

Overcoming Barriers to a Global Treaty on Medical Funding and R&D

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It has long been recognized that the developing world needs better and more accessible medicines. However, ensuring that medicines now widely available in the developed world are delivered at affordable prices, and incentivizing research and development (R&D) for diseases that primarily affect the world's poor, has proven a stubborn challenge. World Health Organization (WHO) has been working to develop a cohesive international framework to address these problems, first with the Commission on Intellectual Property Rights established in 2003, then with the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property.

Now the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) has moved the debate forward with its excellent report recommending negotiation on a Global Treaty on Funding and Coordination of Medical Research and Development. While the proposal is deliberately vague on the specific contents of an agreement, which would be determined by negotiations between WHO Member States, it does recommend key provisions. As proposed, the treaty would require Member States to spend at least 0.01% of their GDP on R&D that addresses the special health needs of developing countries, and it would require at least 20% of that funding to be spent through a single pooled funding mechanism. The Working Group report has resulted in a new level of discussion regarding a global treaty, but this is not a new proposal. Tim Hubbard and James Love have been advocating for a binding international convention on medical R&D since at least 2004.²

This treaty would certainly benefit patients in developing countries. A hard law regime in which Member States had to contribute a fixed percentage of their GDP for R&D on developing country health needs would avoid the insecurity of voluntary contributions, and essentially double the current level of spending in this area to around six billion USD annually. It would also be an achievement for WHO, which has long been committed to championing the needs of developing countries and improving global health.

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² Tim Hubbard & James Love, *A New Trade Framework for Global Healthcare R&D*. PLOS BIOL (Feb. 17, 2004), <http://www.plosbiology.org/article/info:doi/101371/journal.pbio.0020052>.

However, obtaining funding commitments from Member States will be quite a challenge. The United States is the only country already meeting the proposed targets, and many governments have a newfound unwillingness to commit to foreign spending because of the global recession. For example, donors have largely failed to meet development assistance goals promised at the 2005 G8 summit.³ Such soft law pledges can be more easily ignored than those established as part of a convention with binding force and enforcement mechanisms, and this is precisely why it is harder to obtain hard law commitments. This may be even more of a problem for the developing countries that would be the ultimate beneficiaries under the treaty.

For emerging and developing countries without 0.01% of their GDP available to contribute in-cash, an in-kind sharing option may be appropriate. Developing countries have a number of valuable non-monetary resources they could contribute, such as genetic resources. Access to genetic resources remains a controversial subject even though 193 nations are now party to the Convention on Biological Diversity.

Developing countries might be also able to contribute epidemiological data. Epidemiological research is a critical part of the research this treaty addresses, and this data has significant value for medical researchers. It can be used to identify the burden of diseases, for international comparative effectiveness research, and to help identify best-practices and centers of excellence. In the United States, the Affordable Care Act is making electronic health records and patient data reporting a mainstay of domestic health care. Large databanks of patient data can be used to identify off-label indications and side effects as well as to develop new drugs to treat Type I diseases. Also, a centralized (perhaps WHO-managed) reporting service would help promote research coordination, and, to the extent this will require new infrastructure, it might result in technology transfer and capacity-building in developing countries.

Achieving consensus on funding and coordination mechanisms may be even harder than achieving commitments to funding goals. The CEWG reported that it analyzed over a hundred different financing and allocation mechanisms before it chose to endorse fixed contributions and pooled funding. It evaluated these mechanisms using a group of criteria that considered factors like benefits from delinking the cost of R&D from medicine prices. Business models that pass on high R&D costs to consumers under a marketing monopoly often result in high drug prices. Delinking the financing of R&D from the pricing of end products, as occurs once generics enter the market, would allow medicines to be sold competitively near production costs. If R&D can be financed upfront, this may remove the need to extract additional innovation rent from consumers. The pooled funding recommendation is expected to help share the costs of R&D so that technology

³ *Development Aids Reaches An Historic High in 2010*, OECD, http://www.oecd.org/document/35/0,3746,en_2649_34447_47515235_1_1_1_1,00.html (last visited Aug. 27, 2012).

developed by one firm can be used by all. On the other hand, cooperation has the potential to de incentivize R&D by encouraging anticipatory free-riding and anticompetitive behavior. Each firm's individual incentive to develop new technology is diluted, because there is no longer a competitive advantage to be gained. Cooperative research has impeded innovation in the U.S. automotive industry for example.⁴ Striking an appropriate balance between coordination and healthy competition can be difficult.

The United States and the European Union remain opposed to the treaty, particularly to the mechanisms advanced by the CEWG. For global treaty proponents, the most important consideration in this debate may be how to get developed countries, and the multinational medical industries that play a behind-the-scenes role in negotiations, to sign-on.

There is some willingness on behalf of developed countries to engage. After all, the United States invests more than 1.5 billion USD annually on R&D for neglected diseases.⁵ Also, the United States was the first country to establish a significant prize voucher system (a mechanism recommended by the CEWG) to reward innovation on 16 neglected diseases.⁶ Under the prize voucher system, prizes are awarded when new treatments or vaccines for selected diseases are successfully registered, and winners are entitled to accelerated United States Food and Drug Administration (FDA) drug assessment, which they may sell. Additionally, patents are permitted for these prize-winning innovations.

