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Rutgers Business School
Newark and New Brunswick

2015 Issue No.8 | www.business.rutgers.edu/lerner

The Blanche and Irwin Lerner Center for the Study of Pharmaceutical Management Issues

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Director's Message

It gives me a great pleasure to present to you the eighth 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 10th Annual Healthcare Symposium held on April 29, 2015. The theme of the symposium was *The Future of the Biopharmaceutical Industry: Challenges and Opportunities*. The Keynote address by Dieter Weinard, Global President for Pharmaceuticals, Bayer, was on global markets and macro trends in healthcare. Angeliki Cooney, Director of Strategic Planning at IMS Healthcare spoke about drug pricing.

The symposium contained a panel discussion on the issues of pharmaceutical innovation participated by Francois Nader, Formerly President, CEO, and Director, NPS Pharmaceuticals, Neal Masia, Vice President, Global Economics and International Treasury, Pfizer, and Ed Adamcik, Vice President, Pharmaceutical Strategies & Solutions, Express Scripts. The panel discussion was moderated by Cole Werble, Co-Founder, Prevision Policy LLC. Please visit *http://www.business.rutgers.edu/lerner*, click on Annual Healthcare Symposium, click on videos to watch full presentations. You can also click on photo gallery to view highlights of the symposium.

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 industry.
- On-site customized executive training programs for bio-pharmaceutical 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, Celgene, GenR Media and Eisai, for their generous support. We welcome your comments and feedback on the Center's activities and programs.

Mahmud Hassan, Ph.D.
Director

Annual Healthcare Symposium: Keynote Speaker

Buzz abounded as **Dieter Weinand**, the Global President of Bayer HealthCare Pharmaceuticals, entered Bove Auditorium. The audience felt privileged to hear from such a prominent global leader. Bayer has a very long history in New Jersey, but Mr. Weinand's visit represented a rare opportunity to learn about global markets and macro trends in healthcare. Many folks that work in the industry manage global initiatives, but other roles require managers to consider only the US market. Understanding challenges that impact all global healthcare markets can only help US-based teams develop the best possible solutions.

Mr. Weinand began with the most significant overarching trend – the world's rapidly aging population. He postulated that streets and buildings will need to be designed differently due to walking problems.

Unfortunately, healthcare systems across the globe will need to manage the aging populations with continued limited healthcare budgets – Mr. Weinand does not expect budgetary issues to change. Accordingly, he expects continued increases in out-of-pocket costs incurred by patients, but the silver lining for patients will be heightened patient centricity. Innovation will remain as the industry's key driver – patients can expect online interactive visits with their primary care physicians, and increased prevalence of wearable devices.

2013 was a record year for the industry – the FDA approved 41 drugs.

Innovation will also drive increased efficiency of gathering clinical trial data. For example, Mr. Weinand spoke about feeding non-clinical data into IBM Watson to automatically qualify and enroll patients into clinical trials. 2013 was a record year for the industry – the FDA approved 41 drugs, the most since 1996. Bringing a drug to market costs billions of dollars and only 2/3 of drugs recoup that investment. Furthermore, less than 1% of compounds are commercialized. A marginal cost savings at the clinical trial stage could result in exponential benefits during the research and development lifecycle, especially as healthcare costs rose by 4% last year (compared to 1.6% GDP growth).

The final topic was off-label drug usage. Legally, a pharmaceutical firm cannot advise a physician to prescribe a drug for a condition that the drug is not specifically approved for. However, Italy and France, for example, recommend preferentiality for off-label use of products.

Broadly, the pharmaceutical industry is moving away from its historically product-centered mindset to an outcomes-centered mindset. Patients will become more involved in their healthcare treatment decisions as healthcare records become available in real time.

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

IMS Health data is widely prevalent within the industry, making the opportunity to hear from **Angeliki Cooney**, Director of Strategic Planning at IMS Health, especially exciting. She switched gears from Mr. Weinand's Global-centric presentation to US-based content.

She presented the highlights of IMS' report of what happened within the industry in 2014.First, we experienced an unprecedented growth in spending, to the highest level (13%) since 2001 (17%). Ms. Cooney described the specific drivers of the increase. Most significantly, there was record spending on brand new drugs, and the spending is derived primarily by price increases. Relatedly, there are fewer patent expirations coming up, so pharmaceutical firms will experience fewer drops in revenue.

Ms. Cooney described the industry as bipolar, citing invoice list price inflation as an example. Also, a significant portion of spending came from one disease state – Hepatitis C. The price of Hep C drugs sparked the most pointed questions and debate topics initiated by the audience throughout the day. Since there is no price transparency in the US, all industry players are forced to reverse engineer to learn about pricing details. Rebating strategies also lack transparency. Regarding Hep C specifically, most new patients have commercial insurance, but most patients with Hep C are Baby Boomers and/or on Medicare/Medicaid.

