



**MIT** Massachusetts Institute of Technology  
Program on the Pharmaceutical Industry (POPI)

The Future of the Pharmaceutical Industry Symposium  
*"Pharmacogenomics, Drug Development and the Cost of Health Care"*

December 9 - 10, 2003

**Speakers**

<b>Speakers</b>	<b>Professional Title(s), Title of Talk, &amp; Short Description</b>
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**Thomas J. Allen, Ph.D.**

**Professional Title(s):**

Howard W. Johnson Professor of Management,  
Professor of Engineering Systems  
MacVicar Faculty Fellow  
& Co-Director, Program on the Pharmaceutical Industry  
(POPI)  
Sloan School of Management  
Massachusetts Institute of Technology

**Dr. Donald C. Anderson,  
M.D.**

**Professional Title(s):**

Senior Vice President & Chief Scientific Officer, Adaptive  
Therapeutics

**Title of Talk & Short Description:**

**Challenges Towards the Implementation of  
Pharmacogenomics in Mainstream Pharmaceutical Drug  
Development**

The acceptance and successful implementation of pharmacogenomics into major pharmaceutical R&D programs has been impeded by: a) a limited critical mass of human genetics science in the industry, b) a general lack of identified pharmacogenomic markers of use in guiding clinical medicine, c) a poor understanding of commercial strategies to exploit pharmacogenomic data, d) perceived or real risks involved in conducting clinical genetics research, and e) a short sided vision of the ultimate

rewards of personalized medicine based on genetic diagnostics.

**Charles L. Cooney, Ph.D.**

**Professional Title(s):**

Professor of Chemistry & Biochemical Engineering,  
Department of Chemical Engineering  
Executive Officer & Co-Director, Program on the  
Pharmaceutical Industry (POPI), Sloan School of  
Management,  
Massachusetts Institute of Technology

**William H. Crown, Ph.D.**

**Professional Title(s):**

Vice President, Outcomes Research & Econometrics, The  
MEDSTAT Group, Inc.

**George D. Demetri, M.D.**

**Professional Title(s):**

Center for Sarcoma and Bone Oncology, Dana-Farber Cancer  
Institute

**Stan N. Finkelstein, M.D.**

**Professional Title(s):**

Senior Research Scientist &  
Co-Director, Program on the Pharmaceutical Industry (POPI)  
Sloan School of Management  
Massachusetts Institute of Technology

**Title of Talk & Short Description:**

**Economic and Policy Implications Occasioned by  
Advancing Science and Technology of Drug Development**

Bringing innovative new therapies to market that are based on advancing science and technology of drug discovery and development represents a huge challenge but is only the beginning of the challenge. If these new drugs are to be considered "cost effective," likely that will result from their being both much more effective, but also more costly. Health care payors are already taking steps to limit access to some of the newest therapies. This presentation will review and comment on the how barriers to accessing drugs based on the "new biology" may affect medical practice and the future of drug development.

Irving H. Fox, M.D., C.M.

**Professional Title(s):**

Medical Advisor, Millennium Pharmaceuticals, Inc.  
Clinical Professor of Medicine, Harvard Medical School

**Title of Talk & Short Description:**

**Biomarkers to Optimize Clinical Drug Development: Use and Process**

Biomarkers are an integral part of the clinical development strategy. They are used when necessary and as they are available to optimize drug development in early and late stage clinical trials. In addition, biomarker discovery research may be performed during clinical trials to optimize the development of the next products or enhance the value of new drugs after approval by improving the benefit to risk ratio for patients.

Biomarkers must be planned and developed to meet the needs of clinical drug development and product approval as appropriate. A beneficial way to implement biomarker strategy is to form a biomarker development subteam during the discovery phase of research. This subteam plans and executes biomarker research and coordinates strategy and timelines with the product development project teams.

Geoffrey S. Ginsburg,  
M.D., Ph.D.

**Professional Title(s):**

Vice President, Molecular and Personalized Medicine,  
Millennium Pharmaceuticals, Inc

**Title of Talk & Short Description:**

**Personalized Medicine: Changing the Paradigm of Patient Care in Cardiovascular Disease**

We are already in the *Era of Personalized Medicine* in cardiovascular disease. The Personalized Medicine approach has been developed in part out of the need for a more effective strategy in pharmaceutical R and D for developing novel cardiovascular therapeutics. This strategy takes advantage of the genome and allied technologies (expression profiling, proteomics, molecular imaging) that together provide an unprecedented means to probe disease mechanisms and pathways in atherosclerosis, heart failure,

and thrombosis and will provide important biomarkers for these diseases as well as for their risk stratification and treatment. Pharmacogenomic biomarkers that predict patient responses to therapies are an imperative in cardiovascular therapies where the treatment benefits are imparted on only a few of the patients treated. Yet, despite the availability already of many such markers, significant challenges exist in the translation of the results of clinical research into clinical practice

