Center for Biomedical Innovation

The Center for Biomedical Innovation (CBI) was formed in 2005 as a collaboration among the School of Engineering, the MIT Sloan School of Management, the School of Science, and the Harvard-MIT Division of Health Sciences and Technology to address challenges within the pharmaceutical, biotechnology, diagnostics, and medical devices industries involving innovation, productivity, costs, and predicting and managing risks.

Led by executive director Gigi Hirsch, MD, and faculty director Anthony Sinskey, ScD, CBI's mission is to transform discovery, development, manufacture, and distribution of cost-effective therapeutics and devices. To achieve this goal, CBI has created a safe haven in which academic, government, and industry experts communicate and collaborate in generating and disseminating high-impact systemic solutions that enhance the efficacy, safety, and quality of patient care worldwide.

Through its research and educational programs, CBI concentrates on four key areas:

1. R&D redesign to improve productivity through new collaboration and research models
2. Safety assessment breakthroughs driven by new biomarker technologies that are validated in human clinical trials and postlaunch surveillance of electronic claims and medical records
3. Manufacturing supply chain rationalization and new "Quality by Design" implementation
4. Economic and regulatory risk management through systematic, holistic approaches that anticipate stratified medicine, regulatory change, and reimbursement evolution

Within these areas, CBI focuses on a three-pronged program strategy to catalyze action:

- Creating new solutions through collaborative research efforts with broad participation from scientists working in industry and in government agencies. Through our research programs, we seek to generate new methods, insights, and tools that are demonstrably effective in applied biomedical settings.
- Educating the broader stakeholder community about new tools created by the focused collaborations. Building broad consensus for comprehensive implementation requires that the success of new solutions be disseminated to all relevant stakeholders, including those who did not participate in their development.
- Transforming biomedical innovation through broad adoption of the new methods. Achieving substantial change in the biomedical industry requires the concerted efforts of all stakeholders to implement the new solutions. CBI helps provide a transparent mechanism for change through its implementation consortia, safe haven approach, and generation of new concepts.

In response to significant changes within the health care industry, as well as the evolving interests of our stakeholders, CBI is now refining its mission to improve

global health by addressing roadblocks to the development and implementation of biomedical innovations. Based on feedback from members, CBI has begun an aggressive strategic repositioning process that involves redefining the membership model to enable participation by a broader range of stakeholders beyond the pharmaceutical industry, refining CBI's mission statement and programmatic objectives, engaging faculty in discussions and workshops that lead to fundraising efforts for specific research collaborations, and extending the focus of its research portfolio to include the "downstream" world of doctors and patients.

Accomplishments

Safety Surveillance Research Group

The Safety Surveillance research team underwent rapid expansion over the past year. New MIT faculty participants in FY2008 included professors George Apostolakis (Nuclear Science and Engineering), Dimitris Bertsimas (Sloan School of Management), Forbes Dewey (Biological Engineering), Dan Frey (Mechanical Engineering), Richard Larson (Civil Engineering), Stuart Madnick (Sloan School of Management), Deborah Nightingale (Aeronautics and Astronautics), and Roy Welsh (Sloan School of Management). These individuals bring valuable expertise and experience from other industries in data mining, signal detection, quantitative modeling, risk assessment/management, decision analysis, system dynamics, and change management in highly regulated industries, among other areas.

On March 13, CBI hosted a workshop focused on translating knowledge from other industries to improve postlaunch drug safety surveillance. The workshop sought to provide MIT faculty and health care experts from industry, providers, and government an opportunity to work together to assess the current state of the system and identify research methodologies and tools from other fields that might enhance safety surveillance of pharmaceuticals.

