

KEI Supplemental Comments Regarding Research and Development

In the matter of: The Office of United States Trade Representative (USTR) Notice: 2015 Special 301 Review: Identification of Countries Under Section 182 of the Trade Act of 1974. Docket ID: USTR-2014-0025

February 27, 2015

At the February 24, 2015 hearing, KEI was given the opportunity to provide supplemental comments on research and development of new medical technologies.

I would like to include two papers and one prepared testimony as attachments:

- Alternatives to the Patent System that are used to Support R&D Efforts, Including both Push and Pull Mechanisms, with a Special Focus on Innovation-Inducement Prizes and Open Source Development Models, World Intellectual Property Organization, CDIP/14/INF/12, September 19, 2014.
- Prizes for Innovation of New Medicines and Vaccines. 18 Annals Health Law. 155. Summer, 2009
- The de-linkage of R&D costs and drug prices through the Prize Fund for HIV/AIDS will cost less, expand access, accelerate and improve innovation, and replace an incentive system that is expensive, inefficient and unsustainable. Testimony of James Packard Love Hearing before the United States Senate, Committee on Health, Education, Labor and Pensions, Subcommittee on Primary Health and Agency on The High Cost of High Prices for HIV/AIDS Drugs and the Prize Fund Alternative May 15, 2012 Washington, DC

In general, R&D is expensive, but is not a large number compared to the market as a whole.

In 2013, PhRMA members claimed to have spent \$51.6 billion worldwide on R&D. But the global market for drugs was estimated to be \$980.1 billion that same year. This would make the PhRMA member R&D outlays, as reported by PhRMA and unaudited, to be 5.26 percent of global sales for all companies. If one assumed that 25 percent of global private sector R&D was financed by non-PhRMA members (roughly the amount estimated by Burrill & Company in the past), the total private sector R&D outlays would have been about \$68 billion, or less than 7 percent of global sales.

If 7 percent of global sales are reinvested into R&D, it is probably the case that roughly half of that amount is invested in R&D that is medially unimportant, including, for example, for the development of drugs that provide almost no benefits over existing pharmaceutical drugs.

Note that in the 5 year period 2010 to 2014, 54 percent of all new molecular entities approved by the FDA were considered “standard” approvals, which did not offer significant health benefits over existing drugs. The standard approvals also involved trials that enrolled significantly more patients than was the case for the priority drugs.

Companies also spend a lot of money on R&D activities that have little scientific merit, but are useful in marketing products.

The grant of patent monopoly is one way to fund R&D, but there are plenty of others. The NIH outlays of more than \$30 billion per year, the R&D spending at the CDC, the National Science Foundation, and the U.S. Departments of Energy, Defense, Veterans Affairs and Homeland Security are only some of the U.S. federal agencies funding medical R&D. Add to this the 50 percent orphan drug tax credit (available to 9 of 10 new cancer drugs registered in 2014), public sector funding at the state and local government level, and the benefits of tax deductions for charitable donations for medical research. All of these government and non-profit sector investments contribute significantly to medical innovation.

The United States is not the only country whose government funds medical R&D, but we are the largest source of public sector funds. Governments in many higher-income countries, like Switzerland, do relatively little to fund medical research. Many developing countries also consistently under-invest in public sector R&D, relative to their means, and to their growing role in the global economy.

The World Health Organization (WHO) is supposed to be debating new global norms for supporting priority medical R&D, and USTR has been among the U.S. agencies opposing these talks. This is a mistake. We are currently subsidizing the whole world in many key areas of knowledge production, and the costs can and should be shared by other governments, to a greater degree. Our scientists and our private sector drug developers should benefit from higher levels of foreign government R&D spending, and our patients should benefit from expanding foreign government spending on medical R&D. This is one area for trade policy that would be positive for innovation, without creating access barriers and financial hardships for patients.

Our government also needs to reform the incentive system, so we no longer rely on the use of monopolies on life saving drugs to reward innovators. To this end, we need to support the creation of large, robust, well-funded and sustainable innovation prize funds. The money for these prize funds can be financed from exactly the same entities now reimbursing expensive patented medicines, using much of the existing valuation technology, but with more freedom to fashion the incentives to reward drugs and devices that improve rather than match health outcomes.

There are considerable trade related issues for both push and pull funding mechanisms, as outlined in part in the attached WIPO papers. One obvious issue concerns the level of effort

of funding. Instead of reimbursing super expensive drugs, which is an inefficient and indirect method of funding R&D, there can be a greater focus on providing direct research grants (push) and funding for innovation inducement prize funds (pull). Another set of issues concerns the licensing and rights to use the benefits of public sector funded research subsidies. There are plenty of cross borders issues relating to the transparency of R&D investments and subsidies, and of medical outcomes from new innovations. There are negotiations over global R&D priorities, for example, to enhance funding of R&D for new antibiotic drugs, open source diagnostic tests, or new treatments for dementia and other important innovation gaps.

The open source dividend can be a welfare-improving reform, simulating more sharing of knowledge, but it works best in a more holistic global framework, or at least with some enlightened bilateral/plurilateral collaborations.

The main point is this -- high drug prices are a choice, but not a requirement, for funding R&D. We think high drug prices, managed by private monopolies that literally control our right to live are the wrong choice. We have to move toward better choices. This becomes even more important as our population ages, as the lack of mechanisms to curb excessive and predatory pricing of drugs continues to spiral out of control.