**Martha L. Gray, Ph.D.**

**Professional Title(s):**

Director, Harvard-MIT Division of Health Sciences & Technology (HST)

Edward Hood Taplin Professor of Medical & Electrical Engineering

Massachusetts Institute of Technology

**Title of Talk & Short Description:**

**The New Biomedicine: How Emerging Biomedical Technologies are Changing the Medical Paradigm**

**Linda G. Griffith, Ph.D.**

**Professional Title(s):**

Associate Professor, Chemical Engineering & Bioengineering & Environmental Health, Massachusetts Institute of Technology

**David E. Housman, Ph.D.**

**Professional Title(s):**

Ludwig Professor of Biology, Massachusetts Institute of Technology, Center for Cancer Research

**Title of Talk & Short Description:**

**Pharmacogenomics and Cancer Treatment**

In my talk, I will address the direct application of pharmacogenomics to cancer treatment. I will consider the impact of pharmacogenomics on current cancer therapies and discuss the interaction between pharmacogenomics and the development of novel therapeutic interventions.

**Kent Larson**

**Professional Title(s):**

Principal Research Scientist & Director, Changing Places, Massachusetts Institute of Technology

**Title of Talk & Short Description:**

**Creating Proactive Environments for Healthy Living**

A multi-disciplinary team of researchers from the MIT Changing Places/House\_*n* Consortium is studying how to create pervasive computing environments for the home that promote healthy living. They are developing sensor technologies that can be easily installed in places of living and that can be used to infer information about activities of daily living in non-intrusive, non-stigmatizing ways. They are investigating how environmental sensors and wearable sensors can be used together to create user interfaces that motivate health-related behavior changes, from medication adherence, healthy diet, stress reduction, and increased exercise. Kent Larson will discuss the capabilities of the PlaceLab - a unique residential observational laboratory under construction in Cambridge that will be used to study proactive health technologies for the home.

**Douglas A. Lauffenburger,  
Ph.D.**

**Professional Title(s):**

Whitaker Professor of Biological Engineering, Biology, and Chemical Engineering & Director, Biological Engineering Division, Massachusetts Institute of Technology

**Title of Talk & Short Description:**

**The Multiple Dimensions of Systems Biology**

Biological systems are complex in multiple dimensions, including the number of components considered, the kinds of properties measured for the components, and the level(s) of contextual physiological hierarchy. The Computational & Systems Biology initiative at MIT seeks to pursue understanding and manipulation across these dimensions in integrated fashion. We will describe example efforts manifesting this integrative perspective, focusing on design and development of molecular therapeutics.

**Kip Martha, M.D.**

**Professional Title(s):**

Chief Medical & Regulatory Officer, Interleukin Genetics, Inc.

**Title of Talk & Short Description:**

**Clinical Applications of Pharmacogenomics: Initial Disease Targets and Early Drivers of Change**

The technology for studying the relationships among genetic variation, disease risk and drug response has now matured to the point where its cost, availability, accuracy and reliability are no longer the obstacles preventing its use in clinical medicine. Furthermore, on the surface the integration of pharmacogenomics into our health care system has huge potential benefits at several levels from the individual patient to society broadly. So why is it taking so long for it to become a reality?

**Robert N. McBurney, Ph.D.**

**Professional Title(s):**

Chief Scientific Officer & Senior Vice President, Research & Development, Beyond Genomics, Inc.

**Title of Talk & Short Description:**

**Systems Biology and the Pharmaceutical Value Chain**

**Alan C. Moses, M.D.**

**Professional Title(s):**

Professor of Medicine, Harvard Medical School  
Senior Vice-President & Chief Medical Officer, Joslin Diabetes Center  
Adjunct Appointment to Health Sciences & Technology

**Title of Talk & Short Description:**

**Diabetes Mellitus: Technology Implications from Drug Discovery to Patient Application**

1. The epidemics of diabetes and obesity are interrelated and create both a challenge for effective intervention and an imperative for social action. Technology is beginning to help on the discovery front but not on the health policy

side.

2. While the phenotype of diabetes is well understood, the difficulty of identifying specific genetic defects that play a primary role in pathogenesis has hampered drug development and has contributed to the inability to achieve target levels of glucose control in the majority of patients.

