

The Blanche and Irwin Lerner Center of Pharmaceutical Management Issues



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Director's Message

It gives me a great pleasure to present to you the sixth issue of the Lerner Center's News Letter. This covers the activities of the center during the past year and the highlights of the presentations at the eighth annual Healthcare Symposium held on April 30, 2013. The theme of the symposium was Regulations and Reimbursements: Trends and Issues Facing the Bio-Pharmaceutical Industry. The Keynote Speaker was Mr. John J. Castellani, President and CEO of the Pharmaceutical Research and Manufacturers of America (PhRMA). Mr. Seyed Mortazavi, President, IMS Health US Operations made presentation talking about Global & US Pharmaceutical Markets Trends. Dr. Rachel E. Sherman, MD, M.P.H, Director, Office of Medical Policy, at the FDA, and Mr. Joseph Herring, Chairman and CEO, Covance, Inc made presentations on the Transformational Initiatives by the FDA, and Transformation of Drug Development process respectively. The presentations were moderated by Mr. Cole Werble, Senior Editor, RPM Report. Please visit <http://www.business.rutgers.edu/lerner>, click on 2013 Annual Healthcare Symposium to watch the videos of the presentations.

The Center serves as an educational conduit between the pharmaceutical industry, the University and various other organizations. By providing industry data, organizational support and hosting research colloquia and seminars the Center facilitates pharmaceutical management research within Rutgers Business School. The Center offers the following resources to the University and various organizations:

- Short-term executive training programs on issues facing the pharmaceutical, biotech and healthcare industries.
- On-site customized executive training programs for bio-pharmaceutical companies.
- Facilitate faculty and Ph.D students' pharmaceutical management research by providing relevant data and organizational support. The center maintains IMS data bases – NSP, NPA, IPS and NDTI – covering the monthly data for 2000 through 2010.

We would like to thank the following for sponsoring the symposium: Blanche and Irwin Lerner, Robert Campbell, Celgene, Janssen Pharmaceuticals and Ranbaxy Pharmaceuticals. We welcome your comments and feedback on the Center's activities and programs.

Mahmud Hassan, Ph.D.
Director

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Keynote Address*by Jacob Schnipper and Grace Dewi*

John J. Castellani, President & CEO of PhRMA, gave the keynote speech.

Mr. Castellani discussed unique challenges that the pharmaceutical industry faces today. He opened his remarks by comparing the modern R&D process to the process employed by Thomas Edison. He noted that Edison's observation from over 100 years ago still rings true today- "I have not failed. I have just found 10,000 ways that won't work." With only about 1 to 5 approvals for every 10,000 chemical entities tested in research, the modern innovation process is still a difficult and challenging one.

Not only does pharmaceutical industry have to cope with the increase in R&D expenditures and inherent uncertainties in drug research, the industry has to also operate in strictly regulated market. Mr. Castellani stressed that the industry requires strong and encouraging federal and state policies. He highlighted four conditions that have yet to be met to improve the innovativeness in the pharmaceutical industry. He emphasized the importance of an environment that inspires and rewards innovation,

an ecosystem that is conducive for innovation, modernized and transparent regulations, and, finally, an environment that properly value medicine.

Innovative medicine is expected to represent 8% of Medicare and Medicaid costs, but it offers the opportunity to return value in the form of better health outcomes and savings in the form of potential future healthcare costs. PhRMA companies are dedicated to innovation. They have invested nearly half a trillion dollars in R&D since the year 2000. However, the return on investment is far from certain. As a result of this, venture capital has reduced biopharmaceutical investments by nearly 24%.

As a way to promote innovation and encourage the expediency of the process, Mr. Castellani discussed the precautionary principle as it relates to the biopharmaceutical industry. He elaborated that, in areas in which the current is solution is unsatisfactory, the medical need is great, and a potential drug indicates that it can be quite beneficial to many patients, the burden of proof is to show that the drug is unsafe. Not doing so prevents potential lives being saved. Mr. Castellani closed by saying that progress is not an option but a necessity and encouraged the pharmaceutical executives in the audience to push for policies necessary to ensure that innovation takes place so as to save lives and curb future healthcare costs.

