Global Health Council Annual Conference 2006: Excellence, Innovation & Influence: Pathways to Results
Preliminary program available at http://www.globalhealth.org/images/pdf/2006_prelim.pdf

Session Title: New Technologies: The Role of the Private Sector

Designated Slot: Policy Series (PS7)

Session description in program materials: Learn more about how the corporate and academic sectors are working to expand the pipeline of new therapies and treatments to address global health problems.

Date: Thursday, June 1, 2006
Time: 10:30 am to 12:30 pm
Venue: Omni Shoreham Hotel, Washington DC
Location: Congressional Room A & B

10:30 to 10:35 am ***Opening Remarks, Introduction to Session & Speakers***

Session Organizer & Moderator: Usha R. Balakrishnan, Executive Director, MIHR-USA
usha@mihr.org

10:40 to 11 am

Presenter 1: Wendy Taylor, Founder & VP, Strategy, BIO Ventures for Global Health
wtaylor@bvgh.org

Business Planning: Viable markets for neglected diseases treatments?

11:05 to 11:25 am

Presenter 2: John A. Fraser, Director, Office of IP Development, Florida State University
jfraser@techtransfer.fsu.edu

Inventions Management and Technology Transfer Processes at Academic Institutions

11:30 to 11:50 am

Presenter 3: Chad Gardner, Associate Director, The Rockefeller Foundation
cgardner@rockfound.org

Evolution of Global Product Development Partnerships

11:55 to 12:15 am

Presenter 4: Peter F. Young, President & CEO, AlphaVax, Inc.
young@alphavax.com

Biotech's Perspectives on Vaccine Development Alliances

12:15 to 12:30 pm

Q&A, Discussion

Business Planning: Viable markets for neglected diseases treatments?
Wendy A. Taylor, Founder & VP, Strategy, BIO Ventures for Global Health

Biotechnology offers powerful new tools in the fight against the world's toughest neglected diseases. Not only can biotech improve upon conventional approaches, but new technologies can help overcome public health infrastructure constraints in resource-poor settings. Available products are already reaching patients in the developing world and the potential for new innovation is truly enormous. However, the challenge cannot be underestimated. Companies face a complex web of market, funding and information barriers that has impeded scientific progress and precluded industry involvement. BIO Ventures for Global Health (BVGH) has been formed to break through these barriers. Spun out of BIO with support from the Bill & Melinda Gates and Rockefeller Foundations, BVGH seeks to radically change the incentives for innovators to invest their own resources into global health product development.

Our approach is market-based and founded on the belief that economic mechanisms are a critical driver for broad industry involvement. Innovators are caught between passionate perceptions of inequities and market forces that focus their attention on providing the best returns for their shareholders. BVGH – which was formed in response to a demand from industry for new solutions – understands this bind. Because of the high market risk, industry and the public capital markets must have meaningful and credible market signals to pursue development of these products, and the financial incentives must be strong enough to compete with other product opportunities. Companies also need to see a clear pathway to get developing world products tested, licensed and distributed to patients who need them.

After extensive consultations with a wide range of biopharmaceutical companies over the last several years, we have found repeatedly that innovators are hampered by an insufficient understanding of developing world markets and, in the case of resource-constrained biotech companies, lack the internal capacity to generate this knowledge through diligent market research. The prevailing assumption, often in the absence of any underlying analysis, is that these markets are simply not viable. While this certainly may be true for some neglected diseases, we believe there are products for which there is a market and that market opportunity needs to be defined and facilitated. Put simply, the business case has not been made, and companies currently have little incentive to expend any effort to make it.

To direct these new bio-innovations toward the developing world, business opportunities on the scale necessary to attract innovators must be "uncovered" or built.

Through better market information, new models for tapping into emerging markets, and more credible and predictable developing world markets, BVGH can improve the value proposition for companies to pursue developing world products.

Suggested Q&A

- Companies – large and small -- that have invested in global health products are very concerned about issues of rollout/scale-up of new interventions, health services and delivery issues, and ongoing monitoring of how the intervention/technology is being utilized. How do you think these companies and other sectors working in public health can jointly help in addressing these concerns?
- BVGH has promoted collaborations between companies across different regions, especially to address new product development opportunities and needs in the emerging markets. What have been your general impressions of such linkages and collaborations and their prospects for leading to increased dealflows and new product development opportunities?
- Can we possibly develop strategies that take the "product development for the poor" notions beyond the *humanitarian* reasons? Organizations can perhaps enhance their business development strategies from learning that occurs in unique ways by being and operating in resource-constrained settings. What could promote the heightened recognition that such strategies could in fact result in new leads and ideas for product development that would not have otherwise occurred?

