The Role of Universities in global access to essential medicines

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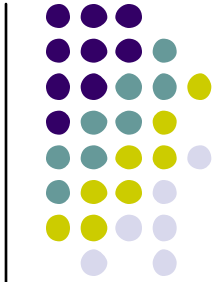
Universities Allied for Essential Medicines

Fostering Innovation… and Protecting Public Health?



- The TRIPS Agreement

  Article 7, Objectives:

  The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

- Doha Declaration

  "The TRIPS Agreement does not and should not prevent Members from taking measures to protect public health"

The right to life includes the right to health and access to treatment.

Articles 1&25, Universal Declaration of Human Rights, 1948.

Montreal Statement on the Human Right to Essential Medicines. www.accessmeds.org

Access gap

Ten million people die needlessly each year because they do not have access to existing medicines and vaccines

Countless others suffer from neglected tropical diseases for which there is little financial incentive for drug development

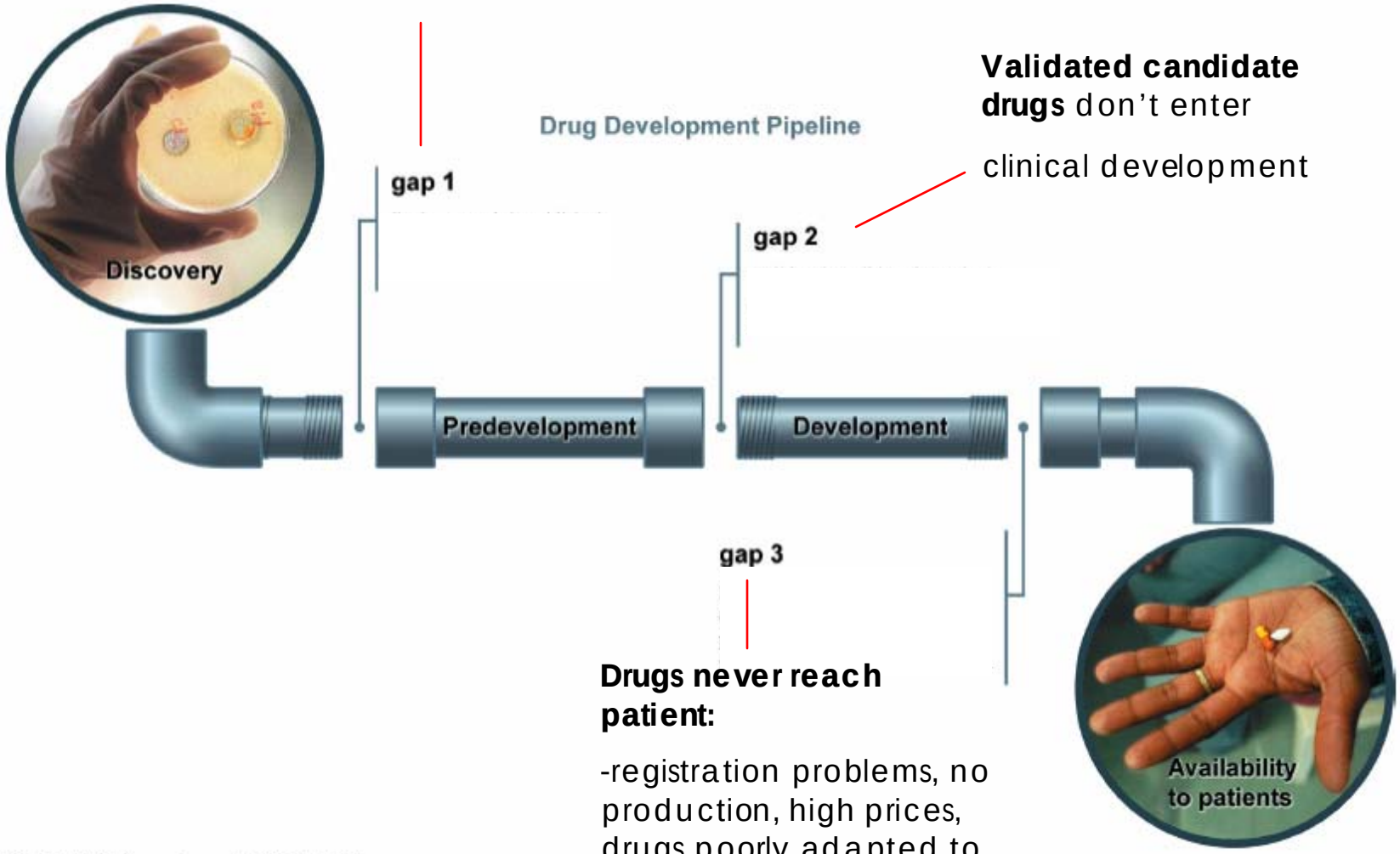
Research gap

Quick, WHO, 2005

The Birth of a Drug

Basic research published but **preclinical** research not considered worthwhile

Validated candidate drugs don't enter clinical development



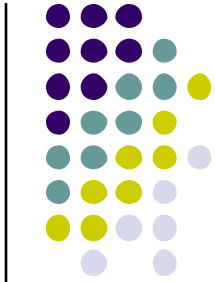
Drugs never reach patient:

-registration problems, no production, high prices, drugs poorly adapted to local conditions

DOI: 10.1371/journal.pmed.0010006.g001

Pecoul, PLoS Med. 2004

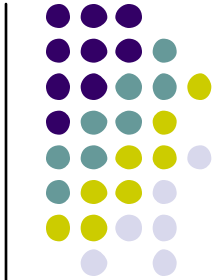
What role do universities play?



- Increasingly important part of U.S. R&D
- Growth in patenting and commercialization:
- "Major players in the biopharmaceutical arena"