Guest Speaker Address*by David Waintraub*

Seyed Mortazavi, the President of IMS Health US Operations, spoke about pharmaceutical trends at the Rutgers Healthcare Symposium. The focus of the speech was where the next leg of growth was going to come from in the healthcare sector. He honed in on the growth by “pharmerging” markets, which is the growth from India and China. There is supposed to be 30% growth in spending in those markets, which is double the 2006 growth. These markets are more challenging to the healthcare sector to penetrate due to their laws and the rise of generics.

According to IMS, China will be the second largest spender in healthcare behind the U.S., Mr. Mortazavi noted that China has a deep and vast population where most cannot afford medications. This leads to many new medications out of reach for most of the Chinese with only 1% or 13.3M with access. This leaves an enormous growth opportunity for the healthcare sector if they can enable efficient access to that segment as it grows.

Another aspect that Mr. Mortazavi touched on was the impact of generics on the healthcare space. It appears that the blockbuster age is coming to an end with most of the big blockbusters going generic recently like Plavix and Lipitor. This has led to a boon in the generic space and has brought Teva, a generics company, into the top ten biggest players in the pharmaceutical space. This also has led to an evolution with the pharmaceutical companies as they try to invest in specialty markets with unmet medical need as their blockbusters enter Loss of Exclusivity (LOE). Instead of having one blockbuster drug the companies are launching multiple drugs in shorter time periods that target unmet need.

Mr. Mortazavi brought to light the main growth drivers of the healthcare space. The two areas noted were in the “pharmerging” markets of India and China and also in the specialty markets. Another key aspect was recognizing the strength that generics and generic companies maintain as all of the blockbusters go off patent.

Pharmaceutical Leadership Panel*by Sarah Kruse*

The panel at this year's healthcare symposium highlighted the viewpoints of two unique participants in the biopharmaceutical industry, the Food and Drug Administration (FDA) and a Contract Research Organization (CRO). Moderator Cole Werble, Senior Editor of the RPM Report facilitated the presentations and conversations with Rachel Sherman, MD, PhD, and Associate Director for Medical Policy at the Center for Drug Evaluation and Research within the FDA and Joseph Herring, the Chairman and CEO of Covance, Inc. Both panelist shared their organization's most exciting new initiatives and how they address specific trends within the industry.

Mr. Werble and Dr. Sherman both highlighted how the FDA can act as an activist within the industry. Ms. Sherman went on

to explain the types of programs the FDA has implemented to help them take an active role in getting effective products to market quickly and efficiently. The pathway for biosimilar approvals, Clinical Trials Transformation Initiative, Sentinel project, Breakthrough Therapies approval process, and Limited Population Antibacterial Drug approval mechanisms were discussed by Dr. Sherman. Each initiative is a specific example of how the FDA is attempting to adapt to industry trends and increase the efficiency of their approval process to better meet society's needs.

Mr. Herring focused his discussion on how CROs have been, and remain to be uniquely positioned to respond to industry trends. The rapid growth of the sector and the correlation of CRO growth to biotech growth was highlighted. He then continued by describing the results of a series of strategic partnerships that Covance has participated in with biopharmaceutical industry giants. Each differs based on the need of the partnering organization and Covance focuses on providing a specialized product for their client. Mr. Herring also discussed some of the exciting new services that Covance is able to provide to the industry. Their Xcellerate program allows them to mine their extensive clinical trial database to identify the highest achieving investigators and clinical study sites for their clients. Molecule Development Solutions and their Biomarker Center for Excellence were also discussed.

Both speakers stressed how their organizations, while different, are working towards the same goal as manufacturers. Efficient and safe delivery of quality medications to the public requires the synergy of all parties involved. Mr. Herring inspired the crowd with poignant personal examples of how the pharmaceutical industry has saved lives. His closing served as a fitting end to an inspiring day of cohesion between both young and experienced industry minds from a variety of biopharmaceutical industry organizations.

