RUTGERS
Rutgers Business School
Newark and New Brunswick

Economics, Applied
Course Number: 22:223:607
Course Title: Pharmaceutical Industry: Issues, Structure & Dynamics

COURSE DESCRIPTION

To develop a successful career in the pharmaceutical industry requires understanding of the market, clients, and the environment. Leaders in the industry must make decisions on a daily basis in order to stay competitive and grow. A company's ultimate survival depends on the successful pipeline of new drugs. Competitive pressure in the market place compels companies to invest continuously in the R & D activities in order to have new drugs lined up to replace the expiring patents. The amount of investment for each new drug developed has been increasing tremendously. Once a drug is marketed, there is no guarantee that it will have its financial success. Other companies might come up with a better drug in its therapeutic class, or the regulatory agency might restrict its marketing due to unexpected health outcome. The point is, it is a very risky business. The course syllabus has been developed with the advice and support from Mr. Irwin Lerner, former President and CEO, Hoffmann-La Roche.

COURSE MATERIALS

There is no text for this course but requires a set of readings mentioned as follows. Other readings may be added later during the semester. The students will be evaluated based on the performances in three equally weighted papers. Requirements for the papers are explained below. Students are required to attend the on-line seminar series by the FDA's Center for Drug Evaluation and Research (CDER) (www.fda.gov/training/forhealthprofessionals/default.htm, and take the available on-line quiz following each of the seminar for your own evaluation. The courses (seminars) available are: Risk Assessment and Communication, FDA Medwatch and Patient Safety, Field Investigators: Adverse Drug Effects (ADE) Investigators, The FDA Process for Approving Prescription Drug Labeling.

Suggested Books

1. Pharmaceutical Economics and Policy by Stuart O. Schweitzer, Oxford University Press, 2007.

2. Understanding Pharma by John J. Campbell, Pharmaceutical Institute, 2008.

LEARNING GOALS AND OBJECTIVES

The objective of this course is to give the students an understanding of the successful development of a new drug. In this context, the students will be exposed to different concepts of drug development phases, the role of the Food and Drug Administration in the development of new drugs, role of patenting & licensing, drug pricing, product life cycle, genomics & biotechnology and other related issues. The course will have many guest speakers from the industry to orient the students on practical point of view. After successful completion of the course, the students should be able to explain the R & D process to their peers, participate and contribute in managerial decision makings with respect to the development of new drugs.

REQUIREMENTS FOR THE PAPERS

You will need to select three topics of your choice involving the issues of pharmaceutical industry. Examples of topics are: Product Pricing Strategies, Impact of Drug Importation on Price, Quality and Access, Impact of Alliances on Drug Development, Impact of Genomics on Drug Development, Valuing Product Pipeline, Impact of Mergers & Acquisitions on R&D Capacity, Examine the Growth of Outsourcing and its impact on Drug Development, Compare Drug Development Costs at Biotech Firms Versus Large Pharmaceutical Companies or any other topic relevant to this course. The selected topics must not be too broad. Examples of too broad topics are: R&D Process, Mergers & Acquisitions, Product Launching etc. The papers must be analytical. Use of actual data is highly recommended.

The Rutgers Library system has subscribed the on-line version of the FDC reports. Check the site www.libraries.rutgers.edu/indexes/fdc_reports for a list of the reports, click on CONNECT, you will get a page by Pharma&MedTech Business Intelligence, use the drop down menu under "Headlines From Your Subscription" to select the publication i.e Pink Sheet, Tan Sheet, Gray Sheet etc. There are other data sets as well such as Parexel's Pharmaceutical R&D Statistical Sourcebook (available in the Science & Medicine library in the Busch campus). The Lerner Center has several IMS data sets. If you would like to use the IMS data sets, you need to talk to me for the procedure of getting access to the data sets.

ACADEMIC INTEGRITY

I do NOT *tolerate cheating*. Students are responsible for understanding the RU Academic Integrity Policy (http://academicintegrity.rutgers.edu/).

I will strongly enforce this Policy and pursue *all* violations. On all examinations and assignments, students must sign the RU Honor Pledge, which states, "On my honor, I have neither received nor given any unauthorized assistance on this examination or assignment." I will screen all written assignments through *SafeAssign* or *Turnitin*, plagiarism detection services that compare the work against a large database of past work. Don't let cheating destroy your hard-earned opportunity to learn. See business.rutgers.edu/ai for more details.

CLASS ATTENDANCE

You are required to attend every class, and participate in class discussion. You should come prepared to ask questions to the speaker of the day. If you are absent for more than two classes, your grade may be lowered by one notch (from A to B+, B+ to B etc).

