









January 13, 2012

The Honorable Timothy Geitner Secretary of the Treasury U.S. Department of the Treasury 1500 Pennsylvania Avenue, NW Washington, D.C. 20220

The Honorable Ronald Kirk United States Trade Representative Office of the United States Trade Representative 600 17th Street NW Washington, D.C. 20508

The Honorable Kathleen Sebelius Secretary of Health and Human Services U.S. Department of Health and Human Services Hubert H. Humphrey Building Washington, D.C. 20201

Dear Secretaries Geithner and Sebelius and Ambassador Kirk:

In anticipation of the upcoming World Health Organization Executive Board meeting on January 16-23, 2012, we wish to draw your attention to item 6.14 of the provisional agenda: the WHO's Consultative Expert Working Group (CEWG) on Research and Development Financing and Coordination.

We understand that the CEWG is currently preparing a report that reportedly will recommend, among other measures, that Member States enter into a globally binding treaty to regulate the financing and coordination of health-related research and development (R&D), with an emphasis on supporting developing countries' needs. Our companies are deeply committed to innovation in public health for the benefit of the developed and developing world. We are concerned, however, that proposals made concerning a binding R&D treaty seek to reopen debate on controversial matters that have been resolved through a delicately-balanced consensus, and may ultimately undermine one of the key drivers for innovation in health products and technologies: intellectual property rights (IPR). In so doing, important innovations in health technologies of particular relevance to emerging markets may never be developed or, if they are, may never reach those markets. Moreover, critical competitive advantages that U.S. industries have spent years to develop may be lost and a dangerous precedent in terms of IPR erosion for other sectors and industries could be set.

Today, healthcare innovators invest heavily and consistently in R&D. As documented by WHO's Global Initiative on Health Technologies, for example, the medical device industry spends up to 12% of its income on R&D and, when the needs are known, innovates specifically to address global health issues. Indeed, many major providers of health technologies engineer solutions for use

in the developing world with price points suited for those markets. Our industry also undertakes product development on the ground in many emerging markets, in close collaboration with health ministries in order to ensure that their products fully reflect developing countries' priorities and needs. In short, innovation is no longer limited to serving the needs of developed-country markets. Today's innovation ecosystem for healthcare products and technologies is truly global.

Intellectual property rights play a critical role in incentivizing these investments in global innovation. For example, the research-intensive and highly competitive nature of the medical device and technology sectors renders these sectors uniquely dependent on robust IPR protections. The large capital costs and significant risks associated with the development of ever more complex medical technologies, along with their adaptation to developing country applications, have rendered patents and trade secrets a critically important way that research is rewarded, value is protected and innovation, as well as the dissemination and broad deployment of technologies, is sustained. IPRs are a key part of the solution to health challenges around the world.

The CEWG dialogue on financing and coordination for research and development is important. The outcome of this process must reflect the reality that research and development will be most robust and can best be sustained when it is led by the private sector, driven by market need, and supported by strong IP protections. In light of this, we are concerned that a proposed global treaty on R&D will open the door to weakening IP protections. An R&D treaty could ultimately serve as an unnecessary distraction from successful and repeatedly proven market-based approaches to innovation in the field of health products and technologies.

We also want to express our concern regarding recommendations for different forms of revenue generation to meet R&D funding commitments. Specifically, we oppose recommendations to levy taxes or fees, either nationally or internationally, on industry as a method of funding R&D commitments. We oppose an increased role for international organizations in areas such as tax policy and the application of revenue measures, which have rightly been the domain of sovereign governments. Recommendations that would move away from traditional decision-making methods in this policy area would have profound implications for business.

In the interests of global public health, as well as the U.S. economy's global competitiveness, U.S. exports and the high-value U.S. jobs that IPR, technological development and manufacturing help create, it is crucial that the U.S. Government protect and promote intellectual property. Any efforts to erode IP, in this or any other sector, must be rejected. Furthermore, the United States should resist efforts to create through this forum what amounts to new international regimes aimed at generating revenue from industry. Given the immediacy of the WHO proposals, we urge you to review proposals made by the CEWG and support efforts that preserve incentives for innovation while rejecting any proposal, including those to negotiate a global R&D treaty, that would undermine such incentives or diverge from longstanding methods of revenue related institutional policymaking. Meanwhile, we stand ready to work with you on efforts to protect and promote intellectual property, with a view to fostering innovation to improve global health and to secure the economic, trade and investment interests of the United States.

Sincerely,

Emergency Committee for American Trade National Association of Manufacturers National Foreign Trade Council United States Council for International Business U.S. Chamber of Commerce