Discussions within the Safety Surveillance program indicated a need to look more broadly at drug safety issues and strategies. This led to the launch of the Drug Safety Futures 2020 initiative, focusing on how the changing environmental forces at play today might converge to reshape drug safety over the next 10–15 years. The group met April 8 to begin identifying key drivers of change in drug safety, envisioning a set of future scenarios and associated strategic imperatives, and ultimately creating a road map for CBI's research agenda in late 2008/2009. Currently, the strategic advisory group for Drug Safety Futures 2020 includes Burt Adelman (CBI), Vikram Dev (AstraZeneca), Peter Farina (MIT), Gigi Hirsch (CBI), Scott Korn (Merck), Professor Robert Laubacher (MIT), Gilbert Burckhart (Food and Drug Administration [FDA]), Michael McGinnis (Institute of Medicine), Gary Neil (Johnson & Johnson), Brad Perkins (Centers for Disease Control and Prevention), Richard Platt (Harvard Medical School/Harvard Pilgrim Health Care), Wayne Rosenkranz (MIT), and Professor Tony Sinksey (MIT).

Biomanufacturing Research Group

Recent FDA guidances and initiatives have highlighted the need for increased process understanding in order to better model, control, and optimize biomanufacturing to

ensure patient safety, reduce manufacturing costs, and improve product quality. In an effort to think through innovations that will modernize the manufacturing of biologics, the Biomanufacturing (BioMAN) Research Program completed the first phase of an industry needs assessment. A series of high-level industry interviews were conducted with input from more than 17 people from 11 different organizations, including seven site visits and four manufacturing tours. From these discussions, several working groups were conceived, including one focused on process analytical technologies (PAT) and one focused on understanding the future of biomanufacturing.

The BioPAT Applied: Sensors for Bioprocessing working group was established with a kick-off meeting in January 2008. With a focus on sensor solutions that will help make real-time product control and release a reality for the future of biomanufacturing, this group discusses everything from sensors for disposable and microscale reactors to calibration challenges to online monitoring of waste streams. Presentations included those from Yossi Shabtai, PhD (Metabolix), Seth Rogers, PhD (Bioprocessors), David Pollard, PhD (Merck), Robert Mattes, PhD (Foss NIR), Maureen Lanan, PhD (Biogen), and Dan Klevisha, PhD (Polychromix).

As part of the CBI-wide Future Scenario Initiative, CBI held a workshop at MIT in March 2008 titled "Future Visions for Biomanufacturing." Presenters included Professor Charles Cooney (MIT), Ingrid Maes (Siemens), Stephen V. Hammond, PhD (Pfizer), and David Radspinner, PhD (Thermo Fisher Scientific). Keith Webber, PhD (FDA), gave summary comments.

CBI also co-organized a special session at IFPAC08 in January, "A 10-Year Vision for Biotechnology," with the FDA, the National Institutes of Health (NIH), and the National Institute of Standards and Technology. The session detailed challenges facing the industry over the next 10 years and outlined approaches to solving critical scientific and technical hurdles. Based on the enthusiasm for these events, CBI is launching a "Future Scenario Roadmapping: Biomanufacturing in 2020" working group this August. The group will engage in a structured collaborative process that will help anticipate and influence the world of biomanufacturing in the year 2020.

In addition, CBI's Biomanufacturing group and the MIT Center for Integrated Photonic Systems (CIPS) cohosted a biophotonics session at the CIPS annual conference in May. This session explored the application of optical systems for monitoring and improving our understanding of biological processes, in addition to covering topics such as spectroscopy and imaging and how these techniques are being used as analytical tools for biotechnology and pharmaceutical applications.

Through a series of interviews and group discussions with key faculty and consortium members, CBI's Biomanufacturing group is also planning projects focused on:

- *The Economics of Biomanufacturing.* This project will develop process-based cost models that will yield a better understanding of the financial impact of introducing new technologies (i.e., continuous manufacturing, disposables) in biomanufacturing.

- *Microsystems for Bioprocessing.* This project will develop a scaled-down microsystem to model the operations of a full bioprocessing unit for the development of process analytical technologies and the requisite control systems.
- *Global Biomanufacturing and US Competitiveness.* This series of projects will investigate the impact of the changing landscape of offshore manufacturing of biologics on firm competitiveness and labor economy, with a particular emphasis on new business and technology drivers of change.