3. The impact of diabetes complications on the health of individuals and the cost of health care delivery require a renewed effort to target specific biochemical pathways and to refine the molecules that target these pathways. Importantly, technology delivered through point of service diagnostics may be particularly important in creating the rationale for pharmacological intervention to prevent these complications early in the course of disease.

4. Continuous glucose monitoring holds the promise of revolutionizing diabetes care but places some unique burdens on the companies that are developing these technologies from the standpoint of data handling and the presentation to patients of automated clinical recommendations. This area provides a unique example of enabling patient care through technology that will reside directly in the hands of the consumer.

**Norman C. Payson, M.D.**

**Professional Title(s):**

Former Chairman & CEO, Oxford Health Plans, Inc.

**Title of Talk & Short Description:**

**Will Pharmaceuticals Lose Pricing Power in the United States?**

Pharmaceutical companies face two great risk factors in pricing their products in the next decade. First, employers will be offering less first dollar coverage in their employee health benefit plans creating significant consumer price sensitivity. Second, if the government becomes a major buyer of pharmaceuticals for seniors, it may demand favorable pricing. Capacity and pricing power for insurers and health care providers has evolved as employer-based financing moved from indemnity to HMO to “managed indemnity” and as governmental payers required progressively more price shifting. Loss of pricing power by

big pharmaceuticals will have significant effects on the capital markets and economics of discovery.

**Thomas G. Roberts Jr.,  
M.D.**

**Professional Title(s):**

Instructor in Medicine, Harvard Medical School  
Thoracic Oncology Unit, Massachusetts General Hospital  
Visiting Scientist, Massachusetts Institute of Technology

**Title of Talk & Short Description:**

**The Impact of Molecular and Imaging Technologies on  
Phase I Cancer Trials**

There has been an explosion in the number of molecules under investigation to treat cancer. Despite enormous public and private investment in cancer drug discovery and development, clinical progress remains slow. One of the major efforts underway is to apply correlative science and advanced imaging technologies to evaluate the potential of an agent at its earliest phase of clinical development; the presenter will review the field's experience with these efforts over the last ten years.

**Robert H. Rubin, M.D.**

**Professional Title(s):**

The Gordon & Marjorie Osborne Professor of Health Sciences & Technology, Massachusetts Institute of Technology  
Professor of Medicine, Harvard Medical School

**Anthony J. Sinskey, Sc.D.**

**Professional Title(s):**

Professor of Microbiology & Co-Director, Program on the Pharmaceutical Industry (POPI), Sloan School of Management, Massachusetts Institute of Technology

**Title of Talk & Short Description:**

**The New Biology and the Future of the Pharmaceutical  
Industry**

There is an increased awareness that the number of new chemical entities (NCE) being launched by the pharmaceutical industry has significantly decreased, while R&D expenditures have steadily increased. In addition, a

large number of patented pharmaceutical products are going off patent. There is increasing pressure from consumers and insurance companies to reduce healthcare costs. This presentation will review these issues in the context of the new biology in order to answer the questions: Can new biology research and development reverse the trends in the pharmaceutical industry? How will the transition for incorporating new biology approaches into the pharmaceutical sector take place? Is there a need for a paradigm shift in order to improve the quality of the pharmaceutical pipeline? What will be required for the shift to occur?

An important challenge will be how to deal with the business and marketing issues in healthcare during the transition phase to new science approaches for the pharmaceutical industry. Where and how value can be generated by new biology approaches in the pharmaceutical industry will be discussed.

**Peter K. Sorger, Ph.D.**

**Professional Title(s):**

Associate Professor of Biology and of Biological Engineering  
Co-Chair, MIT Computational and Systems Biology Initiative,  
Massachusetts Institute of Technology

**Title of Talk & Short Description:**

**Applying Systems Biology to Drug Discovery**

Systems Biology, as it is being developed at MIT, combines systematic experimentation and computational modeling to describe complex biological networks. As an integrative discipline, systems biology promises to knit together data from diverse sources including genomics, proteomics, target identification and small molecule screening into a *Disease Management System*. We will discuss this idea with reference to our work on understanding the mechanisms of action of drugs that target EGF receptor signaling. These chemotherapeutics are becoming increasingly important in the clinic but we do not yet understand how to vary their use to optimize treatment strategies.

Janet Woodcock, M.D.

**Professional Title(s):**

Director, Center for Drug Evaluation & Research, U.S. Food & Drug Administration

**Title of Talk & Short Description:**

**FDA Policy on Pharmacogenomic Data in Drug Development**

This talk will cover the major issues related to the use of pharmacogenomic data during preclinical and clinical drug development, and the resulting regulatory issues.