

The Blanche and Irwin Lerner Center of Pharmaceutical Management Issues



Director's Message

It gives me great pleasure to present to you the seventh issue of the Lerner Center's Newsletter. This covers the activities of the center during the past year and the highlights of the presentations at the 9th Annual Healthcare Symposium held on April 30, 2014. The theme of the symposium was Global Challenges to Pharmaceutical Reimbursements. The Keynote address by Honorable Jonathan Blum, Principal Deputy Administrator, Centers for Medicare & Medicaid Services (CMS), was on the Transformation of the Delivery of Healthcare Services. Dr. Gail Wilensky, Senior Fellow at the Project Hope made a presentation on the Affordable Care Act. The symposium contained a panel discussion on the issues of pharmaceutical reimbursements participated by Indranil Bagchi, Vice President, Pfizer, Anita Burrell, Associate Vice President, Sanofi, and Joseph DiCesare, Global Head, Strategic Pricing & Access, Novartis. The panel discussion was moderated

by Honorable Richard Bagger, Senior Vice President, Celgene. Please visit <http://www.business.rutgers.edu/lerner>, click on 2014 Annual Healthcare Symposium, click on videos to watch the videos of the presentations. You can also click on photo album to watch the highlights of the symposium in pictures.

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 education programs on issues facing the pharmaceutical industry.
- On-site customized executive training programs for biopharmaceutical companies.
- Facilitate faculty and PhD 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, Bayer Pharmaceuticals and Eisai for their generous support.

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

Mahmud Hassan, Ph.D.

Director

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The keynote speaker **Honorable Jonathan Blum**, Principal Deputy Administrator, Centers for Medicare & Medicaid Studies laid out the issues in transforming the Medicare Program as this is the driver of the entire healthcare delivery system in the USA. He described how Medicare has achieved

the lowest per capita growth in healthcare expenditure in decades, specially, since 2007. The per capita spending growth fell below the Medicare CPI growth rate after 2007. It has been achieved by lowering re-admissions rates and containing cost of Medicare Part A and Part D. Medicare 30-day for all conditions re-admissions rate fell sharply from about 19% to below 18%. The decrease in hospital re-admissions rate did not accompany any sharp increase in admissions to other forms of care i.e. outpatient, ER room etc. Number of higher Star Rated Medicare Advantage plans increased dramatically between 2009 and 2014, signifying better coordination of services without sacrificing quality of care. Participation in Accountable Care Organizations (ACOs) has also increased throughout the nation. Areas of weakness include wide variation in per episode cost of care across geographic areas. In 2011, the per capita expense on CT scan in Fort Myers, Florida was \$117, and in Honolulu, it was \$49, the national average was \$76.

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

Dr. Gail Wilensky, Senior Fellow, Project Hope presented on Affordable Care Act (ACA) which she termed as “Healthcare Reform 101”. She focused on long-term spending growth, problems with patient safety, and problems with clinical appropriateness and quality of care. Even though we saw a decline in the growth of Medicare spending growth, most recent data shows an increasing trend. During 2012 and 2013,



spending grew to 3-4 % a year, but during the last quarter of 2013, growth was at 5.6%, the highest in 10 years. It is, however, unclear how much of this is due to the economy and ACA. The variation of clinical appropriateness within a diagnosis is as wide as the variation of appropriateness between diagnoses. The focus of the ACA was on coverage and access with limited attention on delivery of care. The ACA created a few

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pilot projects through Accountable Care Organizations (ACOs), such as, Medical Homes, bundled payments, Patient Centered Outcome Research Institute (PCORI), but it is too soon to conclude that these all have been successful. The bundled payment encourages efficiency within the bundled services but offers no reward for quality or outcome. Physicians’ payment system desperately needs reform. Too much attention has been given to Sustainable Growth Rate (SGR), rather than finding ways to pay for quality and efficiency. Reform of liability insurance looking into ways to protect

physicians and institutions that practice conservative medicine is also needed. Arbitrary caps on pain and suffering will not improve quality of care. She suggested considering a ‘quid pro quo’ strategy by giving protection in liability risks to those who adopt Institute of Medicine (IOM) patient-safety guidelines and evidence-based clinical practice protocols. Given the current trend of enrollments for coverage, the Congressional Budget Office (CBO) estimates that 31 million people will remain uninsured in 2023. Many unknowns are ahead: impact of the newly insured on healthcare services utilizations, and on the use of prescriptions drugs.

