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TECHNOLOGY TRANSFER IN BIOTECHNOLOGY

US POLICY PERSPECTIVE: TECHNOLOGY TRANSFER IN DEVELOPING COUNTRIES

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Thank you for inviting me to speak on the U. S. Government policy perspective on global technology transfer. Scott Adams, the well-know creator of the comic strip "Dilbert," has a favorite saying: "Technology: No Place for Wimps!" The extent to which technology has changed and will continue to change our many global societies is so profound it ***is*** almost scary. Benefits of technology are all around us. Biotechnology, in particular, promises solutions to some of the world's most serious problems: hunger, malnutrition, and disease. But, depending on how we use and transfer technologies globally, those benefits may not reach everyone. We also have to ensure that what benefits some doesn't actually harm others. Meetings such as this one are an important part of helping government, university, and industry developers and consumers of technology keep in touch with the advancing front of progress, understand how technology is being harnessed, and assure that the policies are fair and results, knowledge, and practices are conveyed globally, particularly to the developing world, in ways that enable adaptation to meet specific regional needs.

"Technology transfer" is a somewhat misleading term, suggesting to some that technology's products can be "thrown over the wall" from the developed to the developing world and create a positive result. Real technology transfer, however, is knowledge transfer. In order to have a meaningful impact, scientific and technological knowledge must be conveyed to the developing world in such a way that individuals will not only understand and be able to use the transferred technology, but they will also be able to adapt it to their own circumstances, find new uses for it, maintain it, and repair it. This requires a comprehensive knowledge transfer, or what those in the field like to call "capacity building."

The U. S. policy on technology transfer has been evolving for a number of years. One of the characteristics of the policy is that the decisions on whether and how to transfer technology globally are largely in the hands of the technology developers; industry, universities, and federal labs. The government's policy role has been to provide the legal framework for protecting US intellectual property, for ensuring domestic benefit from the development of the transferred technology, and promoting comparable treatment in foreign countries for US domestic firms.

However, the US government is also committed to ensuring that developing countries get access to important technologies in ways that allow for the development of a domestic infrastructure that can sustain research and development and provide a base for the countries to work on problems unique to their specific situations. For example the National Institute of Health's Fogarty International Center supports research in priority global health areas and also develops human capital and research capacity in the poorest nations of the world. Public and

private sectors spend more than $70 billion annually on health research, yet only 10 percent of the money covers 90 percent of global health problems according to a 1996 World Health Organization report. The Fogarty Center is working to change this picture by sponsoring projects in over 100 countries, health interests must focus substantially more attention and resources on the developing world, the speakers said.

Technology Transfer Mechanisms

Technology transfer may occur formally or informally, and often involves ideas and intellectual property, rather than goods. The mechanisms may be formal – such as Cooperative Research and Development Agreements (CRADA) between Federal labs and industry, licensing agreements, patents, official agency publications, and articles published by researchers in professional journals – or informal, such as presentations made at seminars by researchers or personal contacts between federal researchers and others from throughout the world who may be interested in their work. The appropriate treatment of intellectual property, its protection, and its transfer to, or sharing with, others are increasingly important issues – an importance heightened by the increasing proliferation of electronic mechanisms for transfer (such as the Internet, personal data assistants, and cell phones).

In considering the transfer of research and development, it is important to note that federal technology transfer – whether occurring formally or informally – accounts for only a small share of the technology transfer occurring in the United States or between the United States and other countries. In today's global economy, the private sector funds the major share of research and development (almost 75 percent of all domestic R&D in 2000), and transfers significantly more technology than the government. Moreover, the portion of federal technology transfer that occurs under formal agreements like CRADAs and patent licenses represents only a small fraction of the knowledge transferred by the federal government. The majority of such transfers occur as a result of regular contract activity and knowledge dissemination practices, including publications, presentations, and personal contact.

Even for technology developed from research funded by the federal government, much of the actual process of technology transfer is in someone else's hands. That is because, since the Bayh-Dole act of 1980, universities retain the patents and licenses on the products of their federally funded research and are able to choose whether and how to engage in technology transfer.

