

## UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES

### *Brief on Penn's Role in Improving Access to Medicines in Developing Countries*

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In the 2005 Penn Compact, the University presented a vision for Penn's growth in the 21st century. The document describes Penn's aspiration to "engage dynamically with communities all over the world to advance the central values of democracy and to exchange knowledge that improves quality of life for all." We wholeheartedly support this vision, and believe that Penn should draw on the strengths of its research enterprise in order to realize it. Specifically, we encourage the University to look for ways that its research activities, particularly those in the biomedical sciences, can be harnessed to promote human welfare around the world.

As one of the world's premier research institutions, Penn is already a center for discoveries with significant global impact. Does Penn's responsibility for those innovations end at licensing them out for further development? In this brief, we argue that the answer is a resounding no. Penn has the opportunity to institute intellectual property policies which ensure that the University's innovations reach those who need them most. If carefully developed, such policies need not interfere with Penn's ability to work with private entities, either as funding sources or as downstream developers. Moreover, a clear and sensible policy on intellectual property would elevate Penn's reputation as a trailblazer in addressing one of the most challenging humanitarian crises of our time.

#### ● *Significance and Impact* ○

Approximately ten million people die needlessly each year because they do not have access to existing medicines and vaccines.<sup>1</sup> This access gap stems from several factors, including unreliable health care delivery systems, insufficient public financing for health care, and high prices for medicines.<sup>2</sup> High drug prices result in large part from the temporary monopolies granted to pharmaceutical companies through patent and regulatory systems.<sup>3</sup> Recent history has shown that promotion of generic competition within low- and middle-income (LMI) countries is the most effective way to lower drug prices.<sup>4</sup> A global policy facilitating generic competition in poor countries would have little impact on the profitability of large pharmaceutical companies, which derive only five to seven percent of profits from all LMI countries.<sup>5</sup> While it might be desirable to address these issues through systemic intellectual property reform, existing international trade frameworks make such reform unlikely.

Our proposal centers around the role Penn can play in closing the access gap. Multiple studies have confirmed that university research is vital to the development of new medicines.<sup>6,7,8</sup> Penn has consistently ranked second nationwide in funding received from the National Institutes of Health; in fiscal year 2004, total research funding was \$756 million.<sup>9</sup> Meanwhile, the institutional principles of the University are well-aligned with the goal of improving access to medicines globally. Our strategic plan mentions the goal of improving "the quality, impact, visibility, and translatability of Penn's academic research and scholarly activity."<sup>10</sup> Penn's Center for Technology Transfer explicitly states that its chief objective is to "commercialize Penn research discoveries for the public good."<sup>11</sup>

Indeed, as access concerns have come to the fore, some universities have already taken steps to address health problems in the developing world. In 2001, the humanitarian organization Medecins Sans Frontieres (MSF) requested a license from Yale University to buy generic stavudine – an HIV medication – from an Indian company which had offered to sell it in South Africa for approximately three percent of the price of the branded version.<sup>12</sup> Though Bristol-Myers Squibb (BMS) had an exclusive license to sell the drug, Yale was the key patent-holder.<sup>13</sup> Within weeks of receiving the request from MSF, Yale and BMS announced that they would permit the sale of generics in South Africa and that the price of brand-name stavudine would be slashed thirty-fold for the government and for NGOs.<sup>14</sup> The impact of this intervention was unequivocal: rapid expansion of HIV-treatment programs in sub-Saharan Africa would not have been possible without generic stavudine, a WHO-recommended first-line therapy.<sup>15</sup> Despite this

important success, high prices remain a barrier to access in situations where universities have leverage. For instance, Emory University finds itself in a similar position with its HIV drug, emtricitabine, which is unavailable in poor countries because of high prices.

