

Drug Development for Global Health: A Public Research Agency Perspective

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(From the NIH web homepage: www.nih.gov)

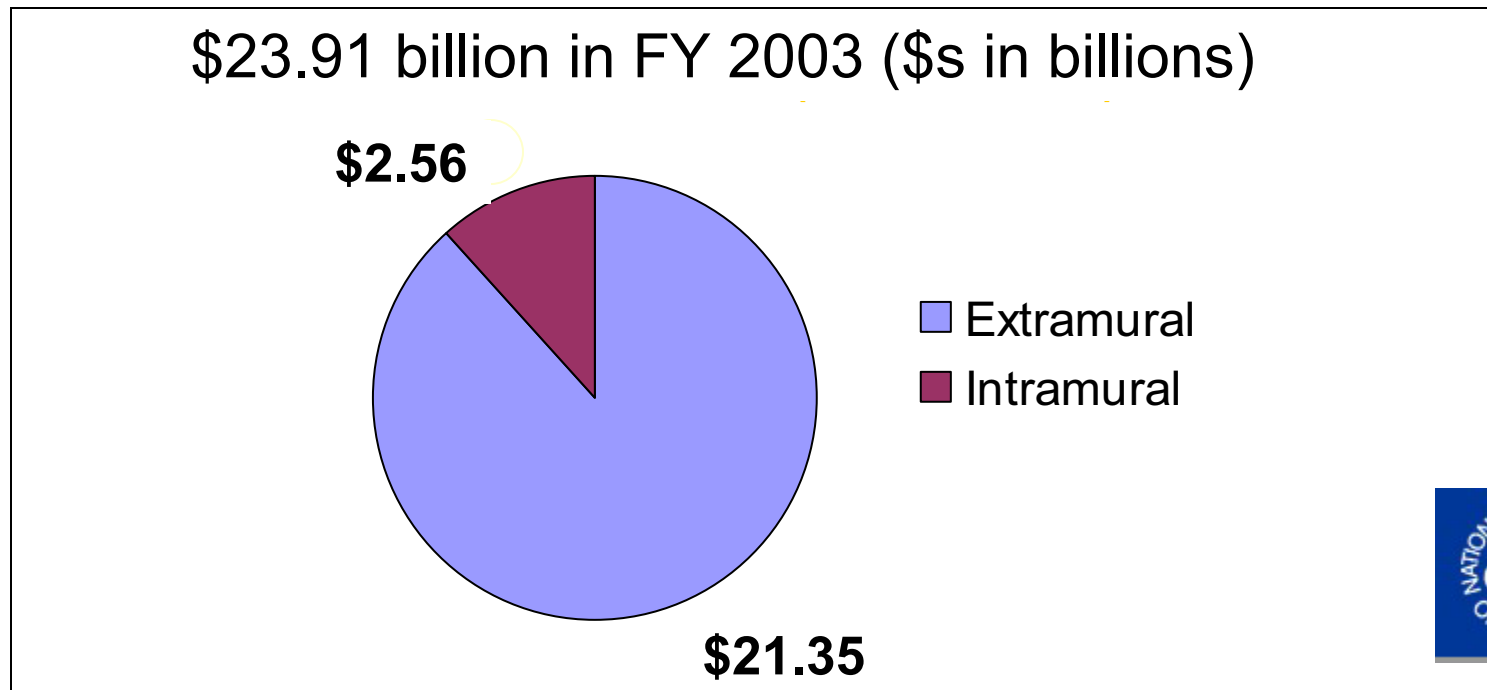
Mission

**To uncover new knowledge that will
lead to better health for everyone**



National Institutes of Health

- **Basic biomedical research in support of the health of the public**
- **Supports extramural research conducted by more than 51,000 principle investigators in more than 2,800 universities, research institutions, and medical centers**