The panel discussion moderated by Richard Bagger, Senior Vice President, Celgene, and participated by Indranil Bagchi, Vice President, Pfizer, Anita Burrell, Associate Vice President, Sanofi, and Joseph DiCesare, Global Head, Strategic Pricing & Access, Novartis, concentrated around the issues of pharmaceutical re-imbursements on a global perspective. In his opening remarks, Richard Bagger laid out the role of pharmaceutical drugs in containing the overall healthcare cost and in enhancing longevity and quality of lives. He described the challenges brought by the ACA in the USA and by technology assessment thresholds around the globe. He also described the role pharmaceutical innovation in enhancing societal value.



In his opening remarks, Indranil Bagchi described a perfect storm scenario, in one hand there is always a budget constraint in reimbursing expensive drugs by payers and on the other hand the pharmaceutical companies' need for margin in developing their product portfolio. Drug development is driven by unmet need, and currently many companies are developing specialty drugs and orphan drugs because of huge unmet need in this space. Many of these drugs are developed in collaboration with specialized research organizations and academia. In the early days 90% of the data on drug development were generated in house and now-a-days, because of external partners in drug development, only about 10% of the data is generated in house. These drugs are expensive due to high development cost. Anita Burrell described the value chain in drug development, and its role in value based pricing. In his opening remarks, Joseph DiCesare explained the evidence based value as analyzed by outcome data. The clinical data collected during the drug development is not enough to get market access as demanded by the payers and prescribers. These stakeholders require real world data of efficacy of the drug in a large patient base.

In response to a question on the challenges and opportunities of orphan drugs, Indranil Bagchi responded that these drugs are safe and efficacious but on the standard technological assessment measures, these drugs do not perform well for small population because those standards are set based on overall social welfare. The pharmaceutical companies need to find better ways to define value of their products. In response to a question on the role of value based pricing and reference pricing on competition and on investment in the R&D effort, the panel members discussed the underlying limitations of practical use of these concepts.

Robert Campbell Pharmaceutical Seminar Series**Differentiate or Die: Case Studies in Pharma Brands**

Presented by Alan Bash, US Brand Leader, Erbitux, Bristol-Myers Squibb

October 2, 2013

Alan Bash explored cases of pharmaceutical products' positioning strategies. He evaluated which brands had done the best job in executing their differentiation. He also reviewed a framework for how we should think about differentiation given the unique scientific context of the pharmaceutical business.

Health Economics, Outcomes Research and Coverage Decision Making: A Global Perspective

Presented by Kimberly McGuigan, PhD, MBA, Executive Director, Health Outcomes, Policy and Economics,

Rutgers University

November 6, 2013

Scientific evidence requirements, including clinical and humanistic outcomes, are designed based on extensive consultation across private, public and academic sector experts to ensure that tests of new treatments are sufficiently rigorous to demonstrate safety and efficacy in patients. However, to achieve market access success, understanding country-based and payer-based coverage decision-making processes is essential.

ACRES: A Global Systems Approach to Enhancing Clinical Trial Quality, Safety and Efficiency

Presented by Greg Koski PhD, MD, Co-founder and President, ACRES

February 19, 2014

The Alliance for Clinical Research Excellence and Safety (ACRES) is a non-profit, non-industry, non-governmental organization working collaboratively with global leaders and like-minded organizations from the entire clinical research/clinical trials enterprise to develop and implement comprehensive integrated systems-solutions to the many challenges facing the clinical research endeavor.