Inventions Management and Technology Transfer Processes at Academic Institutions
John A. Fraser, Director, Office of IP Development, Florida State University

Learning Objectives:

- To provide an overview of the field of "academic technology transfer" and the way the field has evolved in the United States since the passage of the Bayh-Dole Act in 1980.
- To detail the processes that comprise "technology transfer" or "technology development" in many universities and research labs.
- Through the sharing of specific examples, highlight the mechanisms that foster the next steps for the development of a new scientific discovery into actual products that benefit the public (and in the case of medical breakthroughs: the development of products that save lives and/or improve the quality of life for patients). Examples will include patent licensing to industry and other organizations, as well as entrepreneurial spin-off companies.

Several professionals in the academic technology transfer community - many of whom belong to the Association of University Technology Managers (AUTM) - have joined up to work in partnership with MIHR-Centre for the Management of Intellectual Property in Health Research and Development to foster technology transfer practices and mechanisms to promote global health equity, and extend the impact of the work of a university technology manager.

The presenter will talk about: 1) the current efforts within AUTM, including the outcomes from AUTM 2006 annual conference with its theme on "global health" held in March 2006 in Orlando; and 2) the increased necessity to reach out to various industry and nonprofit and governmental partners to continue to effectively address issues relating to the management of academic intellectual property and public policy in the context of global public health.

Suggested Q&A

- Universities – through their R&D and tech transfer processes -- have certainly been credited for playing a critical role in the birth of the modern biotechnology industry sector. What do you see as their emerging role now in facilitating, supporting, and catalyzing the work of companies and public-private product development partnerships engaged in advancing global health causes?
- Demonstrating that a specific creative licensing strategy for a specific invention led to a variation in better health outcomes for the poor in developing countries could possibly take years from discovery to actual product usage and distribution and impact. How can policymakers and funders take such a long-term view and approach to the challenges in R&D translation and technology transfer?

Biotech's Perspectives on Vaccine Development Alliances
Peter F. Young, President & CEO, AlphaVax, Inc.

Learning objectives:
- To provide a biotechnology industry perspective on vaccine development alliances for global health.

AlphaVax is developing the next generation of prophylactic and therapeutic vaccines for the prevention and treatment of infectious diseases and cancer. We are at the forefront of a completely new class of potent biopharmaceutical products based on our proprietary viral vector system. Our technical capabilities encompass vector design and development, new product research, product and process development, GMP manufacturing and technology transfer, quality assurance, and regulatory and clinical affairs. We also manage a GMP clinical supply operation in a leased BSL-3 vaccine production facility in Lenoir, North Carolina. AlphaVax began operations in 1998, is privately owned, and has been financed to date by an unusual mix of grant funding, corporate partnership income, and private equity.

One of our most exciting projects is an HIV clade C vaccine program, originally supported by the International AIDS Vaccine Initiative (IAVI) and now being pursued in collaboration with NIH and the South African Medical Research Council. Other institutions, like Johns Hopkins, the University of North Carolina at Chapel Hill, the University of Cape Town, and Duke University, provide further support. This program is being supported by over $35 million in non-equity funding, not including the cost of its Phase I clinical trial activity, which is being borne by the HIV Vaccine Trials Network.

The urgent need for an HIV vaccine drove this project into clinical trials in mid-2003. At that time, to maximize the probability of a successful HIV vaccine for populations with the highest epidemic prevalence, we selected genes from clinical isolates in South Africa. An ongoing dose-escalation trial is evaluating the safety of a single-gene prototype product. In parallel, we have developed and manufactured a multi-gene HIV product that is also entering clinical trials. If early results prove promising, we expect this program to rapidly expand into projects that can address populations with HIV viral sub-types in other parts of the world.

Suggested Q&A

- In your opinion, what conditions have to exist for successful multi-sector partnerships and product development for neglected diseases? Is it the right personalities, philosophy/culture of the firm and other players, the nature of the disease, the existence of a PDP, etc.
- How should the advocacy/public health community understand the role of the private sector - its limitations and potential?
- The financing picture in global health projects does not follow the traditional pathways. The normal alliance structures are altered creatively as well to pool together and tap into new resources. What do you feel are the barriers that you have uniquely faced in these regards? Are there any that could be specifically addressed by universities, your partners, or your funders?
- How does a typical venture capitalist perceive your firm's strategy and portfolio?
- There is a challenging future ahead in terms of R&D funding and technology transfer, particularly if we have to also deal effectively with emerging threats such as the avian flu, or the expected increase in disease burdens from rising rates of heart disease, diabetes, cancer, and mental illnesses in the developing countries. What are some of your thoughts with regard to academic and corporate collaborations in the future?

