THE PROBLEM

Each year, millions of people in low- and middle-income countries needlessly suffer from preventable and treatable diseases because they lack access to life-saving medicines.

According to the WHO, 10 million people die every year who could be saved by existing drugs.

Universities have a critical role to play in delivering affordable medicines to the sick and suffering worldwide. Universities are dedicated to the creation and dissemination of knowledge in the public interest. Moreover, universities play a major role in the drug development pipeline, as pharmaceutical companies increasingly rely on discoveries made in campus laboratories with the support of federal funds. Paul Farmer and numerous other health-policy luminaries have called on universities to leverage their rights in lifesaving innovations to increase access to medicines in impoverished countries. Unfortunately, to date, this call has gone largely unheeded.

15 of the 21 drugs with the greatest therapeutic impact were derived from federally funded projects at academic centers, according to a 2000 Senate Report.

CONGRESS CAN HELP

At present, universities face a classic collective action problem: as they consider adopting humanitarian licensing terms, no individual university has been willing to take the lead for fear of losing valuable pharmaceutical deals to its less committed peers.

Congress can solve this collective action problem by passing the Public Research for the Public Interest Act (S.4040), which would require humanitarian licensing of essential medicines as a condition for receipt of federal research funding.

HOW IT WORKS

The mandated humanitarian licensing terms would allow generic manufacturers to supply drugs developed at federally-funded institutions in eligible countries at affordable prices. Because these licensing terms encourage the introduction of reduced-price drugs only in markets too poor to otherwise afford them, its terms do not threaten intellectual property, corporate investments, or profits in wealthy nations. Moreover, under the proposal, both pharmaceutical companies and universities would receive royalties from the sale of generics in developing markets.

This legislation would ensure that public funds serve truly public purposes, delivering immense human benefits at little cost to American taxpayers, universities, or pharmaceutical companies.

FREQUENTLY ASKED QUESTIONS

1. Why does the bill focus on enabling generic competition?

- Generic manufacturers can cheaply supply much-needed drugs to countries where the poor cannot afford to purchase brand-name drugs. Competition keeps prices low.

- The Department of State recently reported to Congress under President Bush's Emergency Plan for AIDS Relief that, "in every case generics prices present an opportunity for cost savings; in some cases, the branded price per pack of a drug is up to 11 times the cost of the . . . generic version."

- The renowned humanitarian organization, Doctors Without Borders, concluded, "[T]he most significant factor in lowering prices [is] the introduction of generic sources in a country."[1]

2. Won't this bill damage brand-name pharmaceutical companies' bottom line, leading to diminished R&D?

No. This legislation encourages the introduction of reduced-price drugs only into markets too poor to otherwise afford them. Brand-name pharmaceuticals make minimal profits in impoverished countries.

- The entire continent of Africa accounts for just 1 percent of all pharmaceutical revenue.[2]

- "[L]ost profits from a price cut in Africa would amount to no more than three days' fluctuation of exchange rates," said Michael Scholtz, Executive Director of Health Technology and Pharmaceuticals at the WHO, who joined the WHO after 21 years with Ciba-Geigy and SmithKline Beecham.[3]

- The branded pharmaceutical industry in the United States derives only five to seven percent of its profits from all low and middle income countries.[4]

Moreover, the approach of this bill is in accordance with existing U.S. practice. The U.S. government has already recognized that we can and must look to generics to combat public health crisis in poor countries.

- Bush's $15 billion signature AIDS initiative, the President's Emergency Plan for AIDS Relief (PEPFAR), "remains committed to funding the purchase of the lowest-cost ARVs from any source, regardless of origin, whether copies, generic, or

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[1] Medecins Sans Frontieres et al., Surmounting Challenges: Procurement of Antiretroviral Medicines in Low-and Middle-Income Countries (2003) as cited by Amy Kapczynski, "Addressing Global Health Inequities: An Open Licensing Approach for University Innovations," 20 Berkeley Tech. L.J. 1031 (2005).
[2] Report by IMS Health, a company that provides market intelligence to the pharmaceutical industry, as cited in "An Unequal Calculus of Life and Death," Washington Post December 27, 2000.
[3] *Id*.
[4] William W. Fisher and Talha Syed, "Patent Law, Drugs and the Health Crisis in the Developing World," (2005) as cited in Kapczynski, *supra,* at 1038.

branded…"[5]In fact in FY06, 70% of the drugs procured with PEPFAR funds were generic.