2014 was also a booming year for the Affordable Care Act. For example, where did the contribution to retail growth come from? Medicaid expansion drove the growth of prescription drugs (in the states that decided to expand). Conversely, commercial plans' prescription usage actually decreased in 2014, likely due to increase out-of-pocket expenses. Also contributing to retail growth was decreased costs in end-to-end care – coordinated care helped to reduce cost and waste. Only 9% of people who received Medicaid expansion had no prior insurance. In stark contrast, 25% of people with insurance via exchanges had no insurance previously. With 15 million people insured with plans purchased on an exchange, exchanges represent the second largest area of growth (behind Medicaid expansion).

Regarding charity care provided by pharmaceutical firms, Ms. Cooney pointed out that commercial payers are not in favor of charity care because they lose control of business, political, and financial issues in those cases.

The majority of new drugs approved in 2014 were specialty drugs, with 50% from a spending perspective coming from Hep C. At the same time, primary care is being managed for its cost. Also, the high number of orphan drugs means accelerated approval in the marketplace, which actually reduces the cost of launching the drug by getting to market sooner. Ms. Cooney's closing thought was that the US market has two dimensions:

1. Massive investments in specialty drugs that are paying off
2. The system is unsustainable due to chronic diseases

Cost management and coordination of care are keys to any potential solution. Also, Ms. Cooney wondered how we could make the new expensive specialty drugs most accessible. Historically, the answer in the US has been competition, but she postulated that a policy change might be needed.

2014 was also a booming year for the Affordable Care Act…

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

Annual Healthcare Symposium: Expert Leadership Panel

Cole Werble kicked off the discussion as the moderator, posing a question: What more could the pharmaceutical industry want? The industry is doing well – what could anyone complain about? Three years ago, the discussion was about less productive R&D. Now, we have lots of innovation. Medicaid growth is helping and it was wise for the pharma industry to support the Affordable Care Act. Also, the timing of Hep C could not have been better.

Francois Nader mentioned that the challenge is not what we have, but where we're going. As an industry, we need to reinvent ourselves every year. Being patient-centric means that we need to understand what a patient needs from a drug – there may be technical needs that are clinically irrelevant. Also, we need to make sure that the majority of drugs do not benefit only a few patients. With science and technology moving faster than ever, how can we be sure that regulators have the information they need to regulate.

Neal Masia cited tax policy as critical to how we evaluate investment decisions. The tax rates in the US are the highest in the world, and the general uncertainly make tax implications difficult to manage. For example, tax credits are not permanent, so it's risky to plan around them. In broad strokes, pharmaceutical firms need to predict where the tax rate is going and what the discount rate will be. Dr. Masia also described the dramatic increase in cost sharing though Affordable Care Act plan design. As copayments increase, adherence decreases.

Ed Adamcik defended the prices of Hep C drugs. Express Scripts represents 90 million lives in the US. Before its exclusive contract with AbbVie, patients were not getting cured. Old less effective drugs were being prescribed and some plans would even force patients to get a liver biopsy to qualify for a Hep C drug. Now we're curing Hep C, and all patients on Express Script plans have access. Mr. Adamcik described that Express Scripts loves competition – the more competition in a market the better. The challenge from a payer perspective is making sure drugs are paid for and maintaining patient access to medications. More significantly, how can we ensure that growth is specialty drug growth is sustainable?

Over-valuation of drugs and firms should be avoided because it makes the market very fragile.

Payers meet with pharma companies early in the R&D process to determine prices. Having both sides of the negotiation seated next to each other for the panel was a fascinating experience. While their viewpoints varied, they both agreed that government intervention regarding negotiation would not provide more value that what the free market creates on its own.

Other highlights from the dynamic Q&A period included Dr. Nader's point that over-valuation of drugs and firms should be avoided because it makes the market very fragile. In this case, a political issue could tank the market – inflationary valuation is not sustainable. The audience was also especially interested in exclusionary processes and public health. For example, pharma companies seem to be neglecting Alzheimer's and antibiotics because those areas are not as profitable as specialty drugs. More broadly, Mr. Adamcik described the value of PBMs to patients. Dr. Masia responded that the problem is what happens in five years? Of course, we don't know the answer, but the audience left the room equipped to consider challenges related to all industry players.

From right to left: Cole Werble, Francois Nader, Neal Masia, and Ed Adamcik.