Penn CTT Mission Statement: "Commercialize Penn research discovery for the public good"

Universities are major contributors to drug development



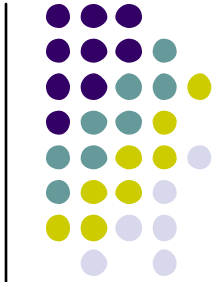
A recent U.S. report found that 15 of the 21 drugs with the most therapeutic impact were derived from federally funded projects at academic centres.

Universities are involved in 26/63 current ND drug projects (2005).

U.S. Senate Joint Economic Committee 2000

Moran, PLoS Med, 2005

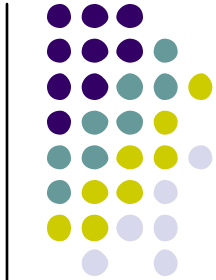
Universities are major contributors to "health-related innovations"



Includes but not limited to:

- drugs
- vaccines
- diagnostics
- monitoring tools
- know-how and technical expertise

Innovations at Various Universities…



- HIV/AIDS
  - Yale: d4t (stavudine - Zerit)
  - U Minn: abacavir (Ziagen)
  - Emory: 3TC (Epivir), emtricitabine (Emtriva)
  - Duke: t20 (Fuzeon)
- Glaucoma
  - Columbia: latanoprost (Xalatan)
- Hepatitis
  - U of Washington: Hep B Vaccine
- Cancer
  - Michigan State: Cysplatin and Carboplatin
  - HPV Georgetown
- Kidney Disease
  - U of Wisconsin: Zemplar
- Others with key university input: Epogen, Erbitux, Prilosec, streptomycin, penicillin, insulin

What do universities do with their research?

Potential for commercialization? Decision to patent

Usually just in high-income countries, given limited resources for tech transfer, but selection bias is important.

Costs $12K-$15K to register a patent in a developing country (plus maintenance and lawyer's fees)

Followed by licensing to industry ... often for further development (likely involving additional patents) and marketing of the invention