For the United States, this treaty would be a great way to leverage funding. Of the 3.2 billion USD invested in research for Type II and Type III diseases in 2010, the majority came from developed countries. Developing countries are only contributing a small and unclear amount—about 70 million USD (not including large developing countries).⁷ Under this treaty, the United States would only need to contribute 1.5 billion USD, which is less than it is currently contributing, the European Union would need to contribute 1.75 billion USD, BRICS (Brazil, Russia, India, China and South Africa) would need to contribute nearly 1.4 billion USD, and other nations would need to contribute 2.3 billion USD.⁸ From a public health standpoint, that should be a no-brainer

⁴ John H. Barton, *IP and Climate Technology*, CHATHAM HOUSE (Nov. 2007), http://www.chathamhouse.org/sites/default/files/public/Research/Energy,%20Environment%20and%20Development/161107_ipclimate.pdf

⁵ James Love, *US Intervention at World Health Assembly on the CEWG on R&D Financing and Coordination*, KNOWLEDGE ECOLOGY INTERNATIONAL (May 23, 2012, 11:06PM), <http://keionline.org/node/1417>.

⁶ Anderson Tatum, *New US Voucher Prize System for Neglected Diseases Launches Amid Doubts*, INTELLECTUAL PROP. WATCH (Aug. 6, 2008, 11:55AM), <http://www.ip-watch.org/weblog/2008/08/06/new-us-prize-system-offers-vouchers-for-neglected-disease-treatments-concerns-arise/>

⁷ Mary Moran et al., *G-Finder Report 2011: Neglected Disease Research and Development: Is Innovation Under Threat?* POL'Y CURES (2011), available at http://www.policycures.org/downloads/g-finder_2011.pdf.

⁸ WHO, *Research Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination* (2012), available at http://www.who.int/phi/CEWG_Report_5_April_2012.pdf

for United States policy makers, who would see a quadrupling of the amount of their current research investments. The treaty would also help to address a long-standing United States concern that other nations are free-riding on their publically funded research. Despite the apparent public health benefits, the United States is presumably opposing the treaty because it perceives it will be against its domestic industry's interests.

Industry should see this global treaty as self-serving because the global medicines market is changing. For example, in 2006 and 2007, Thailand faced retaliation after issuing compulsory licenses for two HIV/AIDS drugs, Sustiva® and Kaletra®, as well as an antiplatelet drug, Plavix®. Abbott, the maker of Kaletra, responded to the issuance of a compulsory license by withdrawing all applications to register medicines in Thailand. The United States Trade Representative (USTR) placed Thailand on the 301 Report's Priority Watch List⁹ and threatened to terminate privileges to export certain products to the United States at low or no tariffs.¹⁰ Abbott faced a costly public relations backlash over the incident.¹¹ In contrast, last March India's Patent Office issued its first compulsory license to a generics manufacturer for an on-patent medicine. The Indian company Natco is now licensed to produce and sell a generic version of the Bayer oncology agent Nexavar® for domestic use.¹² Bayer is appealing, but it is unlikely India will face, or would be susceptible to, the same level of international pressure as Thailand. India's actions may signal a new willingness from large developing countries to challenge the status quo. This is a sign that the days in which Bayer could expect to sell a drug that costs 60,000 USD a year in a country where the per capita income is 1,500 USD a year may be drawing to a close.

This Treaty could be a middle ground for industry—an opportunity to essentially self-regulate and avoid blowback due to pricing policies. As it is currently proposed, there would be no direct cost to industry under this Treaty, although the CEWG had considered directly taxing pharmaceutical industry profits under a proposal from Brazil. While there may be a legitimate concern that countries will eventually try to pass on the cost to originator companies, the CEWG

⁹ Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. Int'l Econ. L. 921, 954 (2007).

¹⁰ *Brazil, Thailand Lose Trading Privilege in Wake of IP Disputes*, FOOD & DRUG LETTER (Aug. 17, 2007), (available on Lexis). In 2006, Thailand had \$4.2 billion in GSP qualified exports to the U.S. Vivian C. Jones, CONG RESEARCH SERV.: Generalized System of Preference: Background and Renewal Debate (2001) available at <http://www.nationalaglawcenter.org/assets/crs/RL33663.pdf>.

¹¹ Jennryn Wetzler & Mihir Mankad, *Timeline for Thailand's Compulsory Licenses*, PROGRAM ON INFO JUST. INTELL. PROP. (March 28, 2008), <http://www.wcl.american.edu/pijip/documents/timeline.pdf>.

