Student Views on Access to Scholarship

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Universities Allied for Essential Medicines

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Outline

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www.essentialmedicine.org

Access and Research Gaps

- **Access Gap:** Ten million people die needlessly each year because they do not have access to existing medicines and vaccines (WHO 2005)
- **Research Gap:** Countless others suffer from neglected tropical diseases for which there is little financial incentive for drug development

History

- **1966:** d4T synthesized under a National Cancer Institute grant at the Michigan Cancer Center
- **1984:** Yale scientists prove that d4T is potent against HIV in cell cultures
- **1986:** Yale files for a "use patent"
- **1988:** Yale issues BMS exclusive worldwide license (and files for patents in South Africa, Egypt, etc.)
- **1994:** FDA approval
- **1999:** Yale earned $40M of its $46.12M in royalties from d4T
  - Almost none of this money came from developing countries

Campaign

- **February 14, 2001:** MSF requests that Yale "issue a voluntary license to allow the importation and use of generic stavudine in South Africa."
- **March 1:** Yale denies the request, indicating that they have granted an exclusive license to BMS, and cannot legally respond to MSF's request without BMS's permission.
- Yale students advocacy campaign: reaching out to the scientist, talks, petitions, etc.
- **March 11:** *NYTimes* story "Yale Pressed to Help Cut Drug Costs in Africa" William Prusoff (the scientist) speaks out.
- **March 14:** The patent for Zerit, rights to which are owned by Yale University and Bristol-Myers Squibb, will be made available at no cost to treat AIDS in South Africa under an agreement the Company has recently concluded with Yale."

Why universities?

- University intellectual property policies matter for global health outcomes
  - Rapid, thirty-fold reduction in the price of d4T in South Africa (from more than $1600 to $55 per patient per year)
  - A recent report found that 15 of the 21 drugs with the most therapeutic impact were derived from federally funded projects at academic centers. (SJEC 2000)
- Nearly all universities have "promoting the public good" as one of their objectives
  - Yale incurred no loss of income and received subsequent major Pfizer investment
- Students, researchers, and taxpayers have leverage in shaping university policies
  - Universities also have leverage as upstream contributers

Mission Statement

1. To determine how universities can help ensure that biomedical end products, such as drugs, are made more accessible in poor countries and
2. To increase the amount of research conducted on neglected diseases, or those diseases predominantly affecting people who are too poor to constitute a market attractive to private-sector R&D investment.

Organizational Structure

- Chapters in 45 Universities in the U.S. and Canada
- National Coordinating Committee, Board of Directors
- Executive Director, National Advocacy Fellow, Advisory Board

Equitable Access License (EAL)

- Require the inclusion of licensing terms in exclusive technology transfer agreements that ensure low-cost access to health-related innovations in thedeveloping world.
- Grant an open license to that data, allowing the medical regulatory agency in a country that lacks access to the drug to rely upon the clinical trial and other data that was submitted in the US or Europe.
- Proactive and not reactive (Emory and Gilead)

Philadelphia Consensus Statement

- Promote equal access to research
  - granting rights to generic companies to manufacture and export university innovations to developing countries, non-patenting requirements in developing countries, and participation in patent pools.
- Promote research and development for neglected diseases
  - engaging with nontraditional partners, such as public-private partnerships or developing country institutions, creating new opportunities for drug development, and carving out neglected disease research exemptions in university patents/licenses.
- Measure research success according to impact on welfare
  - collecting and making public statistics on university intellectual property practices related to global health access and collaborating to develop new technology transfer metrics.

Philadelphia Consensus Statement

- Launched on November 14
- More than 100 luminaries have signed on as well as thousands of students and faculty members
  - Paul Farmer, Jeffrey Sachs, Stephen Lewis, Victoria Hale (One World Health)
  - 5 Nobel Laureates in Science or Medicine, former Deans of the Schools of Public Health at Yale and Harvard
  - Patient groups from India, South Africa, and Thailand
  - 2 former editors of the New England Journal of Medicine
  - Assistant Secretary of Health under Clinton and Johnson

Philadelphia Consensus Statement

- Press: Nature, Financial Times, Time.com. Slashdot, Philadelphia Inquirer
- Stanford White Paper in the Public Interest
  - "We have a responsibility to try to alleviate [the suffering and dying of millions around the world], including finding a way to share the fruits of what we learn globally, at sustainable and affordable prices, for the benefit of the world's poor. Universities should strive to construct licensing arrangements in ways that ensure that these underprivileged populations have low- or no-cost access to adequate quantities of these medical innovations."

Legislation

- **Public Research in the Public Interest Act of 2006 (S.4040):** Senator Leahy (VT) introduced this act "to ensure that innovations developed at federally-funded institutions are available in certain developing countries at the lowest possible cost."
- **'08 Stop AIDS Platform:** "Adopt humanitarian licensing policies that ensure drugs developed with taxpayer resources are available off-patent in developing countries.

Chapters

- Emory and Gilead Access Program for the HIV drug emtricitabine
- SLU Global Access Program
- Berkeley 'Socially Responsible Licensing Initiative' and Center for Neglected Diseases
- University of Washington IPMAC resolution
- University of British Columbia: "A Global Perspective on the Impact of UBC Technologies"

Direction

- Research/scholarship does not occur in a vacuum
  - Scientists/scholars often cannot anticipated the consequences
- The importance of institutional and market design through (university) policies
- Norms and the normative questions about the future of science

Science Commons

- A few bands on the spectrum of access to scholarship
  - Scholar's copyrights
  - Biological materials transfer
  - The intersection of semantic web with Open Access content in neuroscience (the Neurocommons).

Tools

- Patent pools
  - An agreement between two or more patent owners to aggregate (pool) their patents and to license them to one another or to third parties, whether directly by patentee to licensee or through an entity set up specifically to administer the pool
- Compound libraries
- Incentive schemes

Strategy

- **Knowledge:** If people don't know there is a problem, they won't act.
- **Empowerment:** No one likes to advocate alone. We need to create an environment of collective action.
- **Pressure**: Some actors are wedded to the status quo. We need to use positive and negative pressure to help them move.

Players

- Want to do the right thing but didn't know there was a problem: **Knowledge**
- Want to do the right thing but didn't know there was a problem and once they do know are afraid to act alone: **Knowledge** and **Empowerment**
- Want to do the right thing but didn't know there was a problem and once they do know are afraid to act alone and have others pushing against them making change: **Knowledge, Empowerment, and Pressure**

Projects

- Metrics
- Bargaining Power and Business Case Research
- Legislation
- Neglected Disease Curriculum
- Pipeline Surveillence
- Scientists as Supporters
- SRO Meeting Process
- Case studies: Georgetown HPV and Biologics Research; Zemplar