"What can we expect from the Physician Payment Sunshine Act?"

Presented by Sara Parker, PhD, Assistant Professor, Management & Global Business, Rutgers Business School

March 25, 2014

Sara Parker explored evidence on how financial relationships between pharmaceutical companies and physicians, and their disclosures, affect physicians prescribing so that we could understand what to expect when this law takes effect.

2014 Current Research**Drug Safety and the Cost of Monitoring: The Role of REMS**

In 2007, the FDA was authorized to impose post-approval requirements on drug companies through Risk Evaluation and Mitigation Strategies (REMS) to ensure drug safety. Despite the extensive dialogue between stakeholders and lawmakers in the development of the Food and Drug Administration Amendments Act (FDAAA), there remains uncertainty as to the exact impact of REMS on not only operational cost, but impact of REMS requirements on sales in the five years since its implementation. This report seeks to provide greater clarity on the impact of REMS requirements on drug sales.

Comparative Effectiveness Research and the Rise of Orphan Indications

Sarah Jeffers, Mark Slomiany PhD, Rema Bitar, Sarah Kruse, and Mahmud Hassan PhD.

Published in the *International Journal of Pharmaceutical and Healthcare Marketing*, June, 2014, Vol. 8, No. 2.



In this paper we develop a framework on which to model drug development at the intersection

of rare disease legislation and increasing comparative effectiveness research standards for orphan drugs. We review the American Recovery and Reinvestment Act of 2009 that allocated \$1.1 billion for comparative effectiveness research (CER). Complementing this act, 2010 saw the establishment of the Patient-Centered Outcomes Research Institute (PCORI), to manage the funding and conduct of CER. Designed more for large patient populations, PCORI's proposed funding criteria of cost effective research has drawn concern from the rare disease community that fears the erosion of progress made over the past 30 years in public policy and funding of therapies for rare diseases. We show how the CER can be utilized in orphan drug developments.

Pharmaceutical R&D Productivity: The Role of Alliances

Sarah Kruse, Mark Slomiany PhD, Rema Bitar, Sarah Jeffers, and Mahmud Hassan PhD.

Published in the *Journal of Commercial Biotechnology*, April, 2014, Vol. 20, No. 2.



In recent years, the major research intensive biopharmaceutical companies (big pharma) have

come face to face with a perfect storm of eroding profit margins from blockbuster expiration and generic competition coupled with growing R&D expenses and declining advances in truly novel therapeutics. With long-term research divisions shed in favor of short-term outsourcing options and with public good-will at historic lows, industry innovators have sought to reinvent the model of big pharma, its relationship in public-private partnerships, and the role of technology and technology policy in reform. In this paper, we highlight a number of the major alliances reshaping the industry and the role of government, research institutions, and other players in the public-private interface in these endeavors. In particular, this paper looks beyond traditional biotechnology partnerships and focuses instead on the developing consortia between biopharmaceutical companies and with clinical research organizations and academic institutions. We examined each alternative model of alliance, identified specific hurdles and potentials for increased productivity.

Two-Day 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 Education Program in Pharmaceutical Management at Rutgers Business School's Newark Campus.

Participating Companies:

MonoSolRx

Ranbaxy

Daiichi Sankyo, Inc.

BIOTECanada

PhRMA

Ohm Labs

Sunovion Pharmaceuticals, Inc.

L & M Healthcare Communications

Pfizer

Celgene Corporation

Health4Brands Catapult

LEO Pharma, Inc.

Next Session: October 2-3, 2014

REGISTER TODAY!

www.business.rutgers.edu/lerner/certificate-programs

2015 Dates:

April 16-17

July 16-17

October 8-9

Customized On-site Program

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

In recent years, the Center was 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

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



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FRIDAY, NOVEMBER 14, 2014

3rd ANNUAL RUTGERS BUSINESS SCHOOL BIOPHARMACEUTICAL CASE COMPETITION

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