National Institutes of Health

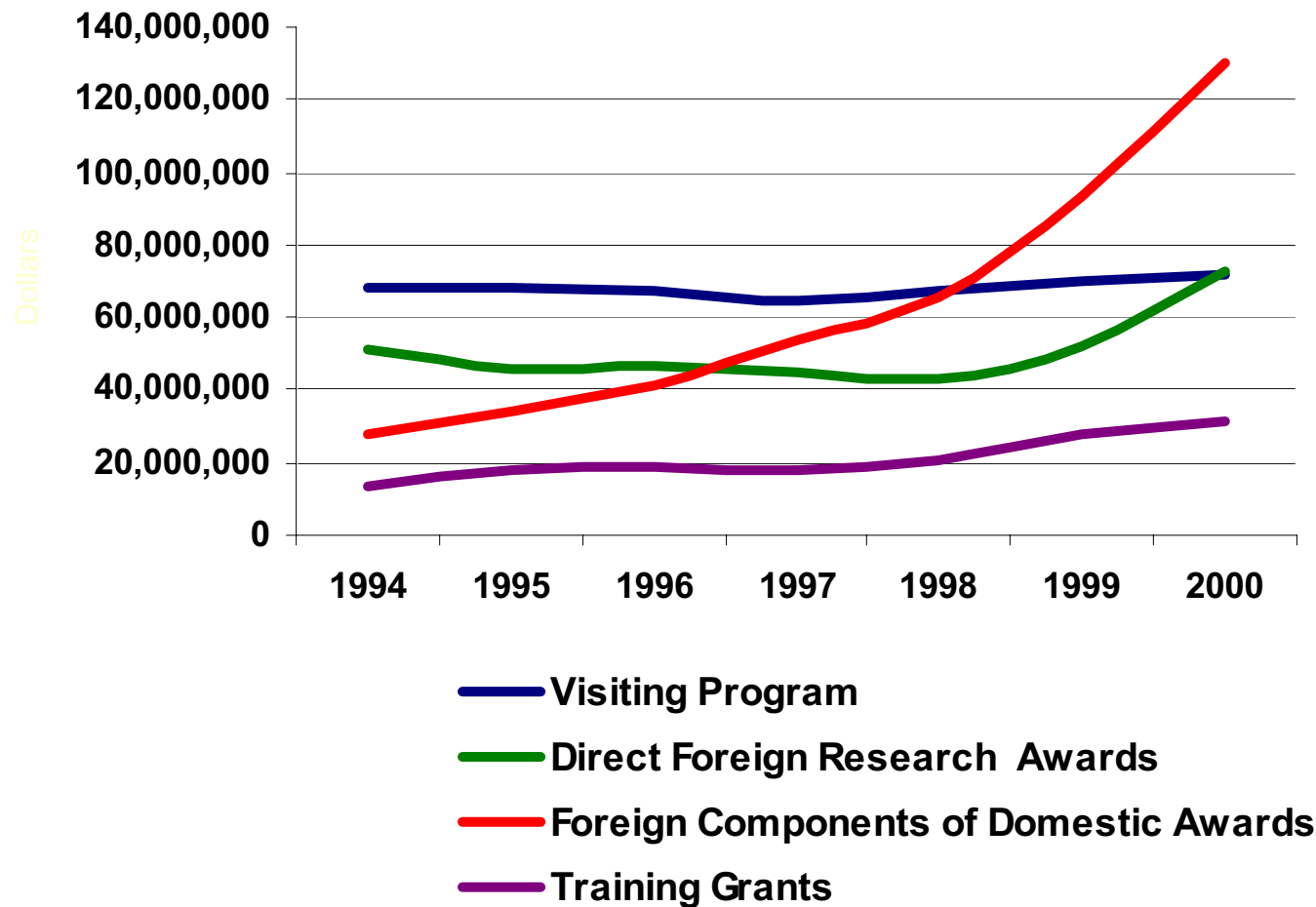
continued

- **Commitment to provide global benefits from its research**
- **Connection between global health and health/well-being of U.S. citizens**
- **NIH promotes global health through:**
 - **Training**
 - **Research**
 - **Clinical trials**



NIH International Research Expenditures

Fiscal Years 1994 to 2000



NIH Mechanisms to Promote Drug Discover/Development

- **Intramural research programs**
- **Traditional investigator-initiated research grants**
- **Drug discovery cooperative agreements**
- **CRADA (Cooperative Research and Development Awards together with academia and industry)**
- **SBIR (Small Business Innovation Research awards linking small business with academia)**
- **Challenge (matching) Grants (with academia and industry)**
- **Technology transfer**
- **NIH Roadmap**
- **Research capacity-building in developing countries**



Fogarty International Center, NIH

Mission

Promote and support
scientific research and training
internationally to reduce disparities in
global health

“Science for Global Health”



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Key Question for Public Funding Agencies

- **Within the current framework of IP ownership rights, how do we enhance the benefits of publicly-funded research to reduce disparities in global health?**

Technology Transfer Legislation

- **Bayh-Dole Act, 1980** — grants rights to universities and small business to patent inventions developed with public funds
- **Stevenson-Wydler Technology Innovation Act, 1980** — grants the right to federal government agencies to patent and license their own inventions
- **Federal Technology Transfer Act, 1986 and Subsequent Amendments** — allows government scientists to retain and share royalty fees with the inventors and provides mechanism for Cooperative Research and Development Agreements (CRADAs)

Possible NIH Mechanisms

- **White Knight Provisions**
- **Conditional licensing (licensees produce a plan to market to developing countries within 2 years of regulatory approval)**
- **Licensing to developing world entities**
- **Seek out more non-profit/PPP licensees to move less profitable technologies into use**



The Role and Promise of the U.S. University

- **Greatest impact of innovative technology management for the benefit of the developing world will come from universities**
- **Balance between fiscal obligations and broader mandate to generate and disseminate knowledge for the public good**

Unique Strengths of Universities

- **Large research universities have unique ability/human capital to think and act with an international focus**
- **Tradition of intellectual and social leadership**
- **Basic research capacity**
- **Experience in technology transfer**
- **Existing relationships with private sector licensees/industry partners**
- **Academic environment encourages/enables collaboration with foreign scientists**

Realities of University Technology Transfer

- **Fiscal limitations**
- **Challenges in attracting private sector to early-stage, unproven technologies**

Possible University Contributions

- **Increased research and training collaborations with the developing world**
- **Help build IP management capacity in the developing world**
- **Employ innovative patenting, licensing, and research tool policies that enable collaborative research**
- **Identify and collaborate with PPPs and NGOs that are developing products for the developing world**
- **Use of public health benefits as a measure of university technology transfer success**

Next Steps

- **Continued efforts in NIH intramural research and tech transfer**
- **Promote models of international research collaboration**
- **Provide a forum for academic partners to generate new ideas re: their role in promoting global health**