Symposium articles written by: Robert Cusumano and Aneesh Vaze

Transforming Big Pharma – Assessing the Strategic Alternatives

John Ansell, President, John Ansell Consultancy
September 29, 2014

John Ansell discussed how a pharma company today can secure sufficient IP. He focused on a few key strategies and steered clear of the many ineffective ones. His main points were why it matters that pharma is different, consider the variety of strategic options to pharma, implications of upward trend in new product pipeline, and getting a true fix on prospects.

Transforming the Clinical Trial Enterprise – Patient-Centered Clinical Trials

Ulrich Neumann, Global Project Director, eyeforpharma
October 27, 2014

Ulrich Neumann explained exclusive cross-industry survey research focus group and in-depth qualitative interviews with over 85 senior pharma executives as well as leading stakeholders (PCORI, FDA, NIH). He made clear that the industry is putting patients at the heart of the trial and how the concept can be both a paradigm shift and a revenue driver.

Applying Supply Chain Mgmt. Concepts to Improve Healthcare Delivery

David Dobrzykowski, Professor, Dept. of Supply Chain Management & Marketing Sciences, Rutgers Business School
February 25, 2015

David Dobryzkowski brought to our attention that hospitals are being under attack trying to reduce costs while improving quality, patient satisfaction, safety and other important outcomes. The solution to these problems are Supply Chain Management concepts such as financial alignment with physicians, process improvement, and integration as means of improving performance.

The Role of Capital in the Development and Life Cycle of a Biotech Company

Winston Kung, Chief Business Officer, Celgene Cellular Therapeutics
March 25, 2015

Winston Kung described the immense investment in delivering innovative biotech therapies to patients and the ability to continually raise capital is one of the key factors in the development and life cycle of a biotech company. The key success factors and pitfalls was also discussed in how biotech companies have successfully raised capital.

Upcoming Campbell Seminars

Counterfeit, Black-Market and Off-Label Drug Use – Rot, Hot or Not

Robert Braunstein, MD, MBA
September 30, 2015

Emerging Technologies in Healthcare: New Strategies for Social Media

Francoise Simon, Ph.D.
Clinical Professor
Columbia School of Public Health and Columbia Business School
October 21, 2015

Biosimilars: Prospects for Competition and Savings

Joseph P. Fuhr. Jr., Ph.D.
November 4, 2015

Rutgers Business School-Newark
1 Washington Park
Conference Room 1123

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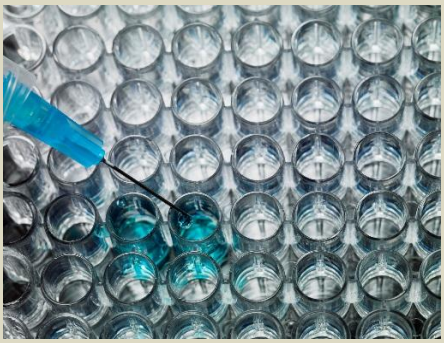
Drug Safety and the Cost of Monitoring: The Role of REMS in Risk Management

July 2015, vol. 49(4):514-523.

Under the Food and Drug Administration Amendments Act of 2007 (FDAAA), the FDA was authorized to impose post-approval requirements on the biopharmaceutical industry through the imposition of risk evaluation and mitigation strategies (REMS) and post-marketing trial (PMT) requirements to improve drug safety. Despite the extensive dialogue between stakeholders and lawmakers in the development of the FDAAA, there remains some uncertainty as to the exact impact of REMS on not only operational costs for both industry and health care professionals but also product sales and prescribing habits in the 5 years since its implementation. We sought to provide greater clarity on the duration of REMS requirements and impact of REMS on drug sales.

Comparative Effectiveness Research and the Rise of Orphan Indications

International Journal of Pharmaceutical and Healthcare Marketing (2014): 8(2), 151-163



The purpose of this paper is to show the link between the comparative effectiveness research (CER) and the interest in developing drugs for rare disease by the pharmaceutical industry. A modern approach to comparative effective research began its rapid rise in the USA when the American Recovery and Reinvestment Act of 2009 allocated $1.1billion for CER. This paper analyzes the implication and impact on the pharmaceutical industry. The study shows that the act encouraged the development of orphan drugs, mainly because of the low budget impact due to a smaller patient base. It also brings out the possible implication of the Affordable Care Act on the pharmaceutical industry with respect to its strategies for drug development and drug portfolio.

Two-Day Certificate Program

The Lerner Center is committed to providing executive education, access to industry experts and networking opportunities to professionals at every level. Three times a year, the Lerner Center conducts a Two-Day Pharmaceutical Management Executive Education Certificate Program at Rutgers Business School's Newark Campus. Attendees may receive up to 12 hours of continuing education credit awarded by the Accreditation Council for Pharmacy Education (ACPE).

Customized On-site Program

The Lerner 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.

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Save the Dates

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