April 19, 2018

The Honorable Robert E. Lighthizer
Office of the U.S. Trade Representative
Executive Office of the President
600 17th Street, N.W.
Washington, D.C. 20006

Dear Ambassador Lighthizer:

The undersigned organizations, on behalf of the American citizens we represent, urge that strong protections of U.S. intellectual property be obtained before finalizing a renegotiated North America Free Trade Agreement.

Patents, as well as copyrights, trademarks and trade secrets, secure private property rights, and these rights and properties are central to U.S. competitiveness. As President Reagan's Commission on Industrial Competitiveness said, "Technological innovation is a mainstay of the American economy. It is the foundation of our economic prosperity, our national security, and our competitiveness in world markets."

The U.S. Department of Commerce and the U.S. Patent & Trademark Office report the significant contribution to our economy and our competitiveness that IP-centered sectors, such as pharmaceuticals, medical device, semiconductors and motion pictures, make. In 2014, IP-reliant industries contributed $6.6 trillion to the U.S. economy, comprised 38.2 percent of GDP, supported 45.5 million jobs, and accounted for $842 billion in merchandise exports and $81 billion in service exports.

In particular, America leads the world in biopharmaceutical research and development, investing $65.5 billion in R&D in 2016. This private-sector R&D has led to new treatments and cures that benefit patients with all kinds of medical conditions. Due to this sector's commitment over the long haul, cancer therapies translate into longer, healthier lives and chronic diseases such as hepatitis C now are cured in the vast majority of cases, thanks to the latest medicines.

Yet, our NAFTA trading partners continue to fall short of keeping their commitments and punitively treating American R&D-based companies. NAFTA provides a mere five years of regulatory data exclusivity — a wholly inadequate term given the R&D, clinical trials and regulatory approval time and costs involved. Canada and Mexico jeopardize their own citizens' health and American industrial competitiveness by the expropriation of U.S. IP, discriminatory pricing, nontariff barriers and otherwise denying practical exercise of the exclusivity patents and IP are supposed to secure. This is not reciprocity, let alone abiding by terms of the agreement.

Canada's government-run health system strictly controls access to health care, including rationing care and imposing price controls on medical goods and services. Canada's policies prolong patient suffering and contribute to compounding their medical conditions. Further, these chokeholds are counterproductive: The National Bureau of Economic Research has found that $24 spent on new cardiovascular medicine saves $89 on hospitalization. Still, Canada impinges the private IP rights of medical innovators, inconsistent with the spirit and the terms of NAFTA.

Regarding Canadian anti-IP policies, its proposed regulatory pricing of patented medicines will further constrain the ability to obtain fair market value and recoup the substantial R&D costs that underlie each innovative new pharmaceutical. Also, Canada has policies that weaken patent enforcement, severely limit market access, such as inordinately tight deadlines and extensive exceptions making certain drug products ineligible for approval, and that expose drug companies to significant, punitive legal liability in patent cases.

Our neighbor to the north deliberately whittles drug patent exclusivity on both the front and back ends. Inordinately slow bureaucratic hurdles in the new drug and vaccine approval process delay patient access and reduce the patent term. Patent term restoration is seriously reduced by restrictive time limits and eligibility criteria.

A change in Canadian drug law regarding government disclosure of confidential business information seriously compromises biopharmaceutical firms' proprietary data, in direct violation of NAFTA and TRIPS.

Additionally, Mexico fails in the same or similar respects as Canada in disadvantaging U.S. pharmaceutical firms' ability to exercise their IP rights. Mexico disrespects and weakens their patent property rights and erects regulatory and legal barriers to fair market access.

Mexico undermines the ability to enforce patents. It does not recognize method-of-use patents and enables irreparable harm to brand drugs by making it extremely difficult to stop the sale of infringing products through preliminary injunction. Further, innovators rarely succeed at enforcing their IP rights in Mexico, and when they do, pursuing monetary damages comes with extreme challenges.

The byzantine process for gaining access to Mexico's market hinders U.S. pharmaceutical firms from reasonable exercise of their patent rights. Bureaucratic hurdles include very long times to become listed on a formulary, as well as a 5-year process to renew a medicine's registration.

Another two years of delayed market access arises from Mexico's long, slow, opaque, uncertain reimbursement system. This byzantine system within a byzantine system keeps three-fourths of approved medicines off Mexico's two main public drug formularies.

Reciprocal principles should be reflected and secured in a renegotiated NAFTA, as this agreement involves our neighboring countries, and must not omit vigorous IP rights. Canada and Mexico must help set a global standard for reciprocity, particularly with respect to strong, secure intellectual property rights.

We urge you to make Canada's and Mexico's agreeing to vigorous IP rights, including for biopharmaceuticals, a nonnegotiable item in NAFTA modernization. Intellectual property is too important to global health and America's industrial competitiveness to accept a new NAFTA lacking in robust IP protections.

Respectfully,

James Edwards
Executive Director
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* Organization names appear for identification purposes only.