

**MEMORANDUM**

To: Transition Team
From: Desiree Filippone, Vice President, Eli Lilly & Co.
Date: November 18, 2008

Re: Protecting Intellectual Property and Providing Access to Medicines in Developing Countries – Lilly’s Perspective from Fighting MDR-TB

The False Choice between Protecting U.S. Innovation and Providing Access to Medicines.

Almost everyone agrees that the U.S. Government should do everything possible to create an environment that promotes a competitive U.S. economy. Promoting and protecting the innovative ideas and products of U.S. workers and companies often tops the list of priorities. Almost everyone also agrees that the world’s poor should have access to life-saving medicines to treat epidemics such as AIDS, TB, and Malaria.

Unfortunately, these two issues are often presented as an “either/or” choice. Some suggest that we can protect innovation – but only if we allow millions with devastating illness to go untreated. Or, the flip side of that argument: The panacea for treating millions of people is to end or severely restrict intellectual property protections.

The reality is that these issues present enormous challenges with complicated, diverse solutions. Clearly, demand for American ideas spans the globe, and while we must ensure that our nation’s innovators have the protections necessary for their work, all appropriate stakeholders must strive to be an active force in helping the developing world.

Lilly does not have the silver-bullet solution for the challenge of access to medicines. But we do believe that our experience with the Lilly MDR-TB Partnership is one example of how we can move beyond the “either/or” debate. This memorandum outlines the key features of our work to combat multidrug-resistant tuberculosis (MDR-TB) throughout the world; a program we believe provides one demonstrated solution to the access to medicine issue. This memo also serves as background on additional challenges to global healthcare, as well as reasons why eliminating intellectual property for American industry would not be the cure-all that some suggest. We hope this brief memo provides some useful information as the new Administration looks to take on this challenging issue, and we look forward to engaging in this important policy discussion.



Global IP: Protecting U.S. Innovation and U.S. Jobs

The competitiveness of the U.S. pharmaceutical industry is fairly well-known. The industry is responsible for over 2.5 million jobs, and directly employs 500,000 Americans. Moreover, IP-intensive manufacturing paid much higher wages, on average, than non-IP intensive manufacturing — nearly \$51,000 per worker compared to just over \$35,000. In the pharmaceutical industry, an average worker earned almost \$72,000 a year. The pharmaceutical industry has also helped drive the increase in science and engineering jobs. Even as manufacturing jobs contracted overall from 2000 to 2004, science and engineering jobs grew — by about 17 percent in IP-intensive industries. Science and engineering jobs in the pharmaceutical industry grew nearly 86 percent. Our employees are also highly productive, with an average worker producing more than \$425,000 in value every year.

In other words, a lot is at stake — good, high-paying jobs in a growing and internationally competitive industry. But U.S. innovative and IP-related sectors, including the pharmaceutical industry, continue to face daunting challenges when trying to protect IP around the world. In its most recent annual report on IP protection, the U.S. Government identified 46 different countries that raise serious concerns over the lack of adequate and effective enforcement of intellectual property rights.

Beyond inadequate enforcement, some countries are using the very loose rules of the WTO to promote increased limitations on IP protection. This problem is not limited to the pharmaceutical industry. We're seeing it more and more with environmental technology — which includes hydrogen fuel cells, solar panels, wind turbines, biofuels and beyond — to the point where a Chinese representative at a recent climate conference in Bali suggested that America should give up IP protection to help speed the transfer of energy saving technologies.

It is vital to the pharmaceutical and other innovative U.S. industries that the U.S. Government works to ensure that countries comply with their international obligations to protect and enforce intellectual property rights. Failure to do so sets a bad precedent for other countries to follow, and hurts U.S. industries' competitiveness by impairing future R&D investment.

Finally, the proliferation of counterfeit pharmaceutical manufacturing in China and Russia, and the sale and distribution of counterfeit pharmaceuticals in many countries, is an increasing problem that poses special concerns because of its health and safety risks.

