health internationally. At a minimum, U.S. trade policies should not compromise our own government’s efforts to prevent potential pandemics.

A final concern is that, while broader intellectual property protections in free trade agreements may benefit the U.S. pharmaceutical industry in the short term, they could have unintended negative consequences in the longer term. The World Intellectual Property Organization’s long-term focus on global patent harmonization, which aims to standardize patent protection laws in all member nations, could adversely affect American consumers and government drug programs, by forcing intellectual property rights from bilateral trade agreements to be included in U.S. law, without the limits or balances in our current laws that help ensure access. This result would especially harm seniors and Americans with chronic but treatable illnesses, by blocking access to affordable generic prescription drugs in our country.

We commend efforts to encourage other wealthy countries to adopt more equitable sharing of the costs of pharmaceutical research and development, so that Americans are not left to pay the bill for the world’s drug consumers. In wealthy countries, intellectual property protections may be appropriate, but the protection of innovation should not prevent access to affordable medicine or stifle the generic drug market in low income countries. In these countries, establishing effective differential pricing, supporting health science research, and encouraging a robust generic drug sector can help to move us toward our goals.

In sum, we urge you to incorporate public health representatives, consumer interests, and global health expertise in the trade advisory system, to ensure that our policies do not harm the health of Americans or people in other countries. We also urge you to defend and uphold the public health protections guaranteed under the Doha

Declaration, by ensuring that countries' rights are not compromised by prolonged data protections, patent extensions, or other short-sighted restrictions that slow access to generic drugs. Bilateral trade agreements are important in accelerating economic development, but they should not undermine global public health or reduce access to prescription drugs for Americans in need.

We thank you for your attention to these important issues, and we look forward to working with you in coming months. If you have any questions, please let us know, or contact David Bowen of Senator Kennedy's health policy office at (202) 224-7675.

With respect and appreciation,

Sincerely,

Ed Kennedy

Robert A. Neuhoff

Arundel A. Fingert

Patrick Leahy

Debbie Stabenow

Max Baucus

Herb A. Wafar

Pete Stark

Sheldon

Calvin Emanuel

Tom Allen

Jim McDermott

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