3. Won't generic drugs sold in the developing world be imported back into the U.S. and Europe on the black market?

- No. Diversion from poor countries is rarely observed. Generic drugs have been produced in India for decades without apparently infiltrating or undermining Western markets.[6] As of April 2002, both the European commission and the pharmaceutical companies, citing an EU working document, acknowledged that pharmaceutical arbitrage from poor countries to the high income was "still largely theoretical."[7]

- Insofar as diversion is a concern, it is addressed in S.4040 using the same methods that the WTO has chosen - by requiring use of different packaging, pill color, and pill shape in different countries to facilitate the identification of illegal imports.[8]

4. Do universities risk losing critical revenue?

No, the equitable access licensing terms mandated by this bill are financially viable for universities

- University revenues from sales in developing countries are "vanishingly small – only a few percent of those few percent of total revenues that PhRMA companies make in low and middle income countries."[9]

- Universities will receive royalties from each generic sale. (See Section 4(3))

5. Will this bill inhibit the ability of universities to license future innovations?

No. Pharmaceutical drug development relies on innovations developed in campus laboratories with federal funds. The monetary value of these innovations far outweighs the minimal costs that might be incurred by humanitarian licensing terms. "While an individual university may be dispensable to the pharmaceutical industry, universities in aggregate are not."[10] Universities will continue to drive innovation and the economy, while simultaneously ensuring their innovations actually *reach* those that need it most. This bill goes to the heart of what it means for America to have great research universities.

6. Given the funds that the United States Congress already allocates to these problems, why is this bill necessary?

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[5] "Bringing Hope: Supplying Antiretroviral Drugs for HIV/AIDS Treatment," The President's Emergency Plan for AIDS Relief Report to Congress Mandated by H.R. 3057
[6] Andrew Farlow, "Costs of Monopoly Pricing Under Patent Protection," Presentation at Columbia University.
[7] Kapczynski, *supra*, at 1038.
[8] "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health," World Trade Organization (2003).
[9] Kapczynski, *supra,* at 1089.
[10] *Id*. At 1089.

The Public Research in the Public Interest Act of 2006 both complements and supplements existing efforts. By guaranteeing a steady supply of generic medicines, the bill ensures that America's aid dollars will be used as efficiently as possible. In its report to Congress, PEPFAR recognized, "Every dollar that can be saved can be used to support additional prevention, care and treatment services."

7. Does the Judiciary Committee have jurisdiction?

Yes. On September 29, 2006, S.4040 was referred to the Senate Committee on the Judiciary, which has jurisdiction over intellectual property law.

8. Does this legislation pose a takings problem?

No. The legislation does not apply to retroactively to existing intellectual property. Instead, it applies only to inventions that are conceived or reduced to practice on or after the date the bill is enacted. (See Section 3(11))

9. What is Universities Allied for Essential Medicines (UAEM)?

UAEM is a coalition of students and faculty at more than 30 major research universities in the United States and Canada. In 2001, UAEM helped forge a deal between Yale and Bristol-Myers Squibb to lower the price of one of the most widely used AIDS drugs by 96% throughout Sub-Saharan Africa. The first major patent concession on an AIDS drug, the Yale/BMS deal helped create a tipping point for access to affordable AIDS treatment. UAEM has since worked to make such agreements a standard part of university licensing. The organization also works to promote university research on neglected diseases predominantly affecting those in impoverished countries.

10. Who else supports this idea?

A 2006 report released by WHO's Commission on Intellectual Property Rights, Innovation, and Public Health recommended:

> "Public research institutions and universities in developed countries should seriously consider initiatives designed to ensure that access to R&D outputs relevant to the health concerns of developing countries and to products derived therefrom, are facilitated through appropriate licensing policies and practices."

In addition, many prominent individuals and organizations have signed on to the Philadelphia Consensus Statement, urging universities to "require the inclusion of licensing terms in exclusive technology transfer agreements that ensure low-cost access to health-related innovations in the developing world." (For more information, see www.essentialmedicine.org/cs)