

APPENDIX A: SAMPLE OP-ED FROM YALE

Univ. must democratize access to key drugs

Patrick Toomey and Sara Crager

For five years, students at Yale and across the country have been calling on their universities to make the life-saving drugs discovered in campus laboratories available in the developing world. This weekend, a chorus of stentorian voices joined the cause.

On Friday, Sen. Patrick Leahy (D-Vt.) introduced legislation requiring all federally-funded research institutions, including Yale, to ensure the drugs they develop are supplied to poor countries at the lowest possible cost. Just two days later, Universities Allied for Essential Medicines released a consensus statement signed by health policy luminaries, calling on universities to take the same steps voluntarily. Signatories include Paul Farmer, whose paradigm-shifting treatment projects in Haiti were made famous in *Mountains Beyond Mountains*; Judge Edwin Cameron of the South African Supreme Court; and Jonathan Quick, former director of Essential Drugs and Medicines Policy at the World Health Organization. This list is only growing.

Each year an estimated 10 million people die from diseases that are treatable with existing drugs, according to the WHO. But these medicines instead sit on the shelves, priced far beyond the reach of many of the sick and dying.

This problem could be solved by giving generic drug companies the right to manufacture and distribute patented drugs in the developing world. Patents are temporary monopolies granted by the government to encourage innovation. But rewarding innovation need not always mean limiting access to the fruits of these discoveries - especially where millions of lives hang in the balance. Allowing the generic production of life-saving drugs for low-income countries harnesses the logic of the market, driving down drug prices in those countries so that more people can afford them.

At the same time, both Leahy's bill and the UAEM consensus statement call for safeguards to ensure these cheaper drugs are not imported back into the United States or other lucrative markets. This combination of measures gets the incentives right: protecting the profits that drive pharmaceutical companies to pursue new drugs, while maximizing access to medicines developed right here. As we have seen at Yale, America's universities have a critical role to play in delivering affordable medicines to the sick worldwide. Like many premier research institutions, Yale holds patent rights to an ever-increasing number of compounds discovered by its scientists. In 2001, an unprecedented campaign by students, scientists, and the organization *Medecins Sans Frontieres* erupted over Yale's patent on stavudine, a key HIV/AIDS drug.

Yale had licensed stavudine to Bristol-Myers Squibb, which marketed the drug for \$1,600 per patient per year. Meanwhile, generics manufacturers promised to produce the same drug at a fraction of the price. MSF urged Yale to help increase access to this urgently needed drug. It was at this moment that MSF approached Yale, as the patent-holder, to help widen access to an urgently needed drug. Under pressure from students and researchers, Yale and Bristol-Myers Squibb agreed to permit the sale of generics in certain markets, lowering the price of stavudine throughout sub-Saharan Africa to \$55 per patient per year - a 96 percent reduction. The stavudine campaign revealed the immediate, substantial price reductions that universities can secure for those who need their drugs the most.

But this was five years ago. The stavudine success was a moment of enormous importance for which Yale deserves much credit, but it also heralded an opportunity that remains unfulfilled without a wider commitment to equitable access. Today, missed chances with very real human costs continue to pile up. Last year, Emory University sold emtricitabine - a second-generation AIDS therapy - to the pharmaceutical company Gilead absent any provisions for access. Similarly, Yale has licensed 13 drug candidates for cancer, three for AIDS and one for Hepatitis B - all of which are currently in development. Stavudine proved that universities like Yale can wield substantial leverage in their negotiations with pharmaceutical companies. But these research institutions, including Yale, have failed to embrace a forward-looking policy that guarantees access.

Yale, again, has the opportunity to be a leader among its peer institutions, and to leave its footprint on an intellectual property regime responsive to human need. But students, faculty and alumni must demand this sense of responsibility from their university. In the fight for access to medicines, we stand at a unique pressure point: We belong to a community engaged in world-class innovation supported by strong ethical commitments. If one mission of a research university like Yale is to improve the human condition by developing powerful cures to disease, the University must take an interest in ensuring that its discoveries reach the sick and dying.

Yale should not need an act of Congress to revive its sense of public mission. But Leahy's bill represents a growing consensus that universities themselves have failed to act on an issue uniquely within their power. We urge Yale to heed this call and to take the lead at another watershed moment, by leveraging its most innovative assets to save lives worldwide.

