

## 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 fifth 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 seventh annual Healthcare Symposium held on May 4, 2012. The theme of the symposium was Regulations and Reimbursements: The Future of the Bio-Pharma Industry. The Keynote Speaker was The Honorable James C. Greenwood, President and CEO of the Biotechnology Association (BIO). Ezekiel Emanuel, M.D., Ph.D, Vice Provost at the University of Pennsylvania, and Susan Dentzer, Editor-in-Chief, Health Affairs made presentations on 'Healthcare Reform and the Future of American Medicine', and 'The Role of Bio-Pharma in the Healthcare Delivery Systems of the Future', respectively. The symposium also contained a panel discussion with senior executives from Celgene, Daiichi Sankyo, Boehringer-Ingelheim, and PDR Networks.

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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 individuals and companies for sponsoring the annual healthcare symposium: Blanche and Irwin Lerner, Robert Campbell, Celgene, Daiichi Sankyo, and InVentiv Health.

We welcome your comments and feedback on the Center's activities and programs.

Mahmud Hassan, Ph.D

**Director**



Watch the full presentation at <http://business.rutgers.edu/lerner> then click on *Healthcare Symposium 2012*

The honorable James C. Greenwood began his talk by stating bluntly that the limiting factor will not be the scientists or the investors, but rather the development of policies surrounding such issues as reimbursement or intellectual property. Greenwood reminisced about screening for his recent position, particularly how to answer the question that was bound to come up: “Do you have a passion for biotechnology?”. His thoughts that emerged late in the night before his interview point to the role of biotechnology as a tool in Man’s ability to “outrun Darwinian evolution”, to decide one’s own fate through modification of conditions that would otherwise cruelly limit his potential.

Greenwood roused the audience with the importance of the United States as the leader in biotechnology and how despite competition from centrally

### Unleashing the Promise of Biotechnology: Advancing American Innovation to Cure Disease and Save Lives

James C. Greenwood, President and CEO, Biotechnology Organization (BIO)

planned initiatives i.e. China, the United States has a stake in keeping its edge. He outlined a series of challenges, but focused primarily on the mounting financial pressures related to rising Medicare costs in light of the aging Baby Boomer generation. The increased spending in chronic disease was presented as astronomical, threatening to consume the available budget in an unsustainable manner.

*“the enemy is not medical costs or reimbursement, but rather the chronic conditions.”*

According to Greenwood, the enemy is not medical costs or reimbursement, but rather the chronic conditions. He defended medical costs, citing the deleterious effects on innovation any ratcheting down of medical costs or reimbursement would cause. The Europeans appear to have solved the access problems, through quality and innovation lag. In contrast, Greenwood presents the United States as leading in quality and innovation, though lagging in access. He noted the particular value in prescription drugs in reducing healthcare costs, though public perception of the

cost-saving value of pharmaceuticals is lacking.

Unfortunately, the stringency and uneven regulation of the FDA has made the pharmaceutical approval landscape difficult, pushing venture capital to health-services related applications. Greenwood took this issue and began focusing on how to improve the regulatory environment. Specifically fighting for the Prescription Drug User Fee Act V (PDUFA V), which can play a critical role in making more life-saving medicines available to patients in a timely manner, strengthening the scientific base of the FDA and providing a steady, reliable stream of resources for Agency scientists. More simply put, would allow scientists a more direct line of contact with the FDA to speed along the drug development process.

In his final remarks, Greenwood evoked the personal value of his own parents in his dislike of the European system of healthcare rationing, i.e. the discrimination of elderly patients from expensive treatments. Rather, he sees the value in the evolving U.S. healthcare system and its uniqueness, concluding: “The vision is that we all can live long healthy dignified lives and die quietly in our sleep”.

### **The Role of Bio-Pharma in Health Care Delivery Systems of the Future**

**Susan Dentzer, Editor-in-chief Health Affairs**

There are major changes in the healthcare ecosystem as Affordable Care Act comes into place in the near future. Healthcare reform will provide coverage to 32 million people, out which 16 million will be Medicaid patients and 16 million will be receiving private insurance through state-based exchanges. There will also be insurance market reforms to broaden and stabilize private coverage. Delivery/payment reforms will slow growth of healthcare spending. In addition, there will be health promotion and prevention initiatives, along with workforce development.