View full presentation at <http://www.business.rutgers.edu/lerner/healthcare-symposium>

Robert Campbell Seminar Series**“The Revolution that never arrived: Clinical and genetic paradigms in bio-medical discovery and the R&D Productivity Paradox”**

Presented by Michelle Gittelman, Associate Professor, Department of Management and Global Business
September 13, 2012

This presentation described the epistemic divide between major medical paradigms, and the ensuing shifts in the institutional landscape supporting biomedical research in the United States.

“The Value of Consumer Choice and the Decline in HMO Enrollments”

Presented by Gerard J. Wedig, Associate Professor, Business Administration, University of Rochester
October 16, 2012

Health Insurance contracts may restrict consumers' choice of medical provider (e.g., hospital) in order to minimize moral hazard inefficiencies. In his presentation, Professor Wedig explained the economic value of this strategy by comparing the estimated “option value” that consumers assign to provider choice to the negotiated discounts that insurers can achieve by negotiating with a restricted set of providers.

“Organizing for Complex Innovation in Bio-Pharmaceuticals”

Presented by Deborah Dougherty, Professor and Vice Chair, Management and Global Business Dept., CEO and Academic Director, NEID (Network for Innovation Expertise Deployment)
November 13, 2012

Presenter created a new framework for enhancing the management and organization of drug discovery. The framework synthesizes insights from five studies based on more than 100 in-depth interviews with discovery scientists, managers, and industry experts.

Translational R&D and Personalized Medicine: What does this mean for the pharmaceutical Industry?

Presented by Christopher P. Miller Ph.D. Bristol-Myers Squibb, Group Director of applied genomics, Head of Genomic and Proteomic Sciences
February 13, 2013

In his presentation, Dr. Miller explained the approaches applied in different disease areas and the roles of genomics and biomarker technologies.

“Is Drinking and Driving a Rational Decision?”

Presented by Frank A. Sloan, Ph.D. Duke University, J Alexander McMahon Professor of Health Policy and Management and Professor of Economics
March 27, 2013

A puzzle for economics is why people engage in behaviors that are harmful to their health. Many economists have struck to the notion that even harmful behaviors can reflect rational forward- looking decision-making. Dr. Sloan's presentation showed the empirical evidence consistent with rational forward- looking agents engaging in drinking and driving.

THE BIOPHARMACEUTICAL INDUSTRY REPORT*An Annual Research Initiative of the Lerner Center*

In conjunction with the Rutgers Business School Alumni Association, the Blanche and Irwin Lerner Center for the Study of Pharmaceutical Management Issues is undertaking a research initiative to explore challenges facing the biopharmaceutical and healthcare industries. With pressing topics sourced from leading executives and thought leaders in the biopharmaceutical and healthcare space, our graduate business student team will leverage the research capabilities of the Rutgers Business School with an extensive network of industry contacts to deliver insight unavailable through conventional resources. We aim to publish select findings in peer-reviewed journals initially, followed by a detailed report for distribution through the Lerner Center.

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Research Projects**Risk Evaluation and Mitigation Strategy (REMS):
Implications on Key Stakeholders and a Proactive Approach**

The Risk Evaluation and Mitigation Strategy (REMS) component of the FDA Amendment Act (FDAAA) of 2007 has a number of profound implications on the biopharmaceutical industry. In particular, it will have a significant effect on the commercialization process of drugs and on the way healthcare providers and patients will attain access to these drugs. To date, there are 99 drugs with approved REMS programs, 32 of which fall into 6 different shared system programs. An additional 133 drugs originally required REMS programs but have been released from these requirements. With specialty drugs dominating the new molecular entity (NME) market, it is estimated that 75% of these newly approved drugs will be required to have a REMS. The objective of this report will be to categorize and define the effects REMS will have on the biopharmaceutical industry, healthcare providers, payers, and patients and to identify a strategy that would integrate these stakeholders and allow for implementation of a streamlined REMS process going forward.