COURSE SCHEDULE

Class Schedule

Day **Topic, speaker, Readings, and Due Dates of Assignments**

Course Information

Readings

Frank, Richard; and Newhouse, Joseph. "Should Drug Prices Be Negotiated Under Part D of Medicare? And If So, How?", *Health Affairs,* Vol. 27, No. 1, 2008:33-43.

Berndt, Ernst; Mortimer, Richard; Bhattacharjya, Ashoke; Parece, Andrew; and Tuttle, Edward. "Authorized Generic Drugs, Price Competition, and Consumers' Welfare", *Health Affairs,* Vol.26, No. 3, 2007: 790-799.

Lopert, Ruth; and Moon, Marilyn. "Toward A Rational, Value-Based Drug Benefit For Medicare", *Health Affairs,* Vol. 26, No. 6, 2007:1666-1673.

Centers for Medicare & Medicaid Services "Health Care Industry Market Update - Pharmaceuticals" , January 10, 2003.

Reinhardt, Uwe E. "Perspectives On The Pharmaceutical Industry",

Health Affairs, Vol. 20, No. 5, September/October, 2001, pp:136-149.

Berndt, Ernst R. "The U.S. Pharmaceutical Industry: Why Major Growth In Times of Cost Containment?", *Health Affairs,* Vol. 20, No. 2, March/April, 2001, pp:100-114.

Cutler, David M. and McClellan, Mark, "Is Technological Change In Medicine Worth It?", *Health Affairs,* Vol. 20, No. 5, September/October, 2001, pp: 11-29.

Mullins, Daniel ; Wang, Junling ; Palumbo , Francis; and Stuart, Bruce "The Impact Of Pipeline Drugs On Drug Spending Growth", *Health Affairs,* Vol. 20, No. 5, September/October, 2001, pp: 210-215.

Lichtenberg, Frank R. "Probing The Link Between Gross Profitability And R & D Spending" , *Health Affairs,* Vol. 20, No. 5, September/October, 2001, pp:221-222.

Scherer, F. M. "The Link Between Gross Profitability And Pharmaceutical R & D Spending", *Health Affairs,* Vol. 20, No. 5, September/October, 2001, pp: 216-220.

Overview of the Drug Discovery and Development Process

Speaker

Readings

NDA Pipeline Online, FDC Reports.

Scannell, Jack; Blanckley, Alex; Boldon, Helen; and Warrington, Brian, "Diagnosing the Decline in Pharmaceutical R&D Efficiency", *Nature Reviews – Drug Discovery*, Vol 11, March 2012, pp: 191-200.

Sturm, Andreas; Dowling, Michael; and Roder, Klaus, "FDA Drug Approvals: Time is Money", *Journal of Entrepreneurial Finance,* Vol. 12, No. 2, 2007, pp: 23-54.

Adams, Christopher and Brantner, Van. "Estimating the Cost of New Drug Development: Is It Really $802 Million?", *Health Affairs,* Vol. 25, No. 2, 2006:420-428.

Kola, Ismail; and Landis, John, "Can the Pharmaceutical Industry Reduce Attrition Rates", *Nature Reviews – Drug Discovery,* Vol. 3, August 2004, pp:711-715.

DiMasi, Joseph; Hansen, Ronald; and Grabowski, Henry, " The Price of innovation: new estimates of drug development costs", *Journal of Health Economics,* 22, 2003, pp: 151-185.

Cockburn, Iain M. and Henderson, Rebecca M. "Scale and scope in drug development: unpacking the advantages of size in pharmaceutical research", *Journal of Health Economics,* Vol. 20, 2001, pp: 1033-1057.

Fuchs, Victor R. and Sox Jr., Harold C. "Physicians' Views Of The Relative Importance Of Thirty Medical Innovations", *Health Affairs,* Vol. 20, No. 5, September/October, 2001, pp: 30-42.

Schweitzer, Stuart O. "Pharmaceutical Economics and Policy",

Oxford University Press, New York, 2007, Chs. 1, 2 and 9.

Competitive Pressure:

Mergers, Acquisitions and Restructuring

Of the Pharmaceutical Industry

Speaker

Licensing, Partnering and Contracting for Product Development

Speaker

Readings

TBA

Patents and Intellectual Property Rights

Speaker

Readings

Basis of Patent Protection, U.S. Patent and Trademark Office (last visited December 14, 2016) https://www.uspto.gov/sites/default/files/about/offices/ous/Cooper_Union_20130604.pdf

Frequently Asked Questions on Patents and Exclusivity, U.S. Food & Drug Administration (last visited December 14, 2016) http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm

Intellectual Property Underpinnings of Pharmaceutical Innovation: A Primer, By Will Rinehart (2012) (last visited December 14, 2016) https://www.americanactionforum.org/research/intellectual-property-underpinnings-of-pharmaceutical-innovation-a-primer/

Zinner, Darren E. "Medical R & D At The Turn Of The Millennium", *Health Affairs*, Vol. 20, No. 5, September/October, 2001, pp:202-209.