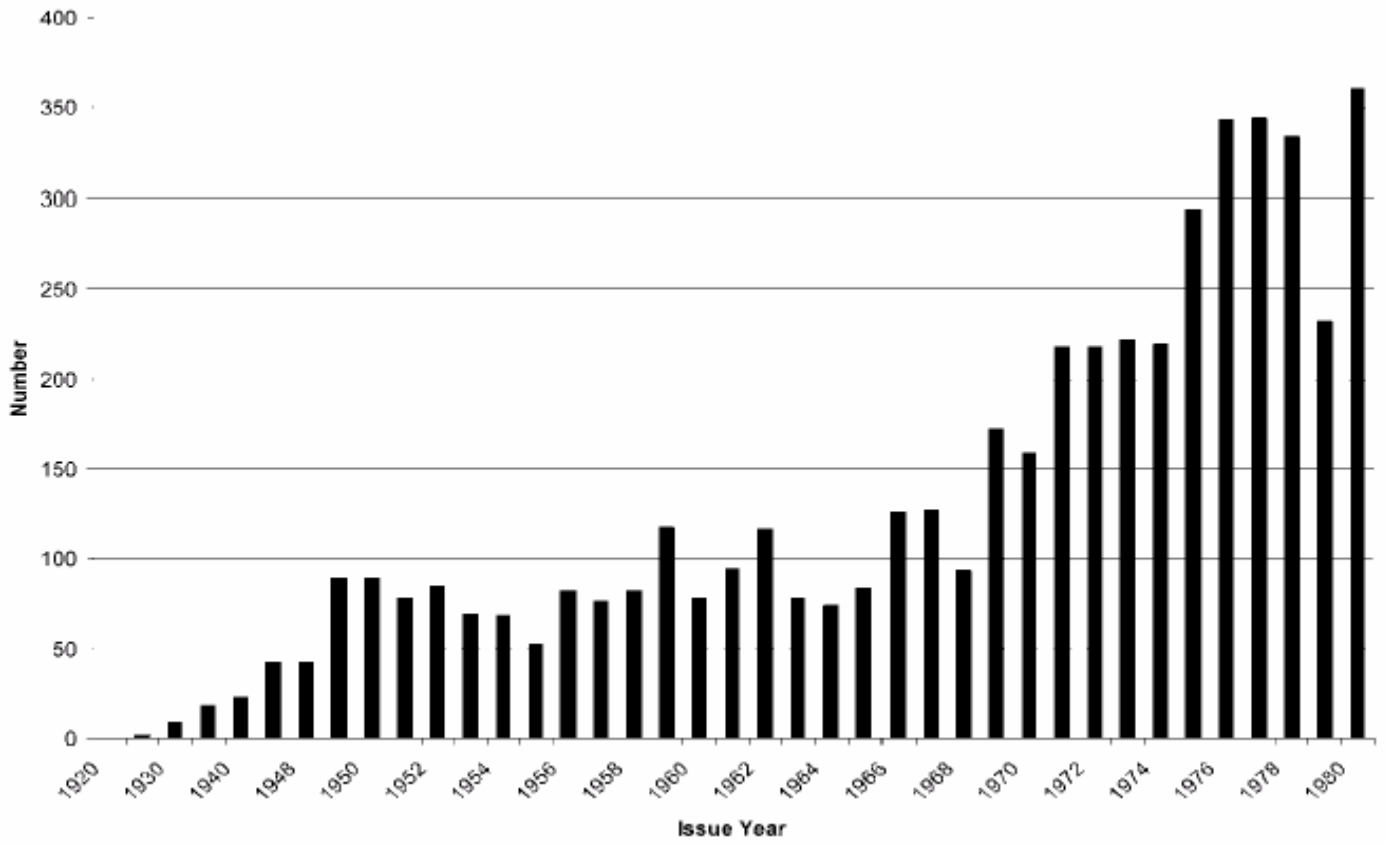
"Upstream research", improvement patents, exclusive deals

Exclusive licenses generally used for products requiring additional development / deals with start-ups

Universities receive royalties and/or other payments in exchange for the license.

What do universities do with their research? Historical Perspective

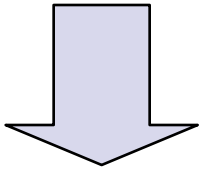
For much of the 20th century, universities rarely patented their research output



Increase in U.S. Patenting and Commercialization: Bayh-Dole (1980)

- Goal: Increase technology transfer and utilization of federally-funded research

- What did it do?
  - Universities given the right to OWN, LICENSE and MARKET the fruits of their research.
  - Exclusive licensing permitted
  - Special provision for the public domain (march-in rights)



Growth in Patenting
(faster than other patenting in the United States)
Surge in Licensing Activity
Increase in Royalties from Licensing

Who funds university research?