The Bayh-Dole Act amended the Patent and Trademark Law to facilitate transfer of federally-owned technology into the private sector, giving the rights to patents generated using Federal funds, to the inventors, frequently university scientists. Later amendments (P.L.98-620, 1984) stimulated the development of inventions from government installations, allowing some portion of royalties to be retained by the government scientists and their laboratories.

A subgroup of the President's Council of Advisors on Science and Technology (PCAST) recently looked at the Bayh-Dole Act and its implementation over the years. They found that Bayh-Dole has been largely successful, particularly in the life sciences, and has played a significant role in the growth of the U.S. biotechnology industry. If you've heard that there are criticisms of Bayh-Dole that have been percolating primarily in the information technology arena, PCAST also looked at that and concluded that many of the difficulties frequently ascribed to provisions of Bayh-Dole were actually linked to inconsistent implementation and interpretation of the law, rather than the law itself.

Global Agreements and Initiatives

Whether it's the war on terrorism, or the sequencing of the genome, or the emergence of a global economy, or the fundamental physics discoveries that led to medical technology breakthroughs in PET or MRI's, major influences on the future of biotechnology can come from many different directions.

For example, nothing embodies the dynamism and potential of U.S. agriculture more than biotechnology. And nothing would appear to have a brighter future than agricultural biotech products. Since 1996, when biotech crops were first commercialized, acreage devoted to biotech crops has grown to over 100 million acres worldwide. Biotech's commercial success is indeed astounding. USDA predicts 79 million acres of biotech crops will be planted in the U.S. alone this year, up 13%. USDA predicts that 74 percent of soybeans and 32 percent of corn will be planted in biotech varieties in the U.S. this year. Biotech corn, soybean, and cotton biotech varieties and byproducts (feeds and oils), and related processed foods, are a significant and growing part of our foreign trade.

Agricultural biotech has demonstrated potential to enhance sustainable development and food security by increasing crop yields, reducing the need for chemical and water inputs, and increasing resistance to crop stress such as drought. It can also cut losses from spoilage, pests, and crop diseases, extend product shelf life, and deliver life-saving medicines and vaccines more affordably and accessibly to large populations. This new technology will be especially useful for developing countries with growing populations, food shortages, and land, water, and other resource constraints.

The US State Department is working to ensure that U.S. foreign policy and the underlying regulatory environment is as favorable to mutually beneficial technology transfer in the biotechnology arena as possible. U.S. foreign policy is also devoted to a longer-term struggle to gain world acceptance of agricultural biotechnology products. Whatever strategies we develop must be flexible and responsive to changing conditions and motivations' not just in the industry but across the geopolitical, scientific and technological, economic, and social landscapes.

I'd like to touch on some of mechanisms we use for facilitating this technology transfer to the developing world. Science and technology umbrella agreements, in particular, are an important mechanism to promote and facilitate international cooperation in science and technology. These framework agreements set the overall parameters of bilateral S&T relationships between the United States and overseas partner countries. They define the responsibilities of each partner, and how the partnership will be monitored and evaluated by both partners. Most importantly, the umbrella agreement provides a definitive understanding of how intellectual property which may be furnished or created during the course of a collaboration will be protected and allocated. This provides a conducive framework for agencies to negotiate individual project-specific MOU’s under the umbrella agreement, without having to go through the labor-intensive elaboration of Intellectual Property Rights (IPR) each time. The traditional type of umbrella agreement relies on three basic principles: Mutual interest, equal benefit and a parity of resources brought to the collaboration by each party.

This last requirement, in particular, had limited the potential partner countries with which we could sign umbrella S&T agreements to a set of advanced industrial countries with well-developed S&T establishments and sufficient resources to match those we can bring to a

cooperative project. Developing countries could not meet these criteria and were thus precluded from being partners for the U.S. under umbrella S&T agreements.