The healthcare reform has a triple focus: better health, better healthcare and lower cost. What can Bio-Pharma do to assist with this goal? There are several new ways to empower the patients, such as providing one-on-one

education and partnering with other companies to create a support system. Specialty pharmas are known to increase patient adherence of medications. These pharmas currently account for 25% of spending and they are estimated to increase to 40% by 2030. Research collaborations are also on a rise, such as Astra Zeneca and Wellpoint subsidiary Health Core participating in a real-world evidence collaboration.

Some of the challenges that Bio-pharma is currently facing include increasing efficiency and productivity of R&D pipeline and demonstrating value to payers, especially for high-cost cancer drugs that extend life of patients for a few months. In order to decrease the total cost of drugs for patients, Accountable Care Organizations (ACOs) may work directly with pharmaceutical companies. There

are 27 ACOs that were rolled out in the first wave and 32 pioneer and transition programs will come into place soon. All in all, Bio-pharma has several opportunities with the new reform: creating more patient-centered health system, supporting medication adherence and high-cost specialty drugs, and participating in research collaborations and risk-sharing agreements.



Watch the full presentation at <http://business.rutgers.edu/lerner> then click on Healthcare Symposium 2012



Dr. Emanuel started off by giving a quick over view of the current healthcare system in the USA. He described the uneven distribution of the healthcare costs across U.S. population, spending 63 percent of the costs on 10 percent population, and while 50 percent of the population spending only 3 percent of the costs. The issues of access, cost and quality are all at unacceptable levels at American standard. The Affordable Care Act (ACA) of 2010 is expected to reform the healthcare system in all those three fronts.

The reform act will bring 32 million Americans under the coverage of health insurance. Knowing that prevention is the key in saving costs, the bulk of the costs are due to chronic illness and the extensive use of emergency rooms and hospitals. For achieving a significant savings, the preventive care needs to be extended to tertiary care as well for the chronically sick people. He described the concepts of Medical Homes in the form of examples of Metro Seattle based Group Health Cooperatives.

These Medical Homes consist of teams of health practitioners – physicians, nurses, and pharmacists – taking care of a panel of members, taking care of their healthcare needs, including follow up and outreach for abnormal test results, chronic disease management, collaborative care planning across specialties, health maintenance reminders, etc. Through these practices, the Group Health Cooperative achieved significant results over a period of 21 months lowering inpatient admissions by 6 percent, and lowering emergency room visits by 29 percent.

He also cited examples of Milstein’s Medical Home Runs - four primary healthcare practices across the United States. Patients in these organizations consume 15-20 percent per year less in total healthcare spending. These practices manage disease for their patients in chronic conditions – diabetes, hypertension, end stage renal disease and other, in addition to regular preventive care, home healthcare, wellness program, hospice service, podiatry and other. These practices achieved 24 percent less hospitalization, 38 percent shorter hospital length of stay, and 18 percent less healthcare costs for their members than the national averages for those metrics.

Dr. Emanuel described the impact of Accountable Care Organizations (ACO), and Patient-Centered Outcome Research Institute (PCORI) on the innovation in practice and reimbursements lowering costs, increasing quality, increasing compliance with medications, and improving comparative effectiveness of medical interventions. He explained the impact of Electronic Medical Records on innovation as well. Simplification in administrative practices will also save healthcare spending - \$11 billion alone for using electronic fund transfer instead of paper based transactions.

### Healthcare Reform and the Future of American Medicine

Ezekiel J. Emanuel, M.D., Ph. D



### Pharmaceutical Leadership Panel

The Leadership Panel moderated by Cole Werble, Senior Editor, RPM Report. Members of the panel were: Joseph Pieroni, former CEO of Daiichi Sankyo, Barbara Senich, Senior Vice President, Marketing & Products, PDR Network, Andrew Zembrak, Executive Director, Government Affairs & Public Policy, Boehringer-Ingelheim, and The Honorable Richard Bagger, Senior Vice President, Corporate Affairs & Strategic Market Access, Celgene Corporation.

Cole Werble laid out the issues at stake for the biopharmaceutical industry. He began by describing the year ahead for the industry involving regulation and reimbursement. The overhauls of Prescription Drug User Fees Act (PDUFA) V, safety features of newly approved drugs, evidence based reimbursements, sunshine act for drug promotion, rebates and

studies with the standard of care. The changing regulatory and economic environment also adds another challenge with economic benefits playing a bigger role.