Over the last decade, nearly 60% of academic R&D was funded by the federal government, while industry supplied 6%

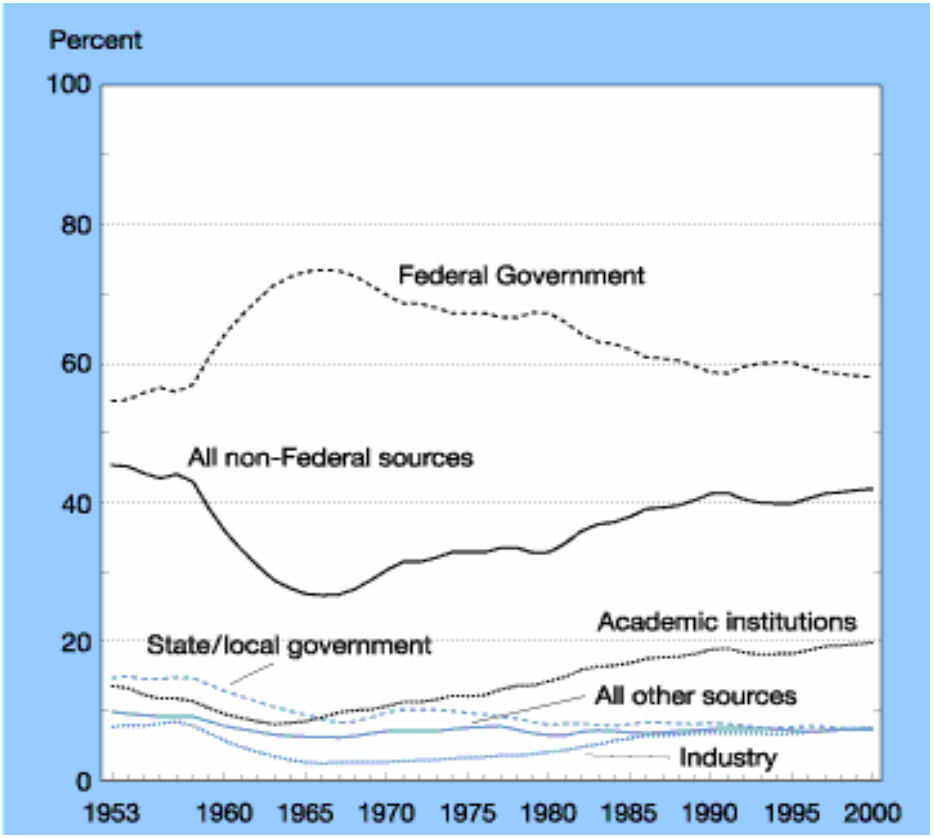
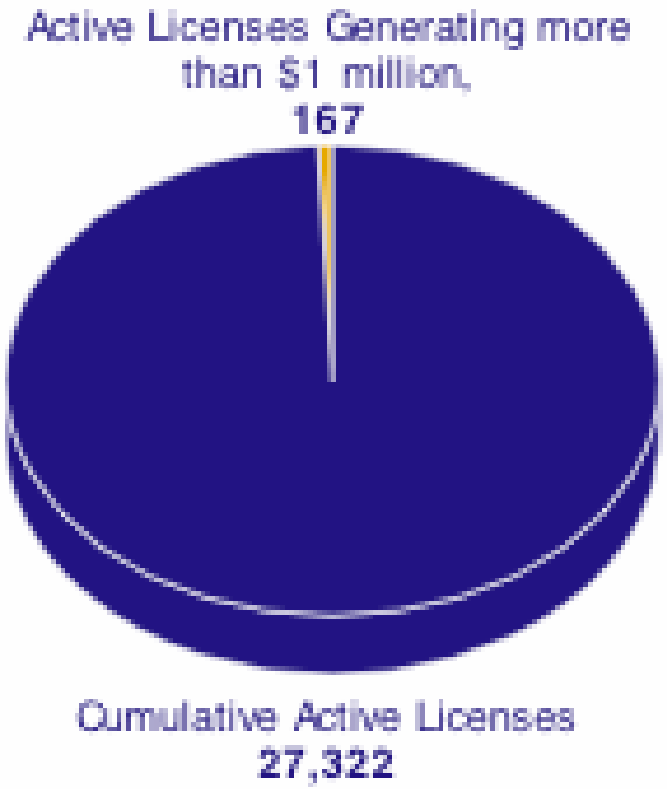
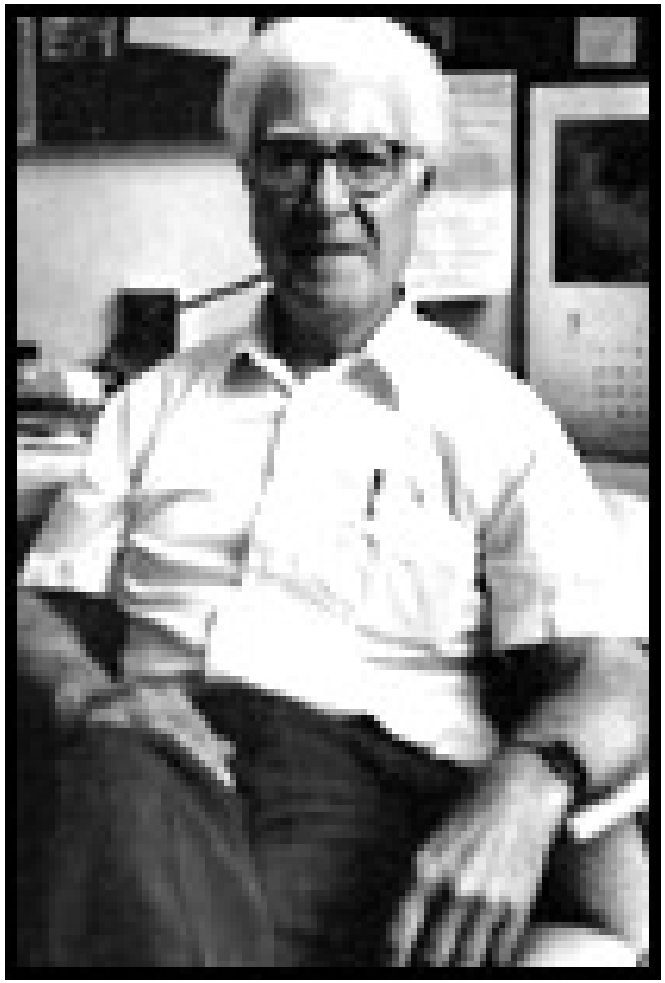