Lilly's MDR-TB Program and Lessons Learned

There are over nine million new cases of TB every year, of which nearly one half million are multidrug-resistant. Multidrug-resistant TB, or MDR-TB, is as contagious as TB but its treatment is more complex, expensive, and longer in duration. TB robs the world of an estimated \$12 – 16 billion in lost income every year. Poor, crowded living conditions also increase the risk of contagious infection.



With the rise of globalization and worldwide travel comes an increased risk for the spread of TB and MDR-TB. Recently, the world has seen a greater incidence of TB and MDR-TB throughout Western Europe and North America. As a matter of national security and social well being, we must all work to control TB's reemergence.

The Lilly MDR-TB Partnership to fight the increasing global threat of multidrug-resistant tuberculosis is comprised of 18 public and private partners on five continents.

For six years the alliance has supported a comprehensive, multi-pronged strategy to fight this disease. Working primarily in the four countries hardest hit by MDR-TB, China, India, Russia, and South Africa, the Lilly MDR-TB Partnership:

- Promotes community support and patient advocacy, involving communities and business in MDR-TB prevention and treatment;
- Implements MDR-TB health care treatment and training programs, and strengthens surveillance of drug resistance;
- Transfers Lilly drug-manufacturing technology to local pharmaceutical companies and supplies medicines at preferential prices;
- Conducts research for new drug discovery;
- Works with policymakers to raise awareness and prevent the spread of MDR- TB.

With Partnership operations in some 60 countries, Lilly invested an additional \$65 million in 2007 to combat MDR-TB, bringing its total commitment to \$135 million for long-term, sustainable initiatives.

In addition, Lilly is also actively looking for new ways to fight TB. In June 2007, we created the Lilly TB Drug Discovery Initiative, a public-private partnership in Seattle, Washington. The goal of the Initiative is to fill the early-stage pipeline for future TB drug development. The Initiative's primary members are Eli Lilly and Company, the Infectious Disease Research Institute, and the National Institute of Allergy and Infectious Diseases, part of the U.S. National Institutes of Health.

For this Initiative, Lilly has opened access to its greatest assets, a library of 500,000 compounds. The company also is lending its immense drug discovery expertise, and is contributing the latest, most innovative technologies used in drug discovery to be applied to the search for new drugs to fight TB. In October 2008, the Initiative announced its first acquisition of compounds for further development into TB drug candidates. The announcement also marked the commencement of the Initiative's work and the opening of new laboratories focused on early drug discovery for TB.



Lessons Learned: Challenges to Global Healthcare

- ***Health System Strengthening.*** While access to drugs is critical, donations alone will not provide a solution to the long-term need for essential medicines in developing countries. Our experience has taught us that we must work with governments and others to address the underlying barriers to health care, such as weak and fragmented health systems, lack of trained personnel, and inadequate resources overall.
- ***Investing in Local R&D.*** Investing in local R&D capacity and national research systems is one way innovative pharmaceutical companies help strengthen health systems. Local production can play a valuable role in building overall local capacity and enabling developing countries to increase access to essential medicines.
- ***Building Infrastructure.*** Many countries lack the physical infrastructure - roads, transportation, electricity, communication capability and a clean water supply - needed to operate an effective health care system. Impassable roads and weak transportation systems block patients, providers and medicines from reaching health facilities. And electrical outages prevent hospitals from functioning effectively and vaccines to go unrefrigerated, rendering them unusable. Equal attention must be given to strengthening medicines procurement, storage and distribution systems.
- ***Health Care Providers.*** Fifty-seven countries – most of them in Africa and Asia – face a severe health workforce crisis. The World Health Organization (WHO) estimates that a total of 4,250,000 health workers are needed to fill the gap. Pharmaceutical companies train vast numbers of healthcare workers. Lilly, for example, supports training for thousands of nurses, doctors and hospital administrators in TB prevention and treatment.
- ***Patient & Provider Education.*** In addition to health care training, companies sponsor community and work-based education programs on health issues to help spread prevention messages while also sharing disease management techniques and increasing adherence to treatment protocols for those who are infected.

Next Steps. Lilly looks forward to working with the new Administration. Please call Desiree Filippone at (202) 434-7151 if you have any questions about the issues in this memo.