¹² Ed Silverman, *Malaysians Seek License For Abbott AIDS Drug*, PHARMALOT (May 18, 2012, 10:11 AM), <http://www.pharmalot.com/2012/05/malaysia-an-abbott-hiv-med-a-compulsory-license>.

funding target's full cost would only be around half a percent of total sales in a market projected to reach 1.1 trillion USD in 2014.¹³

GDP-based fixed spending and pooled funding aren't the only mechanisms to incentivize global R&D. Alternate financing and allocation mechanisms would be preferable to the absence of a meaningful convention. The United States has proposed a market exclusivity regime like the Orphan Drug Act.¹⁴ The Orphan Drug Act has been widely acknowledged as successfully incentivizing research on rare diseases within the United States. Prior to this Act, only 38 drugs were approved by the FDA to treat rare diseases. Since its passage, the FDA has approved more than 360 orphan drugs and granted orphan designations to more than 2,250 compounds. In particular, market exclusivity has been identified as responsible for incentivizing companies to develop orphan drugs. A similar regime exists in Australia, Japan, and the European Union.

However, market exclusivity has a bad reputation in developing countries. It is widely associated with data exclusivity based on pre-existing registrations, which may negatively impact developing country public health.¹⁵ The CEWG came out against a market exclusivity regime like the Orphan Drug Act, noting that the existing Orphan Drug Acts have not had a significant effect on public health in developing countries.¹⁶ The Working Group determined such systems fail to delink research costs from profitability, have unclear equity and distributive impact, fail to promote capacity-building in developed countries or technology transfer, and may lead to high prices in developed countries during the exclusivity period. The CEWG concluded, "It is not clear how orphan drug schemes could be adapted for use by developing countries to meet their own needs... their impact could be substantially transformed only by linking them to another 'pull' mechanism such as a priority review voucher, a transferrable intellectual property right or a prize fund."¹⁷

Despite such critiques, a market exclusivity regime could play a vital role in meeting developed country R&D needs. Non-communicable (Type I) diseases are a greater public health threat to the world's poor than neglected diseases, with non-communicable conditions projected to

¹³ *Global Drug Sales to Top \$1 Trillion in 2014: IMS*, MONEYCONTROL.COM (Apr. 20, 2010, 2:04 PM), http://www.moneycontrol.com/news/business/global-drug-sales-to-top-361-trillion2014-ims_452580.html.

¹⁴ James Love, *The WHA Negotiations So Far on R&D Financing*, Knowledge Ecology International (May 24, 2012, 1:14 AM), <http://keionline.org/node/1418>.

¹⁵ Ryan B. Abbott et al., *The Price of Medicines in Jordan: The Cost of Trade- Based Intellectual Property*, 9 J. GENERIC MEDS. 75 (2012).

¹⁶ Itaru Nitta, *International Fund For Innovation (IFI): An Innovative Financing Mechanism For Medicines in the Developing World* (last visited Aug. 27, 2012), available at http://www.who.int/phi/news/phi_13_who_itaru_en.pdf.

¹⁷ WHO, *Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination* (2012).

cause more than three-quarters of all deaths worldwide in 2030.¹⁸ There is already a strong market incentive for research on these diseases, which are incident with a large number of vulnerable patients in both developed and developing countries.

However, because of their prevalence in developed countries, new therapies for Type I diseases would not be eligible for market exclusivity under an Orphan Drug Act. But, they could be eligible under a new market exclusivity regime designed to promote access in developing nations. Market exclusivity in developed countries could be offered in return for making the drugs available in developing countries at an affordable price or at cost. Under this system, originators could be required to submit an adequate distribution plan for developing countries at the time of marketing approval, or, if they fail to do so, compulsory licenses would be issued for those nations. Most developing countries represent a small market, so the issuance of a compulsory license in a developing country is unlikely to have a significant effect on global incentives.

Under this system, it is more challenging to address the BRICS countries, which has been an issue with the Medicines Patent Pool. Emerging nations have greater national resources available to purchase medicines, but public health situations closer to developing countries than to developed countries. Although there is some consensus that medicines should be given to least developed countries, the idea runs into greater resistance for countries that are higher up on the development chain. The BRICS countries could be treated as developing countries, or as developed countries, or as a special case. For example, BRICS members could be required to pay a premium proportional to their per capita GDP over what developing countries are paying. Alternatively, BRICS members could simply pay reasonable compensation for a compulsory license, which is already permitted by the Agreement on Trade-Related Aspects of Intellectual Property and what is already happening in India.

The same system would work to incentivize research on some Type II diseases, like tuberculosis and adult HIV/AIDS, for which poor countries account for the majority of cases, but where a significant market exists in developed countries. A distribution plan for a new HIV/AIDS medicine might require the drug to be made available in every developing country, either at cost or at an objectively reasonable price based on a country's capacity to pay, in sufficient quantity to meet patient demand within a designated timeframe (for instance, a year). This system would not address concerns about prices in developed countries, and the CEWG is probably correct in noting

¹⁸ WHO, *World Health Statistics* 2008, 2008, available at http://www.who.int/whosis/whostat/EN_WHS08_Full.pdf.

that market exclusivity alone would do little to incentivize R&D on Type III diseases without additional financial incentives.

The Working Group has pressed for upfront financing, but if that is not possible in these times of fiscal austerity, a market exclusivity regime could achieve some of the same R&D outcomes with little to no up-front costs. The system could also be structured to protect patients in poor countries from unaffordable monopoly prices. While it wouldn't be a panacea for all developing countries' problems with R&D, it still has the capacity for a meaningful impact.