Figure US-28: Active Licenses Generating More Than $1 Million in 2004



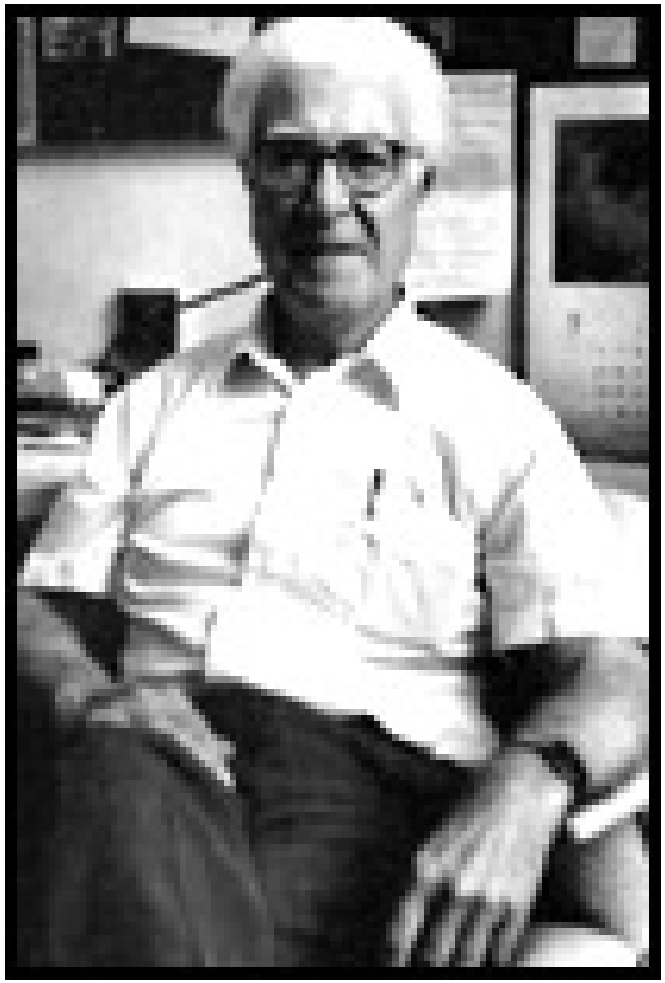
AUTM U.S Licensing Survey, FY 2004

words of a scientist



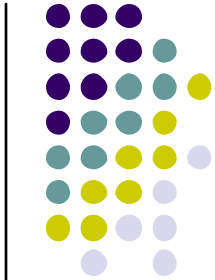
“I once helped create a drug that could enable millions of people to lead better and longer lives.”

