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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 10th 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 13th annual Healthcare Symposium held on April 25, 2018. The theme of the symposium was Challenges to Bio-Pharmaceutical Innovation. The Keynote speaker Robert Zirkelbach, Executive Vice President, Pharmaceutical Research and Manufacturers of America (PhRMA), made presentation on five trends shaping the conversation on drug pricing. He mentioned that the debate on drug pricing ought to be in the light of value of breakthrough innovation that led to the development of revolutionary drugs curing the once incurable diseases. The guest speaker Ed Adamcik, Chief Pharma Trade Relations Officer at Express Scripts stressed on the need for a dialogue between the payers and the manufacturers six to a year ahead of launching an innovative drug to prepare the market place for providing access to the drug along with cost control mechanism.

The symposium contained a leadership panel discussion focusing on the issue of risk and strategies to mitigate failures in drug development. The members in panel were: Bruce Car, Vice President and Head of Translational Sciences, Bristol-Myers Squibb, Paul Deutsch, Vice President and Head of Translational Medicine, Sanofi, and Francois Nader, Chairman, Acceleron. It was moderated by Richard Bagger, Executive Vice President, and Celgene. Please visit <http://www.business.rutgers.edu/lerner>, 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 training programs on issues facing the pharmaceutical industry.
- 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 2017.

We would like to thank the following for sponsoring the symposium: Blanche and Irwin Lerner and Robert Campbell 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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Annual Healthcare Symposium Keynote

From Car-T cell engineering to RNAi therapeutics, new innovations in the pharmaceutical industry are popping up everywhere. These treatments not only feature new mechanisms of action and modalities, but also exhibit enhanced effectiveness compared to their more aged counterparts. With some of the industry's most innovative drugs launched last year and many new ones on the horizon, it appears that the R&D productivity slump that plagued the industry just a few years ago is over. But the launch of new, innovative drugs has been accompanied by a new set of challenges for the industry. It only seems appropriate that "Challenges to Biopharmaceutical Innovation" was the topic of discussion and debate at the 2018 Lerner Center Annual Healthcare Symposium hosted by Rutgers University. At the symposium, members representing every facet of the healthcare system assembled to discuss biopharmaceutical innovation challenges through conversations led by key industry executives.

Five Trends Shaping the Drug Pricing Conversation

Arguably, the biggest challenges facing biopharmaceutical innovation are the cost to society and society's willingness to pay for new drug innovations. Robert Zirkelbach, Executive Vice President of Public Affairs for Pharmaceutical Research and Manufacturers of America (PhRMA) kicked off this discussion in his Keynote Address, entitled "Five Trends Shaping the Drug Pricing Conversation." Mr. Zirkelbach asserted that although the national debate on drug pricing has persisted for years, the conversation has been primarily economic. What has been missing from the conversation, he contends, is value of scientific innovations in the industry – innovations that have resulted in the development of revolutionary drugs that not only treat but cure once incurable diseases. In discussing his first trend, "the rapid acceleration of biopharmaceutical innovation," Mr. Zirkelbach



“ Debates around prescription drug pricing must be merged with conversations on the value of breakthrough innovations ... inadequate policy decisions could be made in the absence of either component. ”



Pointed out that 74% percent of drugs in the industry's pipeline have first-in-class potential, meaning that they utilize a new approach to treat or cure a disease. In addition, he noted the FDA's efforts to support continued innovation by working with the industry to simplify and expedite the approval process for innovative drugs. For its part, PhRMA has launched the GoBoldly campaign to showcase the industry's innovative potential, highlighting the types of innovations that should be central to drug pricing conversations.

Mr. Zirkelbach contends that the new wave of drug innovations is coupled with a second trend: a decline in medicine cost growth. He remarked that the 2014 spike in prescription drug costs that sent lawmakers and the public into a frenzy was "not the new normal," and pointed to data showing that prescription drug cost growth has slowed and is projected to flatten over the next few years to a little over 6% per year. He also noted a decrease in overall healthcare cost growth. As key drivers of the declining cost growth trend, Mr. Zirkelbach cited increased Pharmacy Benefit Manager (PBM) negotiation power due to consolidation in the industry, as well as an influx of lower priced, generic medications.

Generic medications were also referenced by Mr. Zirkelbach as a key driver for another trend: the growing momentum for improving patient affordability. He emphasized that in 2017 there were 1,027 generic drug approvals – the highest on record – which have created more affordable options for patients. Furthermore, drug manufacturers and payers continue to explore and pursue the development of value-based contracts, in which manufacturers shoulder more of the financial risk in an effort to link value to payments. Moreover, he noted that health plans such as United Healthcare have committed to passing on rebates directly to patients. In the past, insurers have maintained that these rebates had been retained to keep premium costs in check. In addition, Mr. Zirkelbach mentioned that legislators are proposing Medicare Part D reforms to make medications more affordable for seniors.

