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LERNER CENTER
RUTGERS BUSINESS SCHOOL

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

## In this issue:



**The Blanche and Irwin Lerner Center for the Study of Pharmaceutical Management Issues**
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# Director's Message

It gives me great pleasure to present to you the ninth 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 11th Annual Healthcare Symposium held on April 20, 2016. The theme of the symposium was "*Biosimilar: Boon or Bane"*. The keynote address by Robert J. Hugin, the Executive Chairman of Celgene Corporation, was on Partnership in Medical Innovation: Delivering Value for Patients, Healthcare and the Economy. He spoke about the importance of the industry-academia engagement with Rutgers being important to the economic vitality of state. In his opinion, Rutgers provides the skill set to the individuals who choose to pursue a career in the pharmaceutical industry. The guest speaker, Michael Kleinrock, Research Director of the IMS Institute, made a presentation on spending trends within pharma that was truly riveting. The media causes one to believe that the pharmaceutical industry is filled with greedy executives who simply want to drive up drug prices. When in reality, drug spending has been relatively flat over the past ten years – it has increased about 1.6% per year due to the introduction of the transformative Hep-C and immuno-oncology treatments.
The symposium contained a panel discussion on the issue of biosimilar, the generic version of biotech drugs, participated by Carlos Settler, M.D, Sandoz Inc.; Gillian Woollett, D. Phill, Avalere Health; and Molly Burich, M.S, Boehringher Ingelheim. It was moderated by Cole Werble, founding editor of FDC Reports and the Co-Founder of Prevision Policy LLC. Please visit http://www.business.rutgers.edu/lerner, on 2016 Annual Healthcare Symposium to watch the highlights of the symposium and also the pictures of the event in our photo gallery.

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 databases – NSP, NPA, IPS and NDTI – covering the monthly data for 2000 through 2010.

We would like to thank our symposium sponsors: Blanche and Irwin Lerner, Robert E. Campbell, Bayer HealthCare Pharmaceutical and Celgene Corporation 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

**Mr**. **Robert J. Hugin**, Executive Chairman of Celgene Corporation, was the keynote speaker for the Annual Healthcare Symposium hosted by the Rutgers Business School on April 20, 2016.

In his opening remarks, Mr. Hugin spoke about the importance of the industry-academia engagement with Rutgers being important to the economic vitality of state. In his opinion, Rutgers provides the skillset to the individuals who choose to pursue a career in the pharmaceutical industry. Having said that, he did confront the present day facts that things could be better. He portrayed the reality of NJ being the medicine chest turning out to be a little hollow because the industry has not been able to pursue joint research initiatives with institutions and academia. He rightly brought attention to the faculty who invest their careers through research and teachings to build the next generation of leaders.


Mr. Hugin then moved forward to appreciate the importance of the symposium because it provides a forum to discuss and debate the issues that confront the industry from time to time. Mr. Hugin then made a call to action to the audience to participate with the industry to solve these issues, which are fundamental to the economic progress of our society.

Mr. Hugin provided his recipe for success, which was to be open minded and willing to learn, which was fundamental to long-term success. He outlined the importance of the MBA degree, which essentially provides the tools and frameworks for problem solving. At the same time he spoke about the importance of strategic thinking in terms of "Thinking Big" – knowing where you are headed - and "Thinking Small" – what steps do you take to get there -.

Drawing towards the main theme of his speech, Mr. Hugins painted a strong picture of the healthcare field as one where the vision, mission and purpose of the industry and organizations alike have been about something that makes a difference in people's lives.

**"Mr. Hugin provided his recipe for success, which was to be open minded and willing to learn, which was fundamental to long-term success"**

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

# Industry Trends - IMS Health

**Topic: Medicine Use and Spending in the U.S.**

The media causes one to believe that the pharmaceutical industry is filled with greedy executives who simply want to drive up drug prices. When in reality, drug spending has been relatively flat over the past ten years – it has increased about 1.6% per year due to the introduction of the transformative Hep-C and immuno-oncology treatments. The reason why the heat is on pharma is because of the high price tag of these specialty drugs – while consumers want the most effective treatments for themselves, the larger population wants affordable drugs. In fact, patient use of new treatments drove a historically high level of $24.2B of growth in 2015 alone.


Mr. Kleinrock also discussed how innovation is at an all-time high right now and that the time period between 2016 and 2020, will set a record for launches when the current innovation-rich pipeline is approved. Increasing numbers of specialty drugs will drive spending upwards and put greater pressure on drug manufacturers to demonstrate value in their products.

Given the overarching theme of biosimilar, Mr. Kleinrock spoke about the promising impact of biosimilar on healthcare – the cumulative savings over the next five years, due to biosimilar, could range from EUR49 billion to EUR98 billion, in Europe and the U.S. The challenge that lies ahead for biosimilar is to ensure that all stakeholders – physicians, patients and payers – are sufficiently educated on the benefits of biosimilar and appropriately incentivized. We are venturing into uncharted healthcare territory.