Evolution of Global Product Development Partnerships
Charles A. Gardner, Associate Director, The Rockefeller Foundation

Learning objectives:

- To understand how global public-private partnerships have been and are being used to accelerate product development and ensure access for the poor in developing countries.

Global public-private partnerships have been the Rockefeller Foundation's primary programmatic instrument to accelerate product development and ensure access for the poor in developing countries. In the mid-1990s, product development pipelines for diseases of the poor were nearly empty. For many priority diseases, prevention measures simply didn't exist (e.g., HIV and dengue vaccines, and microbicides). In other cases, existing interventions were inadequate in the face of expanding epidemics and increasing drug resistance (e.g., AIDS, TB and malaria), or entailed such lengthy treatment and cumbersome infrastructure that it would be impossible to reach all those in need (e.g., TB).

Since the mid-1990s, Rockefeller has worked with other donors toward the creation of five global public-private partnerships (often now called product development partnerships, or PDPs). The Foundation's objectives were three-fold: 1) to link public sector goals with private sector know-how in order to accelerate product development for diseases of the poor; 2) to raise global awareness of health inequities and attract substantial new funding to the field; and 3) to promote "culture change," that is to incorporate methods from the private sector into public sector practice, and to encourage more private players to enter the field of neglected diseases. Disease priorities were chosen based on the magnitude of health inequities and expert assessment of "social demand" (a combination of disease burden and donor willingness to pay). Technology goals were based on maturity of the science, and an intention to deliver products that are cheaper, easier to supply and/or more effective than existing interventions. Thus, by their very nature, the new technologies could increase health equity even if donor investments do not increase.

Since their creation, these five public-private partnerships have collectively raised more than $750 million from other donors toward their specific disease and technology goals. Their advocacy efforts have helped to raise global attention for all neglected diseases. There is growing consensus that the global health community's understanding of the role of the private sector has indeed increased, while the private sector has made increasing contributions to global health. Since 1999, at least a half-dozen similar organizations have been created by other donors, and the overall field has now raised more than $1.5 billion for product development (global public-private partnerships collectively spent about $200 million in 2004).

Suggested Q&A

- Global product development partnerships serve as a partner to university R&D and technology managers. This could especially be the case where the anticipated outcomes from funding for "neglected diseases" related R&D projects requires attention to access issues, i.e., Global Access Plan under Gates Fndn Grand Challenges in Global Health awards. What are the future resource challenges that PDPs may experience as they get closer and closer to later-stage clinical trials and product manufacture and distribution? What are some ways to collectively bolster the success of PDPs' goals?
- Continuing pipelines of health product innovations could come from anywhere, particularly from "Innovative Developing Countries." How do we ensure that the R&D outcomes in these IDCs get translated for our collective global benefit as well?
- Universities are being asked to be both an engine for local economic development and contribute to global health equity and the evaluation of the impact of technology transfer itself is undergoing some serious reconsideration. "Best returns" for shareholders may need to increasingly embed the rationale for enhancing collective global good. How are private foundations or other funders addressing these balancing dilemmas faced by their grantees and stakeholders in the US and abroad?

Biosketches

Usha R. Balakrishnan

Usha Balakrishnan is a Founding Board Member and the first Executive Director of MIHR-USA, a 501c3 nonprofit entity which represents the US operational base of MIHR (Centre for the Management of Intellectual Property in Health R&D), a global nonprofit headquartered in Oxford, United Kingdom. As founder of the Technology Managers for Global Health (TMGH) group within the Association of University Technology Managers, Usha has introduced global health-related academic technology transfer sessions at key conferences, and has spurred dialog and seminars on a number of campuses in the US and abroad. These efforts are supported by grants from the Rockefeller Fndn and the Ewing Marion Kauffman Fndn.

Prior to joining MIHR in 2005, Usha worked in progressively responsible positions at the University of Iowa (most recently as Director of Corporate Partnerships), and was active on several civic boards (including as a gubernatorial appointee to the Iowa Economic Development Board, 2001-2005). Usha has conceptualized and launched complex multi-sector alliances; initiated bilateral exchanges with institutes in India; evaluated hundreds of academic discoveries for patentability and commercial potential; negotiated patent licenses with pharmaceutical and biotechnology companies; and advised small business owners and high-technology entrepreneurs.

