

UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES

Response to Key Issues Raised

How important is university licensing in limiting access to medicines in poor countries?

Historical data suggest that changing university licensing practices presents a non-trivial and actionable opportunity to lower prices and thereby improve access to medicines in developing countries.

- The ownership position of universities in pharmaceutical technologies is both substantial and increasing.¹ These doubled between 1993 and 2003.² A major share of this university intellectual property is in the biomedical field.³ Furthermore, Columbia has met enormous success in this arena.
- The case of antiretrovirals for HIV treatment shows the impact that changing licensing practices could have on prices. Stavudine (from Yale), lamivudine (from Emory), and abacavir (from U. Minnesota) were part of the World Health Organization's original recommendations for first-line therapy.⁴ Substantial negotiations and public pressure were needed to decrease prices for antiretrovirals (in some cases from over \$10,000 per patient-year to \$120 per patient-year).⁵ Had access-minded licensing provisions been in place *ex ante*, these difficulties would have been avoided and an untold number of lives could have been saved.
- It is difficult to appraise the precise impact of a university licensing intervention in improving access. Essentially, this is a problem of measuring missed opportunities. While one might argue that it is difficult to point to cases where university licensing was the limiting factor in expanding access, this misses the crux of why licensing is important. University licensing presents an *opportunity* for increasing access. This opportunity arises because universities lie far upstream in the drug development process and because universities respond to a different set of incentives than companies.
- The view that university licensing is only important for tropical and other infectious diseases does not acknowledge the potential for helping curb morbidity and mortality caused by noncommunicable diseases in developing countries. Chronic conditions, not just infectious diseases, afflict the developing world as well. Of the 35 million deaths that will occur in 2005 from chronic diseases, 80% of them will take place in low- and middle-income countries.⁶
- Changing university licensing practices is something tangible and something that universities can do relatively easily if there is the volition to do so.

Isn't this a crisis better dealt with governmentally? Why not bother our representatives instead?

We have been, and we still are.

- On 9/29/06 Sen. Patrick Leahy (D-VT) introduced S.4040, a bill to require all institutions receiving federal funding to adopt EAL policies.⁷ This is a direct result of a UAEM member who worked in Sen. Leahy's office during the past summer. This is exciting work, but given the current political climate, we expect little positive movement on this bill, so we continue work at the university level. Universities like Columbia have the opportunity to lead now!

How could the problem of potential diversion of drugs (from developing countries to developed ones) be addressed?

Diversion of generic drugs has rarely been observed historically. Were it to present a greater problem, steps can be taken to ensure this diversion does not undermine pharmaceutical markets in high-income countries.

- Diversion from poor countries is rarely observed. Generic drugs have been produced in India for decades without apparently infiltrating or undermining Western markets.⁸ Meanwhile, the only significant media reports of diversion have been shown to be overblown.⁹¹⁰
- Insofar as diversion is a concern, it can be addressed in the same manner that the WTO has—by requiring use of different packaging, pill color, and pill shape in different countries to facilitate the identification of illegal imports.¹¹
- The equitable access approach actually reduces the risk that medicines would be diverted to markets in high-income countries compared to a drug-donation or voluntary differential pricing approach. Differentially-priced products sold by the original, branded company (as in Canada) may be susceptible to parallel trade, particularly if they are similar in appearance. Regulatory barriers exist to prevent these medicines from entering high-income markets easily, though they are sometimes not enforced.¹² Generic versions of the same medicines have to overcome a second legal barrier (due to patent protection) governed by customs procedures.

What would be the economic impact of equitable access licensing on Columbia?

If carefully developed, we believe that access-minded licenses need not jeopardize Columbia's strong relationships with the private sector or its own financial bottom line.

- There are reasons to believe the economic impact to the pharmaceutical industry would be minimal. Low- and middle-income countries currently represent only five to seven percent of pharmaceutical industry revenue,¹³ so the markets directly affected by equitable access licensing are small.
- In addition, impact to Columbia's bottom line is likely to be small. In order to more precisely estimate the impact of the EAL at Columbia we have constructed a conservative financial model that yields possible yearly financial losses incurred due to excluding low- and middle-income (LMI) country markets from possible revenues. Preliminary data using conservative assumptions suggest that the impact on Columbia's licensing revenue would represent less than .1% of the university's annual budget.¹⁴ We hope to improve this model in collaboration with S&TV and Columbia's world-renowned health economics experts to better predict the economic impact.
- Any small revenue losses could be offset by growth of global health grant awards. An access-minded licensing policy could help attract new funding through the rapidly expanding field of nontraditional partners such as the Gates and Rockefeller Foundations. Their interest would likely be heightened by Columbia's elevated status as a leader in global health. Evidence of this was shown at Yale, which met little financial loss after access provisions for d4T were adopted.¹⁵

Would equitable access licensing be a nonstarter in contract negotiations?