***{ "Mr. Kleinrock's discussion on spending trends within pharma was truly riveting" }***

# Healthcare Expert Panel

The expert panel members were Gillian Woollett from Avalere Health, Carlos Sattler from Sandoz, and Molly Burich from Boehringer-Ingelheim. It was moderated by Cole Werble from Prevision Policy. The members in their opening remarks started off by differentiating the concept of biosimilar from generics.

**Biosimilar are to biologics, as generics are to drugs - exclusions include - biosimilar are highly similar to biologics and have *No Clinical Meaningful Difference* In terms of safety and effectiveness from the biologic, side effects are similar to the biologic reference product but still NO official guidance out yet for "Interchangeability".**

Biologics have been around since a long time, not just within the last few years. EU is leading in the development and approval of biosimilar, biologics vary in complexity and in structure, which that makes it difficult to replicate.

Approval and competition of biosimilar take into account various global and Regional/National considerations and the US healthcare system makes it challenging for patient access. The scale of approvals and development of biologics are challenging, yet have increased tremendously in the last few years and is expected to dramatically increase as companies try to find that niche market for their products. Unlike generics, companies need to run clinical studies to establish high similarity for a biosimilar to be approved by the FDA.

For a biosimilar to be approved for multiple indications, clinical studies in each indication is NOT required rather totality of evidence is sufficient.

Properly Naming and Labeling a biologic and biosimilar is very important, biosimilar do save on the initial R&D costs (avg of less than $250 million compared to $1.4B for Biologics). Three main hurdles for biosimilar are regulatory related issues, these are: the requirements for biosimilar vary across highly regulated markets across the globe since the laws differ. In US, FDA has approved only 2 biosimilar (Zarxio in 2015 and Inflectra in 2016), Health Canada has approved 3 biosimilar in Canada. In Europe, 22 biosimilar have been approved by the EMA.

On issue of commercialization, biosimilar have limited data exclusivity (about one year), educating the health care professionals, patients, advocacy groups, payers and others are going to be the key for success in commercializing a biosimilar product. Physicians only have basic knowledge about biosimilar; a lot more has to be done in terms of education/webinars.

On the issue of reimbursement, currently CMS does not have J-codes for these and there isn't a way to differentiate from the branded biologic, causing pricing autonomy. Medicaid considers biosimilar as Branded drug and biosimilar are excluded from Medicare - dough nut hole coverage – so the patient is responsible for 100% of costs during the gap (vs Biologics are not excluded).

# Research Publications and Campbell Seminars

## *Role of Alliance in New Drug Approvals*

The center is conducting a study on the role of alliance in new drug approvals. It is well documented in the literature that the industry's business model is changing moving toward more alliance based drug development. In the early days, when the entire R&D infrastructure was in house, it was found to be very capital- intensive, too risky and too time consuming. Now it is more alliance based, using licensing, forming partnerships, sharing capital, and talents. Our research question focuses on the extent of the drugs acquired through alliances and their impact on the market, i.e. size, therapeutic class, etc.

***Increasing Efficiency in Late Stage Drug Development***

Pharmaceutical companies are always looking for solutions which will allow them to combat the time delay and other potentials wastes in the late phase clinical trials so that they could get their novel drugs to market sooner, to gain on the 'marketable patent life of their compounds'.

## *Robert E. Campbell Pharmaceutical Seminar Series 2016-2017*

***FALL SEMESTER SEMINARS:***

***"Rethinking Translational Research"***
Wed, September 28, 2016, 11:30-1:00pm
Michelle Gittelman, PhD, Associate Professor
Rutgers Business School, Management & Global Business

***"Improving Success In Collaborative R&D"***
Wed, October 26, 2016, 11:30-1:00pm
Farok Contractor, PhD, Professor, Rutgers Business School
Jeongho Choi, PhD, Asst. Professor, St. John Fisher College

OFF CAMPUS? Join us via **Live Webcast**

***2015-2016 SEMINARS:***

***"Counterfeit, Black-Market and Off-Label Drug Use: Rot, Hot or Not"***
September 30, 2015
Robert Braunstein, M.D., Clinical Professor
Columbia University

***"Emerging Technologies in Healthcare: New Strategies for Social Media"***
October 21, 2015
Francoise Simon, Ph.D., Clinical Professor
Columbia University

***"Biosimilars: Prospects for Competition & Savings"***
November 4, 2015
Joe Fuhr, Ph.D., Economics Professor
Widener University

***"Analytical Tools for Assessing Business Development Product & The Company Opportunity"***
February 24, 2016
Maged Shenouda, MBA, Independent Director
Relmada Therapuetics, Protea Biosciences & AzurRx Biopharma

# 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.


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# Annual Biopharmaceutical MBA Case Competition



**2015 WINNERS:**

**1st Place: John Hopkins University**

**2nd Place: Rutgers Business School**

**3rd Place: Yale University**

**Best Presenter: Brent Schneider**

**Hon. Mention: Georgetown University**

## *Save the Date*

5th Annual Rutgers Business School
Biopharmaceutical Case Competition:
**Friday, November 18, 2016**

2015 Sponsors: novo nordisk, SANOFI, BAYER, CampbellAlliance, Herspiegel Consulting, Buchanan Ingersoll & Rooney PC, NOVARTIS