*Dr. William Prusoff, the Principal Investigator for D4T as quoted in the op-ed, “The Scientist’s Story” he published in the NYT on March 19, 2001.



“[D]4T should be either cheap or free in sub-Saharan Africa.

Universities Allied for Essential Medicines



- **Two-fold mission:**

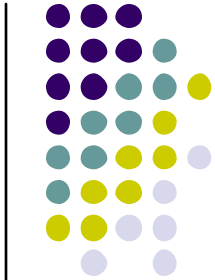
(1) to ensure that **biomedical innovations**, such as drugs, developed in campus labs are accessible in developing countries;

(2) to **facilitate and promote research on neglected diseases**, or those diseases predominantly affecting people who are too poor to constitute a market attractive to private-sector R&D investment.

www.essentialmedicine.org

How can universities ensure that their innovations reach low- and middle-income populations?

What can universities do to promote access to essential medicines?

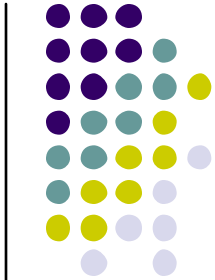


Promote equal access to university research

- Require licensing terms in technology transfer agreements that ensure low-cost access to health-related innovations.
- **Equitable Access License (EAL):** allows generic companies to manufacture and export university innovations to eligible countries.
- Include a transparent, case-by-case global access strategy.

UAEM Policy Statement

What can universities do to promote access to essential medicines?

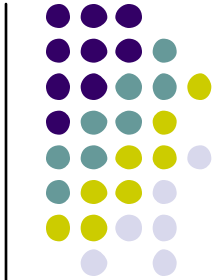


Promote research & development for neglected diseases

- Promote in-house ND research;
- Engage with nontraditional partners to create new opportunities for ND drug development;
- Carve out an ND research exemption for any patents held or licenses executed.

UAEM Policy Statement

What can universities do to promote access to essential medicines?



Measure research and technology transfer success according to impact on human welfare.

UAEM Policy Statement

- Knowledge
- Empowerment
- Pressure

- …..collective action

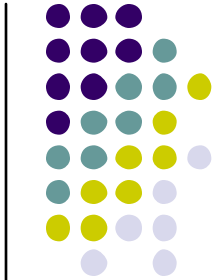
- Over a hundred of the highest profile luminaries in science, medicine, and health policy, including five Nobel laureates, lent their voices to this public call. Thousands of students, faculty, and supporters at over a hundred campuses around the world joined.

- *Nature*, *The Chronicle of Higher Education*, and the *Financial Times* each covered UAEM's activities. The *Boston Globe* endorsed UAEM's proposals. Numerous other campus, online, and local publications also published stories, drawing attention to the issue nationwide.

- Working closely with UAEM, Senator Patrick Leahy (VT) in the 109th Congress introduced legislation that would mandate humanitarian licensing terms, modeled on the terms UAEM is urging universities to adopt voluntarily

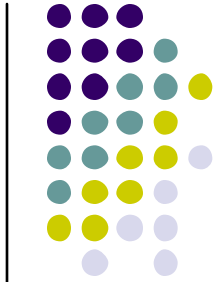
- In March, the American Association of Medical Colleges (AAMC) and eleven leading research universities took an important step forward: in a white paper on best licensing practices, the signatories recognized universities' fundamental responsibility to ensure the fruits of their research benefit the world's poor and committed to the principle at the heart of UAEM's Consensus Statement.