In the last couple of years new thinking has begun to change this process. The realization that the vast majority of mankind now lives in the developing world has sparked a search for new ways to engage the developing world in science and technology, so that those counties can better participate in the global economy and their citizens can benefit from the rapid advance of science. At the State Department, a new model for S&T umbrella agreements was developed, one which recognizes the inherent asymmetry between our huge S&T establishment and resources and those a developing country partner might be able to bring to a collaboration. It also recognizes that the benefits from such a collaboration might be quite different for the U.S. and the developing world partner country. For example, the partner country might benefit from training, new facilities and equipment, and an overall raising of standards from working with U.S. scientists, while on our side the principal benefits might be access to unique research environments or biodiversity for U.S. scientists. This new model incorporates the flexibility to recognize the inherent need and resource asymmetries between the partners in a way which allows both to derive substantial, but different, benefits from the relationship, and to contribute according to their respective strengths and capacities.

The first example of this new type of S&T agreement was recently signed between the United States and Bangladesh. The language and format of that agreement do not differ markedly from what is typical of conventional S&T agreements between the U.S. and advanced scientific countries. The underlying assumptions, expectations and criteria, however, are quite different, as detailed in the cover memo which accompanies the text as it is sent around to the science agencies for clearance. This new set of criteria now allows developing countries to qualify as partners for a formal S&T relationship, something which was never possible under our old format. The text of the U.S-Bangladesh agreement calls for cooperative activities in science and technology which are heavily oriented towards information transfer, training and overall capacity building. Quoting from the agreement, these include:

- Exchange of students, educators, scientists , researchers, technical personnel and experts;
- Exchange of documentation and information of scientific and technological nature;
- Convening joint scientific and technological seminars, symposia, conferences and other meetings;
- Implementation of joint research and experiment on scientific and technological subject s of mutual interest as well as exchange of results;
- Transfer of technology between the parties;
- Enhancement of capabilities of the parties through technical assistance, training, infrastructure strengthening and the like;
- Any other forms of scientific and technological cooperation as may be mutually agreed.

We feel that this innovative new model for S&T agreements will open up a vast new field of potential partners for formal S&T collaboration and will provide a new path for the U.S. science community to engage the developing world. Clearly, the principal thrust of such engagement is building scientific and technological capacity in the developing world. We think this sort of collaboration is very much in the interest of both partners, and will bring tangible benefits – albeit of different sorts – to both the United States and its developing country partners.

Negotiations are currently underway to use this new model as a basis for S&T agreements with several more developing countries. One factor which has facilitated our formal approach to developing countries has been World Trade Organization and the impetus it has given to a great many countries to modernize and align their IPR protection legislation with world standards. For many years the lack of a reliable IPR regime has been a barrier to the signature of S&T agreements with developing countries. India, with its unique patent law which protects only processes, not products, has often been cited as an example of these difficulties. Now India and many other developing nations are moving to overhaul and strengthen their IPR legislation so they can assume full membership in the WTO. A corollary benefit of this development is that these newly strengthened IPR regimes fit into the norms the United States requires for formal S&T agreements, which have to be approved by the USTR as part of the clearance process. This is another example of the close interdependency between science, technology and the global economy.

Another example of US technology transfer policy I would like to mention concerns UNESCO, the United Nations Educational, Scientific and Cultural Organization. As you know, President Bush announced in September 2002 that the United States would rejoin UNESCO after an absence of some 18 years. The United States, one of the original founders of UNESCO in 1946, left the organization in 1984 out of concern for wasteful mismanagement and anti-Western ideology. The Administration feels that those issues have now been redressed and it is time for the U.S. to resume an active role in the organization. The formal ceremony marking the U.S. re-entry will take place at the end of this month in Paris. The President's Science Advisor, Dr. Marburger, will attend the ceremony.

My office, OSTP, has been in the lead on preparations for the U.S. science community's formal re-entry into UNESCO. During the years of our absence, U.S. science agencies such as NSF, NOAA and USGS continued to maintain strong links and cooperative programs with UNESCO. Now, however, we are officially rejoining the UNESCO Science Sector. Those ongoing collaborations will be strengthened, while the U.S. will add its influence and financial contributions towards shaping new science programs.

