COUNCIL *on* FOREIGN RELATIONS

POLICY INNOVATION MEMORANDUM NO. 32

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Re: Preventing Pharmageddon: Treatment Access for Noncommunicable Diseases

A global fight over access to medicines is brewing. In the past year, India, China, and Indonesia have undertaken measures to circumvent patents on medicines for diabetes, cancer, and cardiovascular and chronic respiratory illnesses—the noncommunicable diseases (NCDs) increasing rapidly in developing countries. A decade ago, a crisis over access to patented HIV/AIDS drugs transformed global health, elevating the infectious diseases ravaging developing countries as a foreign policy issue and mobilizing billions of dollars to develop and deliver new therapies. As litigation, trade tension, and controversy mount over NCD treatment access, addressing this latest pharmageddon will require another transformation in global health, this time focusing on low-cost interventions and patient-centered, rather than country-focused, strategies.

THE TREATMENT-ACCESS CRISIS OVER HIV/AIDS

International controversies over treatment access in developing countries are a recent development. Few medicines existed for malaria, tuberculosis (TB), and other infectious diseases prevalent in these countries. Most treatments dated back to the colonial era, developed for foreign militaries or veterinary products. Fewer than forty of the 1,400 drugs approved for human use between 1975 and 1999 were for diseases relevant to developing countries.

Two developments led to an international controversy of treatment access in the late 1990s. First, lifesaving antiretroviral medicines (ARVs) were developed for HIV/AIDS, a disease that gained prominence in the United States and Europe but exploded into a pandemic that ravaged developing countries, particularly in sub-Saharan Africa. Second, global trade talks established the World Trade Organization (WTO) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which mandated minimum standards of intellectual property (IP) protection, including pharmaceutical patents, in member countries.

Pharmaceutical companies, fearful of undercutting remunerative markets in rich countries, charged consistent prices for their patented ARVs internationally. In 1998, ARVs cost more, on a GDP per capita adjusted basis, in South Africa than in

Sweden or the United States; as a consequence, just ten thousand of the nearly four million South Africans living with HIV/AIDS had access to the medicines that could save their lives.

In South Africa and Brazil, patients and advocates protested an international IP system that prioritized profits over lives and had failed to incentivize research to meet their general health needs. These protests spread and disrupted international health conferences and the 1999 Seattle WTO ministerial conference. Bitter disputes erupted over compulsory licenses, a means provided in the TRIPS agreement for governments to license a patented innovation without the consent of the patent holder. Between 2001 and 2005, WTO members issued seventeen compulsory licenses, most involving ARVs. Popular support for the drug industry suffered and developing countries pushed to renegotiate the TRIPS agreement.

The treatment-access crisis over HIV/AIDS catalyzed a surge in global health resources. International aid for health tripled between 2001 and 2010 to $28.4 billion. Annual funding for R&D on HIV/AIDS, malaria, TB, and other neglected diseases surged thirty-fold, to more than $3 billion. The U.S. government, the Bill & Melinda Gates Foundation, and other donors established institutions such as the Global Alliance for Vaccines and Immunization and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) to deliver effective treatment to millions in developing countries. Negotiations, competition, and voluntary price reductions lowered the price of ARVs in poor countries from $12,000 per year in 2001 to $200 per year in 2005. Between 2006 and 2011, the compulsory licensing of patented medicines declined dramatically.

THE EMERGING TREATMENT-ACCESS CRISIS OVER NCDs

The controversy over the affordability of patented medicines in developing countries reemerged in 2012. India issued a compulsory license on a late-stage kidney and liver cancer treatment and has announced plans to issue similar licenses on a leukemia drug and two breast cancer therapies. Indonesia issued compulsory licenses on seven drugs, including a treatment for liver cancer–causing hepatitis B. China amended its patent law, making it easier to issue compulsory licenses for medicines. The Philippines modified its laws to limit the patentability of incremental improvements to already-patented products. These moves highlight four emerging issues in the access-to-medicines debate.

First, the days of potential compulsory licensing disputes being limited to medicines used to treat or diagnose infectious diseases such as HIV/AIDS, malaria, and TB are over. According to the World Health Organization (WHO), 80 percent of deaths from NCDs now occur in developing countries, up from 40 percent in 1990. By 2030, NCDs will be the leading cause of death and disability in every region of the world. A recent report by Harvard University and the World Economic Forum projects that over the next two decades, NCDs will inflict $14 trillion in economic losses on the developing world.