Stratified Medicine Research Group

Led by professors Ernst Berndt and Mark Trusheim, this research group seeks to develop a semiquantitative decision framework for used by corporate decision makers in biotechnology, pharmaceutical, and diagnostics companies, as well as by policymakers. Discussions are under way to identify specific compounds within corporate portfolios that can be analyzed as a first step in populating the decision framework. The first project within this framework, launched in spring 2008, involves developing a case study focused on an early-stage compound within the research and development (R&D) pipeline of one of CBI's corporate members.

In March, the Stratified Medicine team expanded to six investigators with the support of a grant from the Merck Research Foundation. Team members include graduate students Brian Newkirk and Sameer Sabir (both from the Harvard/MIT Biomedical Enterprise Program), David Chan, MD (a physician from Brigham and Women's Hospital and future MIT Economics Department PhD candidate), and Jeong Choi (an MIT student studying mathematics and management).

On April 13, Professor Mark Trusheim was an invited speaker at the American Association for Cancer Research's annual meeting in San Diego, where he presented "Stratified Medicine: Strategic and Economic Implications of Combining Drugs and Clinical Biomarkers." The special panel, Targeted Therapy for Personalized Cancer Care: Matching the Economics to Evolving Science, also included Kapil Dhingra (Hoffmann La-Roche Inc.), and Steve Shak (Genomic Health).

Events and Education

Planning is currently under way for the 3rd Annual Stakeholders' Summit, scheduled for October at the Royal Sonesta Hotel in Cambridge, MA. This year's program will provide selected members of the CBI community with the opportunity to participate in focused, cross-disciplinary working sessions on critical issues in biomedical innovation and network with other thought leaders from academia, industry, and government. The program will also feature a special networking reception that showcases the vast array of research and educational activities across MIT focused on global health.

Alan Krensky, MD (deputy director, National Institutes of Health), and Julie Gerberding, MD, MPH (director, Centers for Disease Control and Prevention), at CBI's April 2 panel discussion, "The Role of Government in Health Innovation."

On April 2, 2008, CBI hosted a daylong event featuring Julie Gerberding, MD, MPH (director of the Centers for Disease Control and Prevention), who delivered a keynote address to the MIT community and took part in a panel discussion, "The Role of Government in Health Innovation," moderated by professor Charles Cooney (MIT). Additional panelists included Randall Lutter (FDA), Mark McClellan (Brookings Institution), Alan Krensky (NIH), Institute Professor Robert Langer (MIT), professor Edward Roberts (MIT); Institute Professor and Nobel laureate Phillip Sharp (MIT), Burt Adelman (formerly of Biogen Idec), and associate professor Fiona Murray (MIT Sloan School of Management).

Phillip Sharp, PhD (Institute Professor and Nobel Laureate), and Edward Roberts, PhD (David Sarnoff professor of management of technology and founder and chair of the MIT Entrepreneurship Center), at CBI's April 2 panel discussion, "The Role of Government in Health Innovation."

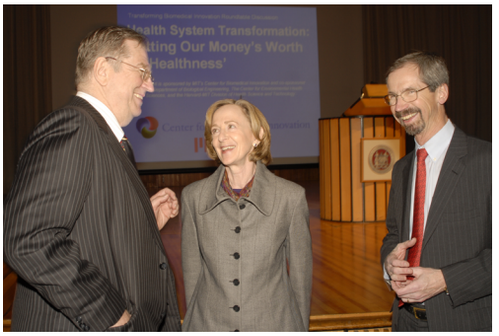
On October 30, 2007, CBI cosponsored a lecture ("In-House vs. In-Licensing: Is There a Need to Balance In-House R&D with In-Licensing and Partnering?") by Martin Mackay, president of global R&D at Pfizer Inc., with the MIT Sloan Biomedical Club and the Sloan Fellow Program. The program was moderated by associate professor Fiona Murray.