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APPENDIX B: SAMPLE OP-ED FROM UPENN

For the past few years, every day has brought fresh news of civil war and terrorists bent on attacking the United States. Worse yet, experts warn, the war on terror will soon find new battlegrounds in Africa. The reasoning is that poverty, poor health, and instability in Africa will cause its desperate population to take desperate measures.

One way to address these disturbing trends is to strike directly at the cause of political instability by helping the developing world become healthier. By improving the health and stability of poor countries, we could contribute to ensuring that they become allies and stable trade partners instead of sources of terrorists.

On the last Friday of September, Senator Patrick Leahy (D-VT) introduced a bill entitled Public Research in the Public Interest Act of 2006. The bill aims to address two unacceptable problems: 1) ten million people worldwide die each year from diseases that are treatable with existing drugs, and 2) diseases that affect the poor are predominantly ignored by the for-profit pharmaceutical industry.

Addressing the first problem, the bill requires federally-funded medical research institutions to grant nonexclusive royalty-free licenses to generic producers who will produce medicines in developing countries. Addressing the second, the bill also extends the licensing requirement to any party conducting neglected-disease research (research on diseases that predominantly affect the poor).

The proposals would make essential medications available in developing countries and lower the cost burdens for countries that spend the majority of their health budgets paying for branded medications. With the new availability of medications and the ability to spend scarce government health resources in developing new health infrastructure, the health of the developing world could see an incredible improvement.

Importantly, the bill would not hurt the bottom lines of the pharmaceutical and medical device industries. Developing countries represent less than 5% of the worldwide pharmaceutical market and practically none of its profits.

While Senator Leahy's proposal is a commendable display of leadership that has placed the issue of global health on a nationwide platform, it will face a stiff opposition in the U.S. Congress. The current political environment tends to promote bombs, sanctions, or in the best cases, programs that pay for branded pharmaceuticals. The bill would also have to pass through the pharmaceutical lobby, which spends over \$140 million a year making sure legislators are aware of its preferences.

Regardless of whether the bill has a chance to pass, however, it is in the interests of universities and other publicly-funded research institutions to address the problem on their own terms before the federal government forces them to adhere to national guidelines. By pre-empting legislation, universities will be fulfilling their mission to improve the public good while preserving the flexibility to do so on their own terms.

The weekend after the bill was introduced, a group of over 150 students from all over the country gathered here in the University of Pennsylvania for the national conference of the international student group Universities Allied for Essential Medicines (UAEM-www.uaem.org). At the conference, they released the Philadelphia Consensus, which argues that universities—the originators of over 50% of all

pharmaceutical innovations—are an important place to address issues of access to medicines and neglected disease research. Included in the consensus statements are specific feasible proposals to improve research and technology transfer policies at universities.

The growing list of signatories include such prominent public health advocates as Paul Farmer, the founder of Partners in Health immortalized in the book *Mountains Beyond Mountains*; Jim Kim, the former director of the World Health Organization (WHO) HIV/AIDS department; Judge Edwin Cameron of the South African Supreme Court; and Jonathan Quick, the former director of Essential Drugs and Medicines Policy at the WHO.

Right here in Philadelphia, the University of Pennsylvania has the potential to emerge as a leader among universities in improving the global impact of our research. In addition to our status as a premier research university with a yearly research budget of over \$750 million dollars, President Amy Guttmann's Penn Compact has promised that we are committed to having a positive global impact through our research and innovation.

We are in an exciting time to address pressing issues of global health. By improving access to medicines around the world, we would not only be fulfilling a humanitarian mission, but also acting in our best interests by helping developing countries become healthier, more stable, and better trade partners. As voters and residents of Philadelphia, a city filled with biomedical research institutions, we must use our voice to show that we are interested in making an impact in the health of the world.

APPENDIX C:

DRAFT SAMPLE OP-ED FROM BERKELEY

In recent years, concerned students, faculty and administrators at Cal and across North America have called on universities to make life-saving drugs discovered on their campuses available and affordable in the developing world. In recent weeks, a chorus of stentorian voices joined the cause.