Philadelphia Consensus Statement October 2006



- Jeffrey Sachs
- Stephen Lewis
- Paul Farmer
- Victoria Hale (One World Health)
- 4 Nobel Laureates in Science or Medicine
- Former Deans of the Schools of Public Health at Yale and at Harvard
- 2 former editors of the New England Journal of Medicine
- Assistant Secretary of Health under Clinton and Johnson
- Patient groups from Thailand, India, and South Africa
- The list just goes on…thousands of signatories

Stanford White Paper 2007



- California Institute of Technology
- Cornell University
- Harvard University
- Massachusetts Institute of Technology
- Stanford University
- University of California
- University of Illinois, Chicago
- University of Illinois, Urbana-Champaign
- University of Washington
- Wisconsin Alumni Research Foundation
- Yale University
- Association of American Medical Colleges (AAMC)

WHO Commission on IP, Innovation & Public Health (CIPIH) Report

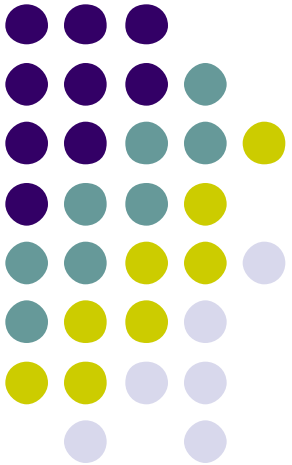
- 2.12 “Public research institutions and universities in developed countries should seriously consider initiatives designed to ensure that access to R&D outputs relevant to the health concerns of developing countries and to products derived therefrom, are facilitated through appropriate licensing policies and practices.”

UAEM PROJECTS

- **LEGISLATION** in the U.S. and Canada
- Developing **ALTERNATIVE TECHNOLOGY TRANSFER METRICS**
- **NEGLECTED DISEASE R&D** Policy Meeting
- Organizing around **COLLECTIVE ACTION**
- Model - **TRANSFER OF UNIVERSITY BIOMEDICAL TECHNICAL EXPERTISE** to a country with limited resources
- Understanding university **PATENTING POLICIES**, monitoring the **DRUG PIPELINE**, developing **ALTERNATIVE LICENSING LANGUAGE.**

Thank you

www.essentialmedicine.org



ACKNOWLEDGMENTS

Slides from Caroline Gallant, Amit Khera, Samantha Chaifetz, Dave Chokshi, & Hillary Freudenthal.

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AUTM Canadian Licensing Survey, FY 2004.

A Survey of Technology Licensing (and Related) Performance for U.S/Canadian Academic and Nonprofit Institutions and Technology Investment firms.

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(2) **Momentum: the 2005 report on university research and knowledge transfer.** Association of Universities and Colleges of Canada, www.aucc.ca

(3) **Mind to Market: A Global Analysis of University Biotechnology Transfer and Commercialization**. Milken Institute, 2006. http://www.milkeninstitute.org/pdf/mind2mrkt_2006.pdf

(4) **HIV/AIDS Drug Pipeline**: see www.aidsinfonyc.org/tag/tx/pipeline2006b.html
www.aidsinfonyc.org/tag/tx/pipeline2006a.html

(5) Moran, M. **A Breakthrough in R&D for Neglected Diseases: New Ways to Get the Drugs We Need**. PLos Medicine vol 12(9), 2005.

(6) **Montreal Statement on the Human Right to Essential Medicines**. www.accessmeds.org

Highlights of the fiscal year AUTM 2004 U.S. Licensing Survey Summary include:

- * Research funding at U.S. institutions was up 7.1 percent compared with fiscal year 2003.
- * Invention disclosures among U.S. institutions increased to 16,871, up 8.8 percent from fiscal year 2003, while patents issued decreased 6.4 percent to 3,680.
- * U.S. institutions executed nearly 4,800 new licenses or options, up 6.1 percent from fiscal year 2003.
- * In 2004 alone, 462 new companies based on academic discovery began operations in North America
- * Institutions responding to the survey reported introducing 3,114 new products to the marketplace since 1998.

Highlights of the fiscal year AUTM 2004 Canadian Licensing Survey Summary include:

- * Research funding at Canadian institutions was up 14.9 percent compared with fiscal year 2003.
- * Invention disclosures among Canadian institutions increased to 1,307, up 2 percent from fiscal year 2003, while patents issued increased 34.6 percent to 572.
- * Canadian institutions executed 544 new licenses or options, up 21.4 percent from fiscal year 2003, and 58.6 percent were with newly formed or existing small companies.
- * In 2004, 45 new companies based on academic discovery began operations in Canada.