

POINT OF VIEW

Universities Have a Key Role in Global Access to Medicines

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Around the world, the fight for affordable medical treatment is intensifying. Headline-grabbing battles are being waged in India, where the Chennai High Court recently decided a major constitutional case over access to lifesaving cancer medication. In Thailand, Abbott Laboratories, a multinational pharmaceutical giant, has withdrawn registration of all its new medicines as leverage in a prolonged battle with the government over drug prices and patent recognition.

Huge pharmaceutical companies and foreign governments, however, are not the only players in the struggle for affordable treatment — universities, too, are at the heart of it. Universities play a critical role in medical innovation and must start using their clout to help make lifesaving medicines more affordable to poor countries. After all, universities are heavily involved in the research and development of many of those treatments.

In India, for example, the drug at the center of the lawsuit is Gleevec (imatinib mesylate), a cancer treatment based on research by scientists at the Oregon Health and Science University and the Dana-Farber Cancer Institute. And in Thailand, at least one of the drugs that Abbott is withholding, Zemplar (paricalcitol), is based on a patent licensed out of the University of Wisconsin at Madison. These examples are no anomaly: In 2000 a study by Congress's Joint Economic Committee concluded that university and publicly financed research helped develop 15 of the 21 drugs considered by experts to have had the highest therapeutic impact.

In 2006 Universities Allied for Essential Medicines, a student organization with chapters at nearly 40 universities, issued a statement calling for universities to "promote equal

access to research, promote research and development for neglected diseases, and measure research success according to impact on human welfare." That document, called the Philadelphia Consensus Statement (<http://www.essentialmedicine.org/cs>), was signed by thousands of students and by scientists, prominent public-health officials, and several Nobel laureates.

One of the central recommendations of the statement was that universities adopt humanitarian licensing policies to ensure low-cost access to drugs developed at universities. In key instances, universities hold patent rights in the innovations discovered in their labs. In addition to the examples mentioned above, universities hold U.S. patent rights in other critical cancer drugs, an anemia treatment, and AIDS medicines. Perhaps the most widely discussed new drug of the past year, the new cervical-cancer vaccine, is based on intellectual property held by Georgetown University.

When universities hold patents, their licensing decisions determine whether the fruits of their research will be accessible in poor nations. Universities, dedicated to the creation and dissemination of knowledge in the public interest, thus have a crucial and obvious role in promoting innovation and access to health-related technologies. What is a more vital component of the public interest than global public health?

Last year, 13 prominent research universities, the American Association of Medical Colleges, and the Association of University Technology Managers committed to principles that may make their medical breakthroughs more available in poor countries (*The Chronicle*, March 7). Their pledge publicly recognizes for the first time that "universities should strive to construct licensing arrangements in ways that ensure that ... underprivileged populations have low- or no-cost access to adequate quantities of [university-developed] medical innovations."

Although their groundbreaking statement is laudable, the group's recommendations failed to offer specifics on how universities might build such provisions into their licensing agreements — despite making recommendations on a number of other issues. Universities should commit to more than principle; they should commit to concrete

licensing terms in exclusive technology-transfer agreements. And this is where they have so far failed to act.

Universities Allied for Essential Medicines has offered one set of model licensing terms of its own: the equitable-access license, which is one way of structuring a licensing agreement to ensure that drugs developed in campus laboratories are made available in poor countries. These licensing terms use a particular legal mechanism — so-called grant-back provisions — to empower all generic manufacturers to cheaply supply university-developed drugs to low- and middle-income countries. Competition would keep prices low.

But Universities Allied for Essential Medicines has also sought to work with universities that might prefer other ways of structuring such licenses, for the underlying goal — a concrete, transparent, and effective mechanism for access at the lowest possible cost in impoverished countries — is more important than any particular set of terms.

The danger of missed opportunities is clearly illustrated by a 2005 licensing deal that Emory University struck with Gilead Sciences and Royalty Pharma. The university sold its royalty stake in anti-AIDS medicines, Emtriva (emtricitabine) and Truvada (emtricitabine and tenofovir), for an upfront fee of \$525-million. At first glance, the deal seemed like a boon for Emory, which no doubt benefited from such a generous infusion of unrestricted funds. The half-billion-dollar price the drugs fetched suggests that Emory had a great deal of bargaining power in the negotiations and probably could have insisted on humanitarian licensing terms and still gotten a huge payoff. By failing to do so, the institution neglected its central mission as a world-class research institution: to develop and disseminate knowledge for the public good.

The Emory-Gilead story drives home the need for universities, when measuring technology-transfer "success," to stay consistent with their core mission. What you measure matters, and most universities measure success purely in financial terms. For example, the Association of University Technology Managers' annual report on the success of university technology transfer focuses almost exclusively on traditional

indicators, including revenue generation, the number of patents filed, and the number of licenses executed.

Instead, technology-transfer officers must measure success not only in terms of revenue, but also by impact on global human welfare. As institutional mission statements reflect, that is what it means to be a great research university. Such "access metrics" might consider whether the deal is transparent, ensures access to university innovations in poor countries, or facilitates research on treatments for neglected diseases. This simple change would encourage universities to act in the public interest.

Pharmaceutical companies will no doubt resist when universities adopt humanitarian terms in their licensing deals. But their most commonly cited reasons — the risk of illegal rerouting of cheaper medicines to wealthier countries and the dampening of incentives for innovation — are weak. Although some pharmaceutical companies express concern about cheaper generic products overcoming regulatory barriers and entering high-income markets illegally, there is no empirical evidence of any substantial flows of medicine from poorer countries to high-income countries. Moreover, companies can easily alleviate any such concerns in the same manner that the World Trade Organization has: by requiring use of different packaging, pill color, and shape in different countries to help identify illegal imports.

Pharmaceutical companies (as well as universities) may also question whether humanitarian licensing terms like those we propose would be financially viable. In fact, humanitarian licensing terms would encourage the introduction of reduced-price drugs only into markets too poor to afford them otherwise. Brand-name pharmaceuticals garner minimal profits in impoverished countries: The entire continent of Africa accounts for less than 1 percent of all pharmaceutical revenue. In fact, humanitarian licensing terms could mean that a university and its private-sector partners could actually reap royalties by distributing drugs in markets that would otherwise be neglected.

It is past time for higher education to claim moral leadership for the biomedical enterprise. We live in an era when decades elapse before advances discovered in the

academic laboratories of rich countries reach the world's destitute sick. Our universities must act collectively and definitively to expand global access to medicines.

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