If we can directly address pharmaceutical company CEOs and scientific directors, highlighting the importance of access to improving global health and our estimates of potential economic impact of these policies, we do not believe that licensing provisions would block contract negotiations.

- Pharmaceutical company leadership could be persuaded by global health concerns and public-relations benefits. It may well be that industry contract negotiators will reflexively resist equitable access licensing provisions at first. But the lawyers are not necessarily the most appropriate representatives of pharmaceutical companies' priorities. Top scientists and CEOs may be more likely to value advancement of global health, especially considering the interest in repairing the industry's public image. Columbia has superb relationships with industry leaders and is well suited to start this dialogue.

- Collective action of universities will help advance discussions with industry. The ultimate goal is for all universities involved in biomedical research to collectively adopt access-minded licensing practices, thereby maximizing impact and bargaining power with industry partners. This will only happen because of the strong leadership of major, globally engaged universities.

What has occurred at other schools? Why should Columbia be the first?

UAEM is an international movement. Serious strides have been taken at other universities.

- Access-minded provisions have been adopted previously on a case-by-case basis. This includes Yale and d4T... Get this from the working paper.
- Other schools plan to soon release policies comprehensively and prospectively enacting access provisions. The most promising developments have occurred at The University of Washington, Emory University, and St. Louis University. Other schools have made progress and will likely follow suit once one school enacts such a policy.

What about access problems for the poor in the U.S.?

The poorest citizens in the U.S. do lack access to medicines, but government action is more likely to provide a solution than university licensing practices.

- An access gap clearly exists within the U.S. and equitable access licensing would not provide a domestic solution. Equitable access licensing and similar mechanisms rely on the ability to divide markets into two groups—those with branded-drug exclusivity and those with generic competition. In order to apply these strategies within the U.S., we would need to believe that we could neatly divide poor and rich markets. This would be nearly impossible. Of course we hope that the access gap will be closed in the U.S. However, government action is more likely to provide solutions to this problem than universities.
- Though licensing provisions are unlikely to provide a solution to the access gap in the U.S., the EAL should not present a PR liability for the pharmaceuticals industry. Will the public criticize pharmaceutical companies for "worrying about people abroad when there are people suffering right here"? This is a concern for any differential pricing mechanism. However, we believe that the specific mechanism of the EAL, generic competition, would offer some PR protection. After all, it would be generics manufacturers, not brand-name companies, selling at low prices. While lower prices for identical branded drugs invite public criticism, generic products do not.

Should middle-income countries like China be included as beneficiaries in an access-minded licensing approach?

Any workable system of differential pricing will have to demarcate categories. Including middle-income countries in equitable access licensing makes sense from the viewpoint of disease burden and of ensuring a viable market for generic companies.

- The selection of territories for market segmentation will, at some point, be an arbitrary one. The theoretical optimum would be Ramsey pricing such that all prices are set on an individual basis according to relative income. This is clearly infeasible, but highlights the fact that any workable system of differential pricing will have to choose some parameters to demarcate categories.
- The only feasible way of demarcating categories is by country because of irreducible legal and regulatory frameworks in place within countries. A category of developing countries could be used to establish a market where true generic competition would reduce prices. We believe the

most sensible category would include all low- and middle-income countries as defined by the World Bank.¹⁶

- Excluding middle-income countries would lessen the potential impact of the EAL on the access gap. Those middle-income countries that do grow sufficiently to be recognized as high-income countries would no longer be subject to the license. Until then, middle-income countries are characterized by highly unequal income distributions. For example, 613 million people in China live on less than \$2 per day.¹⁷ If licenses only enabled generic companies to enter low-income markets, they would leave out many individuals who universities aim to benefit.
- The revenue potential of middle-income countries would help ensure that there are sufficient financial incentives for generic companies to sustain production of a given medicine. Additionally, excluding middle-income countries prevents equitable access provisions from operating where they might work best—for developed-world indications in the developing world. Middle-income countries are in particular need of such medications.¹⁸

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