Barbara Senich elaborated on future marketing challenges; communication, physician education, and patient education. The previous thought in the industry was that more promotion always led to more sales with no diminishing returns, which led to an explosion of representatives. Today, access to physicians has been restricted due to Managed Care and the Sunshine Act making companies responsible for knowing exactly what representatives are saying and where every cent of promotional dollars is spent. While the sales force landscape is changing, they will always play a crucial role in promotion. Electronic Health Records (HER) aim to improve quality and



discounts in Medicare Part D program, and the Supreme Court's ruling on Affordable Care Act (ACA) of 2010 will dominate the legislative discussion in DC in the coming months and year.

Joseph Pieroni described two major regulatory hurdles that will be faced in the future. The first hurdle is the FDA's need for larger patient populations studied over longer periods of time with the previously used surrogate endpoint model pushed aside. This trend evolved from a series of adverse effects in drugs after marketing harming patient populations. The second obstacle is the evolving standard of care. As the standard of care evolves, it is harder for companies to bring innovations to market because they must conduct head to head

meaningful use of records. Right now, electronic health records are used only by the doctor's office, in the future, they will provide a safe portal for two way communication between patients and physicians.

Andrew Zembrak spoke about Medicaid changes and future expansion. First, the expansion will cover roughly 16 million more beneficiaries. This creates a lot of concern and challenges for states to handle the added members. Second, the IPAB, Independent Payment Advisory Board, will be responsible for making cuts to reduce healthcare spending. The controversy is that the 15 members of the IPAB are not elected and have power to make significant changes to spending the

healthcare industry. Third, reporting on quality measures are occurring and are becoming more and more important in utilization of spending.

The Honorable Richard Bagger touched upon how publicly funded healthcare programs will value and pay for innovation under a period of financial stress. The ultimate outcome, life expectancy, has increased by 10 years since 1950. Investments in innovative therapies to treat conditions such as HIV/AIDS and Cancer have great benefits to society well

beyond patient expiry. There are three core principles related to the value of life exceeding costs; first, objectives to improve life must be at the top of the line. Second, we need to think about systems, not just components. The final principle is to support and build upon models that work, such as Medicare Part D. Competition choice resulting in expanded access and higher satisfaction with lower costs is a model that should be protected and expanded upon.

## **Robert Campbell Pharmaceutical Seminar Series (October 2011 through March 2012)**

### **“Opportunity for Analytics in Pharmaceutical Sales and Marketing”**

**Presented by Daniel J. Feldman, Ph.D., Director, Market Research, Plavix, Avapro, Avalide, Bristol-Myers Squibb  
October 26, 2011**

In the age of “Doing More with Less,” should we manage with less analytic support? Many companies are currently struggling with this question. This presentation by Dr. Daniel Feldman – RBS faculty, pharma industry analytics leader, and psychologist – explores the pharmaceutical industry’s response to the latest economic crisis and “patent cliff.”

### **"Obvious and Non-Obvious Policy Influences on the Biopharma Industry"**

**Presented by Neal Masia, PhD, VP and Assistant Treasurer, Pfizer  
November 16, 2011**

Public policy influences the biopharmaceutical industry on many levels, some more obvious than others. Dr. Masia will discuss how the mixture of regulatory policy, Medicare payment rules, evolving tax regimes, publicly supported science research, financial system reform, and other factors combine to influence decisions, investments, and capital allocation within the industry.

### **“Show Me the Value: Market Access Challenges and Opportunities for the Pharmaceutical Industry”**

**Presented by Zeba M. Khan, PhD, Vice President, Global Pricing and Market Access,  
Celgene Corporation  
February 22, 2012**

This presentation will provide an overview of the evolving market access environment, highlighting the key challenges for the pharmaceutical industry and outlining how the industry needs to adapt to be successful

### **"The Contribution of Pharmaceutical Innovation to Longevity Growth: Micro and Macro Evidence”**

**Presented by Frank Lichtenberg, Ph.D., Courtney C. Brown Professor of Business, Columbia University  
March 28, 2012**

This seminar will present both micro (cross-sectional patient-level) and macro (longitudinal country-level) evidence about the contribution of pharmaceutical innovation to longevity growth