Usha serves on the AAAS (American Association for the Advancement of Science) Committee on Scientific Freedom and Responsibility, and the Board of Directors of the Community Foundation of Johnson County. Usha received her MBA from the University of Iowa and her B.Com. from Bombay University.

Wendy A. Taylor

Wendy Taylor is the Founder and Vice President of Strategy and Operations of BIO Ventures for Global Health (BVGH). She founded and raised initial funding for BVGH and led the organization's initial strategy and implementation as its Executive Director.

Previously, she served as Director of Regulatory Affairs and Bioethics for the Biotechnology Industry Organization (BIO) where she negotiated the third reauthorization of the Prescription Drug User Fee Act (PDUFA) and developed the organization's global health initiatives. Ms. Taylor has extensive experience in the executive and legislative branches of the US government, including the Office of Management and Budget where she oversaw FDA regulatory activities, the Department of Health and Human Services and the US House Committee on Ways and Means.

Ms. Taylor received a Master of Public Policy from the Kennedy School of Government at Harvard University and a B.A. from Duke University.

John A. Fraser

Mr. Fraser is currently the Director of the Office of IP Development Programs, Florida State University, Tallahassee, Florida (1996-present). Prior to that he served as Director, University/Industry Liaison Office at Simon Fraser University, Vancouver, Canada. Concurrently with his FSU position, Mr. Fraser and a partner won a government contract to search for dual-use technologies in the six Canadian Military Research Establishments.

Mr. Fraser brings substantial corporate and university experience to the FSU position. He has held positions as Executive Vice President and co-founder of UTC, Inc., a venture capital backed, North Carolina-based university licensing/technology transfer firm; President and CEO of UTI, a University of Calgary based for-profit technology transfer company; Vice President of TDC, Inc., a Toronto and Vancouver-based venture capital firm and President, Burnside Development, a technology commercialization consulting firm. He has co-founded three companies and assisted entrepreneurs launch another twelve technology based firms. He was a member of the Board of Trustees of the technology transfer association, Association of University Technology Managers (AUTM) and is the President-Elect of AUTM; and served a two year term as VP Membership (2001-2003); is a Founding Board Director of the Tallahassee region technology association, the TalTech Alliance and its Executive Committee; is a member of Board of the Florida Research Consortium and its Executive Committee, appointed by the Governor to increase university/company interactions to better the Florida economy, and consults to the Johns Hopkins University technology transfer program by assisting scientists/engineers to write business plans for new startup companies.

Mr. Fraser holds a Masters Degree in Biochemistry from the University of California - Berkeley.

Peter F. Young

Peter Young is the President & CEO of AlphaVax, Inc. He has 25 years of experience in the global pharmaceutical industry, including senior commercial, general management, and development positions at Abbott International and Glaxo Wellcome. He has a strong track record of organizational leadership, policy development, and commercial and product development achievement—particularly in antibiotics and antivirals. He combines a broad cross-functional and international industry background with a respected reputation in public health circles.

Prior to joining AlphaVax, Mr. Young was Vice President of HIV and Opportunistic Infection at Glaxo Wellcome, where he was responsible for combined global commercial and product development and oversaw a five-fold expansion in the latter part of the 1990s. Mr. Young is the Chairman of NC BIO, a member of the national BIO board of directors, Chairmen-Elect of the Council for Entrepreneurial Development, and a member of the board of directors of Memory Pharmaceuticals. Mr. Young holds undergraduate and graduate degrees from Indiana University.

Charles A. Gardner

Associate Director, The Rockefeller Foundation

Dr. Charles Gardner is an Associate Director with The Rockefeller Foundation. He manages a program within the Health Equity division that has provided "social venture capital" to create and support public-private partnerships (PPPs) to accelerate the development of drugs and vaccines against diseases of the poor. The program now focuses on (1) sustainability of product development PPPs, and (2) ensuring product availability and adoption within disease endemic countries.

From 1998 to 2003, Dr. Gardner served as the Official Representative of the U.S. Department of Health and Human Services to South Asia with the title of Science Attaché at the U.S. Embassy in New Delhi. Prior to 1998, he was the Program Officer for Africa, the Middle East and South Asia at the Fogarty International Center, U.S. National Institutes of Health. He also taught bioethics as an Assistant Professor at Howard University, Washington DC.

From 1991 to 1992, Dr. Gardner served on the staff of the House Government Operations Committee, U.S. Congress, with fellowship support from the American Society for Microbiology under the Congressional Science Fellowship program managed by the American Association for the Advancement of Science. Dr. Gardner received his Ph.D. in Cell, Developmental and Neurobiology from the University of Michigan in 1991; his dissertation focused on gene expression and pattern formation in the early embryo.