The case of Yale and stavudine is a retrospective solution to a problem that could have been foreseen. Ideas on how to prevent similar situations from arising in the future have been circulating in academic and policy circles over the past two years. For instance, the American Academy of Arts and Sciences (AAAS) published a report entitled ‘Exploring a Humanitarian Use Exemption to Intellectual Property Protections’ earlier this year.<sup>16</sup> The Association of University Technology Managers (AUTM) has convened a group known as Technology Managers for Global Health to look at intellectual property issues.<sup>17</sup> Yet no university has incorporated ‘humanitarian’ licensing provisions into its intellectual property policy to date. We believe that Penn has a remarkable opportunity to take a leadership role among universities by pioneering such changes.

#### ● *Specific Proposals* ○

We propose that the University of Pennsylvania make both general and specific alterations to its intellectual property policies. The general alteration is the adoption of the official resolution that improving global human welfare is the most important goal of university technology transfer. To satisfy this principle, we submit the following specific policy proposals:

- Penn should adopt licensing provisions that facilitate access to its health-related innovations in poor countries; and
- Penn should promote research on neglected diseases that principally impact the global poor (where market forces fail to stimulate research and development) and find ways to work with nontraditional partners that seek to develop medicines for those diseases.

We advocate humanitarian licensing provisions known as ‘Equitable Access Licensing,’ which can be found appended to this brief. An Equitable Access License (EAL), when applied to a university technology transfer agreement, facilitates generic competition in poor countries by providing open licenses guaranteeing third-party manufacturers the right to compete in low- and middle-income country markets, regardless of patents or other forms of exclusive rights (such as regulatory barriers). In addition, we advocate the institution of policies to promote neglected-disease research. Specifically, we recommend that the University facilitate participation in innovative research activities such as public-private partnerships (PPPs) and promote projects that hold potential for neglected-disease drug development.<sup>18</sup> This includes: ensuring that no barriers exist precluding university scientists from accepting research funding from PPPs, proactively monitoring university innovations for potential neglected-disease applicability, and lowering intellectual property hurdles for the neglected-disease research arena. A full exposition of both Equitable Access and neglected-disease policies can be found at <http://www.essentialmedicine.org/article.pdf>.

#### ● *Feasibility* ○

It is important to note that Equitable Access Licensing works by segmenting the world market—any drug developed using an upstream university innovation can remain under patent protection in countries where the pharmaceutical industry earns the vast majority of its revenue. Generic competition is allowed only in markets where there is little access—and therefore little revenue—in the first place. For any given product, then, a pharmaceutical company’s bottom line remains relatively intact, and, by extension, any decrease in revenue from licensing at Penn would be vanishingly small. A quick look at the numbers for Penn’s licensing revenue and total research budget during fiscal year 2004 – \$11.9 million<sup>19</sup> and \$756 million, respectively – shows the relative scale of effects from these changes.

In fact, aside from any intangible benefits Penn might derive from being a leader on an important humanitarian issue, there are reasons to believe that Penn may gain financially by adopting our proposals. First, as the EAL is written, Penn stands to gain a small but significant revenue stream from its share of royalties for generic end products that would otherwise not be sold in poor countries. Second, combining access-oriented licensing policies with an augmented neglected-disease research agenda can help Penn aggressively position itself as a research center for foundation-sponsored partnerships. The burgeoning field of public-private partnerships for global health research has attracted over \$1.2 billion in funding from sources such as the Gates Foundation, the vast majority of which is contracted out to research scientists.<sup>20</sup> The University of California-Berkeley has recently (October 2005) begun marketing its ‘Socially Responsible Licensing Initiative’ as a way to attract some of this nontraditional funding and has already signed a handful of deals with foundations and nonprofits under that licensing rubric.<sup>21</sup>

We have even loftier aspirations for our own University: by implementing the proposals outlined here, we believe Penn can break new ground in defining the role universities can play in closing the global access gap.

### ● References ○

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MODEL PROVISIONS FOR AN  
“EQUITABLE ACCESS and NEGLECTED DISEASE LICENSE”  
**Version 1.0**

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