## Use of Social Media to Promote Pharmaceutical Products

By Mark Slomiany Ph. D, Brandon Saks M.B.A, and Mahmud Hassan Ph. D

With the declining role of traditional sales force in marketing pharmaceutical products, the industry is experimenting with the use of social media such as Facebook, Twitter, YouTube, and Blogs. A recent study conducted by researchers at the Lerner Center documented the evolution of the use of social media by the pharmaceutical industry in the absence of a formal FDA guideline on its use. With formal regulation lacking, FDA warning letters become de facto guidance for the use of social media. In April, 2009, FDA sent untitled letters to 14 major pharmaceutical manufacturers for sponsored link advertisements on internet search engines i.e Google. In November, 2009, FDA convened public hearing to discuss the challenges posed by

pharmaceutical promotion in providing 'fair balance' within the dynamic and expanding matrix of social media where there is potential loss of control over promotion content. The report documented the effective use of social media to maximize the value of their products but may relinquish a certain level of control over the information content in their domain. This rapidly evolving technological and legal framework has caused deep uncertainty regarding the scope and application of social media. Particularly troubling is that the accelerated interaction through the use of social media among patients, the public and the industry has vastly outpaced the reforms in regulatory framework. **For the full article, see In Vivo, December 2011, pp: 36-41.**

## State of the Long-Term Care Market: Perspective of the Pharmaceuticals

By Laryssa Wozniak M.B.A, Mahmud Hassan Ph. D, and Dale Benner M.B.A

A study of the long-term care market with respect to pharmaceutical products was conducted earlier in 2012 by the Lerner Center in response to a request by the IMS Health. A manuscript prepared based on the report of the in forthcoming in the **International Journal of Pharmaceutical and Healthcare Marketing**, it is scheduled to be published in September, 2012. Below is the executive summary of the study.

It is well documented in the literature that prescriptions drugs prevent hospitalization, and thus lower total healthcare costs. Prior to Medicare Part D, most elderly Americans had no prescription coverage, and received drug therapy only upon admission into hospitals for inpatient care under part A. In the nursing home, coverage of prescription drugs was achieved

through a combination of Medicare, Medicaid and private insurance plans. Now, with the availability of prescription drug coverage through Part D, stakeholder incentives and payment dynamics for prescription drugs have changed. The study highlights key trends and characteristics to help the stakeholders in their decision process under an evolving LTC market.

Long-term care clearly extends far beyond institutional setting, it is estimated that 87% of the population receiving long-term care resides at home or in a community setting versus 13% in an institutional environment. Due to the growth of Home Care Agencies (HCA) and Assisted Living Facilities (ALF), many elderly are moving away from traditional settings i.e. skilled

nursing facilities, and nursing homes to ALFs and other community settings.

Even though the elderly Americans take an average of 9 different medications to treat 6-10 active medical conditions, the study found that the effective market for pharmaceutical products in the long-term care space is limited in a couple of therapeutic classes, such as, Alzheimer's, and Anti-psychotics. The market is concentrated in the North East, South Atlantic, and Middle Atlantic part of the USA. With the increase in enrollments in Medicare Part D Plans, many elderly are moving into low cost Home Health Care from traditional institutional based care. Only future studies will reveal if these changes will lower the overall healthcare cost for the elderly Americans.

### To Arrive or not to Arrive: An Empirical Investigation into appointment No-Shows

Genevieve O'Connor, *RBS PhD Student*

To date, little is known about the behavioral mechanisms that drive an individual to arrive at the doctor's office for a scheduled appointment. Though literature on appointment arrivals in the healthcare domain is robust, this research is primarily limited to demographic and operational characteristics.

In turn, behavioral mechanisms that influence an individual's ability to arrive for an appointment are sparse, thereby creating a great gap in the literature. We seek to address this gap by drawing from normative theory to help predict how service failure, relationship strength and consumer convenience influence an individual's ability to arrive for an appointment.

### Executive Training Program in Pharmaceutical Management

Three times a year, the Center conducts a *Two Day Executive Training Program in Pharmaceutical Management*. In the 2011-2012 academic year, approximately 84 professionals in the biopharmaceutical and healthcare industries attended such training. Participating companies include: Eisai, Celgene, Daiichi Sankyo, IMS Health, Johnson & Johnson, Merck, Sanofi, Medco, Ohm Labs, Novo Nordisk, Actavis, Alliance Healthcare, KnowledgePoint360, PhRMA, and Ranbaxy. The next program is scheduled for October 25-26, 2012. If you are

interested in attending, please visit us at: [www.business.rutgers.edu/lerner](http://www.business.rutgers.edu/lerner)

The Center provided a Customized *Executive Training Program* for Novo Nordisk this year. The Center will provide a similar program for Pharmaceutical Research and Manufacturers of America (PhRMA) this fall in Washington DC. Please contact the Lerner Center at 973-353-1016, or send an email to: [lernercenter@business.rutgers.edu](mailto:lernercenter@business.rutgers.edu) to discuss a customized training program for your company.