Second, better diets and healthier habits—the population measures that have been the focus of international NCD initiatives—are critical, but will not solve the problem. Governments in emerging economies are under increasing pressure to better address the health needs of their ailing citizens. Prevention efforts offer only limited benefits to those suffering from NCDs in the poorest countries, where consumption of processed foods and tobacco is low.

Third, pricing pharmaceuticals for large middle-income countries such as India, China, and Indonesia is a challenge. On one hand, these are fast-growing economies with resources. China and India have international aid agencies and space programs. IMS Health projects that annual pharmaceutical spending in middle-income countries will double by 2016 to more than $300 billion. On the other hand, half of the world's population that lives on less than two dollars per day resides in India and China, with much of the remainder living in other middle-income countries—Pakistan, Nigeria, and Indonesia. NCDs are growing fastest in these countries. Mexico, India, and China are investing to expand the coverage of medicines in their public health sectors, but most drug purchases still occur out of pocket. Expenditures on medicines are already high.

Fourth, conflicts over compulsory licensing of NCD medications are likely to increase unless other strategies can meet developing country needs on NCDs. International trade law is fairly permissive on compulsory licensing. A WTO member may issue a compulsory license on any patent, including for NCD medicines, provided that the member satisfies the few conditions and procedural requirements of the TRIPS agreement. In the end, countries' use of compulsory licensing depends on political will. It is not surprising that middle-income countries with sizable NCD epidemics and pharmaceutical industries have been the first to act. These countries rely on imported patented drugs to treat cancers, and have health and industrial policy interests in encouraging cheaper domestic production. The pipelines of multinational drug firms are heavily invested in oncology and diabetes, and developed countries will fight to preserve those investments.

In a new fight pitting patients against patents, firms may be reluctant to develop or register lifesaving NCD therapies for use in countries with a high risk of compulsory licensing. Support for international IP protection—upon which drug firms and so many other U.S. industries heavily rely—will diminish. Yet the IP alternatives that health activists advocate for spurring drug innovation, such as prizes and R&D treaties, have not attracted donor or multilateral support. Preventing the emerging pharmageddon will depend on finding other ways to meet the NCD treatment needs of emerging nations.

PREVENTING PHARMAGEDDON

A variety of motivations fueled global health investment over the last decade, including humanitarian concerns and the advent of the Millennium Development Goals in 2000. The catalyst, however, was the legitimate critique that emerged during the HIV/AIDS treatment-access crisis that the international systems for trade, IP, and medical R&D were not responding to the needs of developing countries and their citizens. Fortunately, global health programs need not duplicate the massive resources mobilized to address HIV/AIDS and other infectious diseases to counter the rising tide of NCDs in low- and middle-income countries. To make progress, the United States should take the following low-cost steps:

Leverage Existing Procurement Vehicles. Many effective NCD therapies—insulin, beta blockers, and ACE inhibitors—are off patent, but often unavailable in developing countries. A recent study showed that improving access to a generic multidrug regimen for high-risk cardiovascular patients in these settings would save as many as eighteen million lives. Pooled procurement and financial incentives, such as advance market commitments, can help scale up manufacturing of these treatments, ensure their affordability, and facilitate their purchase by developing countries. The United States supports these procurement vehicles and should encourage their expansion to include NCD medicines. The U.S. Food and Drug Administration should help ensure the safety and quality of procured products as it does in the PEPFAR program.

Support Intra-Country Differential Pricing. Differential pricing of patented medicines would be more sustainable if based on the income status of the patient, rather than the country involved. Pharmaceutical companies should charge different prices for drugs to be used by higher-income patients covered by insurance plans or treated in private hospitals and those to be used by lower-income patients treated in public clinics or resource-poor rural settings. Firms should adopt differentiated packaging to help prevent arbitrage. Participating developing countries should commit contractually to ensure that the product is only used in its intended market segment.

Adapt Treatment for Low-Resource Settings. Tremendous resources have been dedicated to NCD R&D globally, but not to the development of therapies usable in poor settings. In contrast to the $3 billion spent annually on neglected-disease R&D, the international organization PATH estimates that $30 million would enable product-development partnerships to adapt essential NCD drugs and diagnostics for use in low-infrastructure settings. The U.S. Department of State should expand the treatment platforms used by PEPFAR to help countries deliver these frugal NCD innovations.

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