The US Agency for International Development (USAID) also sponsors collaborations between the US and developing countries. The Collaborative Agricultural Biotechnology Initiative (CABIO) will help developing countries access and manage the tools of modern biotechnology as part of an integrated drive to improve agricultural productivity, environmental sustain-ability and nutrition. Supported by the U.S. Agency for International Development (USAID), CABIO will embrace a comprehensive strategy for technology development, management, and implementation:

- Research and technology development will address developing countries' crop and animal production needs by providing a better understanding of potential impacts on biodiversity and the environment.

- Strengthening public institutions will lead to research, development of policy and regulatory frameworks, informed decision-making and public outreach to promote safe use of biotechnology.

- Local private sector development will help to deliver new technology and integrate it into local agri-food systems.

CABIO will support collaborations between local, regional and international institutions, both public and private, to address priorities in the following areas:

- **Biotechnology Applications for Developing Countries** - Developing countries can integrate biotechnology into current agricultural research through support for collaborative research with advanced research institutions regionally, internationally and in the private sector.

- **Creating an Enabling Policy Environment** - Biosafety regulatory systems and intellectual property rights (IPRs) play a crucial role in access to, and safe use of, modern bio-technology. Under CABIO, USAID will support regulatory development; capacity building; and analysis of biotech policy in relation to broader economic, food and environment strategies.

- **Human and Institutional Capacity Building** - New linkages and collaborative training connecting local institutions with U.S. and other international institutions will broaden intellectual, government and business relationships, and give client countries access to new technologies and expertise. This will build capacity-a key Agency objective-both in the technology itself and in the enabling policy framework (biosafety, IPR, technology transfer). Activities will target a wide range of stake-holders, including scientists, policymakers and the media.

- **Public Outreach** - Along with scientists and government, the public plays a role in developing policy and adopting technology. Engaging local researchers and policy makers in outreach and communication with the broader public stakeholders is a key component of CABIO.

Future Challenges

Finally, I'd like to touch on what I see are the future challenges in global biotechnology collaboration.

Borrowing a concept from Darwin, regional/country economies are involved in a constantly recurring struggle for existence, and the way to survive is to favorably evolve and change—to anticipate and predict those new technologies that will drive future developments. Governments, industry and academia need to accept the challenge to develop new ideas, to embrace change, and to take advantage of opportunities for renewal and reinvention.

The real promise of international technology transfer and collaboration is the facilitation of innovation. Innovation has been described as "implementing new ideas to create value," and the context of innovation is our mutual response to the changing world. We need to set our sights on catching the next wave.

One component of the next wave will be increased government, industry, academia partnerships, both domestic and global, as have been used to form biotechnology "clusters" both in the U.S. and abroad. These clusters take advantage of the strengths of each partner: the government's ability to sustain risk, the flexibility and responsiveness of industry, and the creativity and knowledge base of academia. Biotechnology clusters are revolutionizing economies, such as in Sweden, or here in the US in the Michigan Life Sciences Corridor.

As part of the federal commitment to investment in the life sciences the NSTC Subcommittee on Biotechnology has been working for over 10 years to coordinate the US

biotechnology research programs receiving federal support. Over 13 federal agencies have interests in biotechnology, representing both research and regulatory responsibilities. The interagency group has conducted inventories of the federal biotechnology research portfolio, identified opportunities and priorities, and proposed strategies that focus on investments that will continue to yield high returns in health, environment, agriculture, and manufacturing biotechnology. They will be making recommendations on what needs to be done to take advantage of this new environment and get the most out of the federal investment.

This is a great time to be holding the discussions we are this week. Biotechnology and other advances in the life sciences are beginning to realize their potential for changing the way medicine is practiced, the way food is produced, and the methods for processing and manufacture with fewer pollutants and less energy. The climate for collaboration, progress and innovative change has never been better and the opportunities are all around us. I hope we can find and develop those strategies that will make the developed and developing world mutual partners in biotechnology R&D, and joint sharers in the benefits.

Thank you.