**The Business of R&D:
Development Outsourcing and Process Improvements in Pharmaceutical Research and Development**

The global biopharmaceutical industry is facing unprecedented pressure to produce innovative new products. Return on investment in R&D estimates for the industry are as low as negative 7%. Overcoming current challenges and taking advantage of scientific opportunities require that companies implement sound business practices within their R&D departments. This report will highlight best practices and lessons learned in a variety of business trends in biopharmaceutical R&D. Outsourcing innovation alternatives discussed will include how to avoid mismanaging a relationship with a CRO or academic institution, along with harnessing open-source innovation. Process improvements discussed include lean management, portfolio management and concentrated therapeutic area focus. The significant potential for increased productivity in each of these alternatives and others will be evaluated.

**Comparative Effectiveness Research:
Current Applications, Future Outlook and Impact on the Pharmaceutical Industry**

Healthcare spending in the U.S. currently makes up roughly 18% of GDP and growing. With increased spending not consistently correlated with better health outcomes, methods of measuring and demonstrating value continues to be a topic of significant importance in the U.S. healthcare sector. Comparative effectiveness research (CER) has been increasingly used over the past decade to improve the decision-making ability of providers and payers by utilizing evidence-based information to assist in the determination of the relative effectiveness and value of different medical technologies. Since it has been linked to healthcare cost savings, the utilization of CER outside of Europe is increasing. The establishment of the Patient-Centered Outcomes Research Institute (PCORI) demonstrates how CER is gaining relevance and acceptance in the U.S. However, CER remains a highly controversial methodology, and thus, our report will examine its strengths and weaknesses as well as potential opportunities for industry leaders. We will also explore whether the potential expansion of CER in the U.S. will extend to reimbursement decisions in the future, and how such a change will impact the biopharmaceutical industry.

Executive Training in Pharmaceutical Management Program

The Lerner Center is committed to providing executive education, industry access and networking opportunities to professionals at every level. Three times a year, The Center conducts a Two-Day Executive Training Program in Pharmaceutical Management at Rutgers Business School's Newark campus. Approximately 90 professionals in the biopharmaceutical and healthcare industries attended our training programs during this academic year.

Participating companies:

MonoSolRx

Ranbaxy

Daiichi Sankyo, Inc.

BIOTECanada

PhRMA

Ohm Labs

Sunovion Pharmaceuticals, Inc.

L & M Healthcare Communications

Pfizer, Inc.

Celgene Corporation

Health4Brands Catapult

LEO Pharma, Inc.

Next Session: OCTOBER 17-18, 2013

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Customized On-site Executive Training Program

The Center also offers Customized Executive Training Programs tailored to fit your company's needs.

This year, the Center is invited to conduct on-site customized programs for Novo Nordisk and Pharmaceutical Research and Manufacturers of America (PhRMA) at their respective corporate locations.

Partnering with Rutgers Business School to develop a customized program will equip your team with training focused on your company's specific challenges and situations. Your team will benefit from:

- World-class faculty and top industry leaders with innovative research and extensive experience in educating business leaders
- Effective job performance training to retain employees, promote career advancement opportunities and attract new talent
- An exclusive curriculum incorporating relevant industry-specific solutions
- Necessary business skills to apply practical methods on the job
- On-site sessions scheduled at the convenience of your staff
- An ideal setting for group learning and networking
- A corporate competitive advantage

Together, we will assess your needs and design a specialized program. By integrating our knowledge, experience, and expertise with yours, we aim to achieve effective outcomes while broadening your perspective and your network.

To discuss a customized training program for your company or inquire about our executive education programs, please contact the Lerner Center at (973) 353-1016 or via e-mail at lernercenter@business.rutgers.edu.



2013 SPONSORSHIP BY:

FRIDAY, NOVEMBER 15, 2013

**2ND ANNUAL RUTGERS BUSINESS SCHOOL
& PHARMA STUDENT DAY
BIOPHARMACEUTICAL CASE COMPETITION**

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of Pharmaceutical Management Issues**

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