On September 29, Senator Patrick Leahy (D-VT) introduced S. 4040, a bill to require federally funded research universities to grant low- and middle-income countries affordable access to the medicines they develop—including those discovered in UC Berkeley laboratories. And on October 1, international student group Universities Allied for Essential Medicines (UAEM) released a consensus statement signed by health policy luminaries, calling on universities to take the same steps voluntarily. Signatories include Paul Farmer, whose paradigm-shifting treatment projects in Haiti were made famous in *Mountains Beyond Mountains*; Judge Edwin Cameron of the South African Supreme Court; and Jonathan Quick, former director of Essential Drugs and Medicines Policy at the World Health Organization (WHO). The list is growing.

According to the World Health Organization, each year an estimated 10 million people die from diseases that are treatable with existing drugs. But many of these medicines sit on shelves, priced beyond the reach of the sick and dying.

We could ameliorate this calamity by allowing generic drug manufacturers to compete with owners of patented drugs in developing countries. Patents are temporary monopolies granted to owners of new inventions by governments to encourage innovation. But they also allow pharmaceutical companies to charge prices much higher than a competitive market would bear. High prices mean limited access, especially in countries where many people live on \$2 a day. The Leahy bill and the UAEM consensus statement would allow poorer nations to produce generic versions of life-saving drugs, promoting competition and driving drug prices down dramatically in those countries so that more people can afford them.

At the same time, Leahy's bill and the UAEM consensus statement call for safeguards to ensure these cheaper drugs are not imported back into the United States or other lucrative markets. This combination of measures gets the incentives right: protecting profits that motivate pharmaceutical companies to develop new drugs, while maximizing access to medicines developed right here on our campus.

Universities play a central role in the availability of medicines. Universities are responsible for XX% of basic pharmaceutical research and development. The terms on which universities license the medical technologies they discover can determine the terms on which people in developing countries have access to drugs derived from those discoveries. For example, in 2001, students, scientists and Médecins Sans Frontières persuaded Yale and Bristol-Myers Squibb to permit generic competition with their patented HIV/AIDS treatment component stavudine in sub-Saharan Africa. The results were dramatic. Stavudine dropped from a prohibitive cost of \$1600 per patient, per year to just \$55 -- a 96 percent reduction.

Today, universities are beginning to explore licensing agreements that set equitable access standards from the outset. On a grant from the Gates Foundation, UC Berkeley has entered a partnership with Amyris Biotechnologies and the Institute for One World Health to develop an efficient means of producing the anti-malarial compound artemisinin. The agreement, which supports the work of Berkeley synthetic

biologist Jay Keasling, includes provisions waiving university royalties for uses of the compound in developing countries.

Surrendering royalties might sound like an expensive proposition for universities. But the market for medicines in developing countries is small by business standards, accounting for perhaps 7% of the global pharmaceutical market. In contrast, human need in many of these regions is substantial. Universities stand to gain not only from the satisfaction of doing good, but also from public acclamation and respect for their humanitarian initiatives.

But there is also a financial incentive for universities to explore equitable access licensing. Recent years have witnessed significant investment on the part of philanthropists, foundations and international organizations into treatments for tropical diseases. Universities can win these sizable funds in the form of contracts and grants for dedicated laboratories. Increasingly, grounds for competition for these grants among universities will include the terms on which a university intends to make any discoveries available to the public. The better a university's commitment to affordable access, the more likely it will be to win a major grant, and to establish relationships and a reputation as an institution that foundations can trust.

The Leahy bill and UAEM consensus statement are signs of burgeoning public expectations of a university commitment to equitable access. Due in no small part to the commitment of stalwarts such as Jay Keasling, Assistant Vice Chancellor at IPIRA Carol Mimura, Special Assistant to the Chancellor Tom Kalil, and Chair of the Center for Neglected Disease Research Geoffrey Owen, Berkeley has an early edge. With enough clamor on campus, Berkeley could be the standard bearer in this coming era of what we might call humanitarian competition among universities – to the betterment of Cal, and the better health of all.

To support this movement, or for more information, visit (OCF website) or attend UAEM's forthcoming teach-in (Virginia's teach in with date, time and place, or announcement of US-Thai FTA event).

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