Despite the movement toward patient affordability, Mr. Zirkelbach said patient out-of-pocket expenses are still increasing. Increasing replacement of co-payments by co-insurance and higher deductibles (the latter of which have tripled on average since 2006) are increasingly burdensome, especially for the sickest patients. Co-insurance and deductibles paid by patients are based on drug list prices, and although plan sponsors and insurers receive rebates which dramatically reduce drug costs, the patient sees little of these savings. The phenomenon has led to what has been referred to as "reverse insurance," in which the sickest patients who pay the most in deductible and co-insurance fees subsidize costs for healthier patients – the opposite of traditional health insurance designs.

Mr. Zirkelbach also noted that higher out-of-pocket costs lead to higher prescription abandonment rates. For instance, for Medicare patients the abandonment rate increases starkly above a \$250 cost-share, which results in an increase of overall costs to the healthcare system. Mr. Zirkelbach said PhRMA has launched the "Let's Talk about Cost" to illuminate the patient burden of prescription drug costs. That campaign, as well as PhRMA's "Follow the Dollar Report," highlight the flow of cash in the pharmaceutical supply chain, with a particular focus on the

PBM's in healthcare costs, with proposals of new legislation to increase supply chain transparency.

In addition, though data is scarce, new investigations are being conducted into the role that hospitals play in prescription drug costs. For example, some of the newest innovative treatments are being administered in hospitals, however, there is little data detailing how much those hospitals pay for drugs and how much they charge patients for the same medications. Mr. Zirkelbach also mentioned the misaligned incentives of 340B institutions as another supply chain component that needs further investigation.

In closing, Mr. Zirkelbach emphasized that the economic debates around prescription drug pricing must be merged with conversations on the value of breakthrough innovations. He warned that inadequate policy decisions could be made in the absence of either components.

Trends and Dynamics of the Pharmaceutical Market



Ed Adamcik

exacerbated by the fact that many of the newest innovations are categorized as specialty drugs. FDA approvals for these drugs are also on the rise with specialty drug approvals being nearly double the number of traditional drug approvals in 2017. Mr. Adamcik noted that this trend is coupled with an increased number of new specialty pharmacy dispensaries, including oncology practices and single drug pharmacies. To counteract these expenses, Mr. Adamcik, noted that payers have been re-structuring benefits designs, include higher deductibles and more co-insurance, in which patients bear most of the cost.

Following the Keynote Address, Ed Adamcik, Chief Pharma Trade Relations Officer at Express Scripts, took to the podium to highlight trends in the industry from the payer perspective. Mr. Adamcik dug deeper into the root causes of the drug pricing debate, citing that increases in specialty drug revenues have resulted in increases in overall prescription drug costs. This is

“ Payers need an opportunity to talk to drug manufacturers about new innovations six months to a year before launch ... to prepare the marketplace for coming innovations [and] to provide access to medications, while controlling costs. ”



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The designs also include more controls such as prior authorizations, exclusions of specific brands from formularies, and increased multi-tiering – particularly four-tier designs. The increasingly complex benefit designs are coupled with the demand for deeper discounts and additional rebates from drug manufacturers, cultivating an ecosystem that does not always lower costs to the system or benefit the patient. What payers need, Mr. Adamcik contends, is an opportunity to talk to drug manufacturers about new innovations six months to a year before launch (currently regulations bar discussions until one month prior). These early discussions would allow Express Scripts (and undoubtedly other PBMs) to prepare the marketplace for coming innovations, allowing drug manufacturers and payers to align on the best strategies to provide access to medications, while controlling costs.

Annual Healthcare Symposium: Expert Leadership Panel



From left to right: Richard Bagger, Francois Nader, Paul Deutsch, and Bruce Car

Finally, a panel discussion was held to garner the perspective of three R&D leaders in the industry: Francois Nader, Chairman at Acceleron; Paul Deutsch, Vice President and Head of Translational Medicine and Early Development at Sanofi; and Bruce Car, Vice President and Head of Translational Science at Bristol-Myers Squibb. The Honorable Richard Bagger, Executive Vice President at Celgene, moderated the discussion.



Mr. Bagger kicked off the panel by highlighting the many hurdles throughout the product lifecycle of a drug, but emphasized that those challenges are balanced by tremendous opportunity. For example, Mr. Bagger said there are currently 7,000 compounds in development and biopharmaceutical companies invest approximately \$75 billion annually in R&D. He was particularly supportive of the balance reflected in the Hatch Waxman Act, stating that the savings to the health system created by generic drugs are now paying for innovation and creating highly effective incentives for innovation. He followed up his introduction with questions for the panel.

“Savings from generics are now paying for innovation and creating much needed incentives for innovation.”