CBI continues to offer 7.549J Case Studies and Strategies in Drug Discovery and Development to graduate students in the Harvard-MIT Health Sciences and Technology program. This unique course employs case studies of actual pharmaceuticals to teach students about the complex stages behind drug discovery and development. Leading students from target identification of lead compounds to the submission of preclinical and clinical data to regulatory authorities, a major goal of this course is to engage students in the analysis of cases and for them to determine how processes might be influenced by new and future technologies. The visiting senior-level scientists who collaborated with CBI this year included Simon Williams and Ajay Ahuja (Tepha Medical Devices), Jotham Coe (Pfizer), Ken Iwata (OSI Pharmaceuticals), and Thomas R. MacGregor (Boehringer-Ingelheim). CBI plans to offer the course again in the coming academic year.

Edward Roberts, PhD (David Sarnoff professor of management of technology and founder and chair of the MIT Entrepreneurship Center), Fiona Murray, PhD (associate professor of management), Randall Lutter, PhD (deputy commissioner for policy, Food and Drug Administration), and Robert Langer, ScD (Institute Professor), at CBI's April 2 panel discussion, "The Role of Government in Health Innovation."

Organizational Changes

MIT's Program on the Pharmaceutical Industry (POPI) merged with CBI this year. Designated a Sloan Industry Center, POPI was founded in 1991 with a major grant from the Alfred P. Sloan Foundation and conducted research into the factors that drive, constrain, and enhance the performance and competitiveness of the industry. Established as a multidisciplinary



Anthony Sinskey, ScD (CBI faculty director), MIT President Susan Hockfield, PhD, and Charles Cooney, PhD (Robert T. Haslam professor of chemical engineering), at Dr. Gerberding's keynote address on April 2.

research and educational program, POPI involved faculty from the School of Engineering; the School of Science; the School of Humanities, Arts, and Social Sciences; and the Sloan School of Management.

In recognition of how seasoned industry executives can provide strategic programmatic guidance as well as access to a vast network of thought leaders, CBI launched the Distinguished Fellows Program. Peter Farina, PhD, was appointed the first distinguished fellow this past year, following his retirement from a 28-year career at Boehringer-Ingelheim Pharmaceuticals Inc., where he most recently was senior vice president for development in North America. This past spring, Burt Adelman and Wayne Rosenkranz were also appointed distinguished fellows. Dr. Adelman served in various capacities at Biogen Idec starting in 1991 and retired in 2006 as executive vice president of R&D. Dr. Rosenkranz is a former director of external relations for the Personalized Healthcare Team and Evidence-based Medicine at AstraZeneca and is now president and a member of the board of directors of the Personalized Medicine Coalition.

Gigi Hirsch, MD, was named executive director after serving as senior advisor for business development and strategic marketing and interim executive director. Dr. Hirsch brings to CBI a diversity of experiences in the provider market, biopharmaceuticals, academia, and entrepreneurship. She practiced emergency medicine at Brigham and Women's Hospital in Boston and served on the faculty of Harvard Medical School and the Brown University School of Medicine. She left clinical practice after receiving a grant from Beth Israel Hospital to become the founder and executive director of MD IntelliNet (MDI), an entrepreneurial venture focused on physician human/intellectual capital management in the changing health care industry. While consulting to Millennium Pharmaceuticals, she was recruited to join the company in Strategic Marketing, where she remained until initially joining CBI in 2006.

Stacy Springs, PhD, was appointed Biomanufacturing Research Program director in May 2008, replacing Elizabeth Bruce, who began her new position as director of industry partnerships at the MIT Computer Science and Artificial Intelligence Laboratory. Before joining CBI, Dr. Springs was a senior research scientist and academic collaborations manager at TetraLogic Pharmaceuticals. Dr. Springs was on the research staff at Princeton University and received her PhD in chemistry from the University of Texas at Austin.

Gigi Hirsch
Executive Director

More information about the Center for Biomedical Innovation can be found at http://web.mit.edu/cbi/.