Question: What are the trends and challenges to biopharmaceutical innovation?

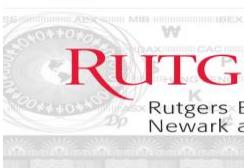
Dr. Car responded by highlighting strides made by the industry to eliminate safety risks, crediting improvements in modeling and simulations that allow for more accurate drug interaction predictions. Additionally, he remarked that though efficacy has improved, failure to prove widespread efficacy is often the downfall of new innovations. The trick, Dr. Car said, is finding the group of patients that will respond with 100% certainty. This could be just 5% of patients in a given disease state, but identification of this group ensures that the right patients receive the right medications.

Dr. Deutsch noted the shifting trend from small molecules to the new modalities that power innovative therapies, with special emphasis on some of the newest therapies touting modalities such as siRNAs and camelid nanobodies.

Dr. Nader emphasized that one problem the industry does not have is capital investment in innovative research. He said that there are currently 2,300 private biotech companies – over four times the number of public biotech firms. These private companies are well-funded by venture capitalist investments, with \$10 billion of VC funds financing 1,000 innovations last year. These biotech's are ripe for acquisition by larger drug manufacturers and thereby shoulder some of the early R&D risk that comes with drug development. Hence, Dr. Nader contended that the challenge is not the source of innovations, but society's willingness to pay for them, especially cures, which are costly upfront but ultimately lower costs for the whole healthcare system. He explained that as the industry develops treatments for smaller and smaller subsets of society, value determinations will become more complex. Finally, he noted commercialization Challenges in the manufacturing of complex therapies, such as the difficulty in consistently manufacturing mRNA or gene therapy constructs.

“The trick is finding the patients that will respond with 100% certainty ... identification of this group ensures that the right patients receive the right medications.”

Question: What will the changes in drug development look like?



Dr. Car responded that he expected changes on two fronts. First, changes in clinical trial regulations such as electronic informed consent forms, will increase the fluidity of trials. Second, he emphasized a shift toward early testing of clinical mechanisms to inform the developability of a compound in lieu of going straight to a Phase I clinical trial, adding that real-world evidence will be increasingly used to inform early Phase I trials.

Dr. Deutsch responded that the quality of clinical trial control groups gleaned from other sources rather than placebos will increase and more virtual investigational sites will emerge. These virtual investigational sites will bring the trial to the patients, as opposed to patients having to travel to the trial site. In addition, he noted that he expected a rise in the development of wearable devices, and even the emergence of non-invasive optical methods for measuring analytes. Finally, Dr. Deutsch emphasized that the shift from “me too” drugs having incremental value to demonstrations of true patient value will take the forefront.

Dr. Nader responded that the shift from physician focus to patient focus will continue, creating a spotlight on the development of clinically meaningful endpoints – outcomes that are most important to the patient – which are often reported as patient reported outcomes (PROs). He asserted that the challenge with PROs is navigating the complexity around measurement, quantification, and linkage of clinically meaningful endpoints to patient quality of life and healthcare cost savings.

In the final moments of the panel discussion, the experts discussed the actions that drug manufacturers can take to ensure that every patient has access to the right medication. Dr. Nader described NPS Pharma negotiations with health plans to ensure that no patient paid more than a \$10 co-pay for the company’s \$300,000 drug, noting that there was a marked decrease in compliance for any co-pay greater than \$75. However, Mr. Adamcik countered with a question: Is a \$10 co-pay for a \$300,000 drug the correct message to send to a public? These closing arguments revealed yet another complicating aspect of the biopharmaceutical innovation challenge debate: What can the market truly bear? In a healthcare ecosystem where drug prices are buried in a complex matrix of discounts, rebates, and middleman transactions, and where historically, patients are accustomed to paying a small percentage of their healthcare costs, an equilibrium reflecting optimal innovation, access, and willingness-to-pay remains elusive.

Symposium articles written by: Tiffany Campolongo, Ph.D.

View photo gallery: <https://photos.app.goo.gl/JnDsD9XUV5hrKchY8>

2018 Research Funding

1. Sarah Edris, “International Technological Specialization in Pharmaceuticals”, Summer 2018.
2. Debopriya Ghosh, “Impact of Multimodal Treatments of Myasthenia Gravis on Patients Health Outcome”, Summer 2017.



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Executive Certificate Program

Two-Day Pharmaceutical Management Executive 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 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 Programs available upon request.



Upcoming Dates: July 12-13, October 18-19

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Annual Biopharmaceutical MBA Case Competition



2017 WINNERS:

1st Place: UCLA Anderson School of Management

2nd Place: Rutgers Business School

3rd Place: Boston University-Questrom School of Business

Save the Date

7th Annual Rutgers Business
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Friday, November 16, 2018

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