Eisenberg, Rebecca S. "The Shifting Functional Balance Of Patents And Drug Regulation", *Health Affairs*, September/October, 2001, pp: 119-135.

Schweitzer, Stuart O. "Pharmaceutical Economics and Policy", *Oxford University Press*, New York, 2007, Ch. 13.

Readings

Commercializing Targeted Therapies : How Things Need to Change

Speaker

Product Commercialization Framework

Speaker

Readings

TBA

Paper 1 due

Impact of Genomics on Pharmaceutical Product Development

Speaker

Readings

"Principles for Codevelopment of an In Vitro Companion Diagnostic 2 Device with a Therapeutic Product" , "*U.S. Department of Health Human Services, July 15, 2016.*

"Use of Standards in FDA Regulatory 2 Oversight of Next Generation 3 Sequencing (NGS)-Based In Vitro 4 Diagnostics (IVDs) Used for 5 Diagnosing Germline Diseases", *"U.S. Department of Health and Human Services, July 8, 2016."*

"Use of Public Human Genetic Variant 2 Databases to Support Clinical Validity 3 for Next Generation Sequencing 4 (NGS)-Based In Vitro Diagnostics", *"U.S. Department of Health and Human Services, July8, 2016."*

David W. Thomas, Justin Burns, John Audette, Adam Carroll, Corey Dow-Hygelund, Michael Hay.

Fontes, Denis et al, "Impact of a Biomarker-Based Strategy on Oncology Drug Development: A Meta-Analysis of Clinical Trials Leading to FDA Approval", *JNCI J Natl Cancer Inst* (2015) 107(11): djv253

Fatiha H Shabaruddin Nigel D Fleeman Katherine Payne, Economic evaluations of personalized medicine: existing challenges and current developments (2015) :8 115–126

Amedos, Monica et al. "The Genetic Complexity of Common Cancers and Promise of Personalized Medicine: Is there any Hope", *Journal of Pathology,* Vol. 232, 2014, pp:274-282.

Meijuan Li, "Statistical Consideration and Challenges in Bridging Study of \ Personalized Medicine" *Journal of Biopharmaceutical Statistics* (2015) 25: 397–407

Paving the Way for Personalized Medicine, *"U.S. Department of Health and Human*

*Services,*October 2013.

Blair, Edward et al. “Aligning the Economic Value of Companion Diagnostics and Stratified Medicines”, *Journal of Personalized Medicine,* vol.2, 2012, pp:257-266.

No Class – Spring Break

Pricing and Market Access: Case of Oncology

Speaker

Readings

TBA

Pharmaceutical Market Trends and Dynamics

Speaker

Readings

TBA

Overview of the Medical Device Market

Speaker

Readings

TBA

Paper 2 due

The Vaccine Market: A Global Perspective

Speaker

Readings

TBA

Project Valuation and Portfolio Management in Pharmaceutical R&D

Speaker

Readings

TBA

Concepts and Applications of Pharmaco Economics

Speaker

Readings

TBA

Paper 3 due

SUPPORT SERVICES

If you need accommodation for a ***disability***, obtain a Letter of Accommodation from the Office of Disability Services. The Office of Disability Services at Rutgers, The State University of New Jersey, provides student-centered and student-inclusive programming in compliance with the Americans with Disabilities Act of 1990, the Americans with Disabilities Act Amendments of 2008, Section 504 of the Rehabilitation Act of 1973, Section 508 of the Rehabilitation Act of 1998, and the New Jersey Law Against Discrimination. More information can be found at ods.rutgers.edu.

[Rutgers University-New Brunswick ODS phone (848)445-6800 or email dsoffice@echo.rutgers.edu]

[Rutgers University-Newark ODS phone (973)353-5375 or email ods@newark.rutgers.edu]

If you are ***pregnant***, the Office of Title IX and ADA Compliance is available to assist with any concerns or potential accommodations related to pregnancy.

[Rutgers University-New Brunswick Title IX Coordinator phone (848)932-8200 or email jackie.moran@rutgers.edu]

[Rutgers University-Newark Office of Title IX and ADA Compliance phone (973)353-1906 or email TitleIX@newark.rutgers.edu]

If you seek ***religious accommodations***, the Office of the Dean of Students is available to verify absences for religious observance, as needed.

[Rutgers University-New Brunswick Dean of Students phone (848)932-2300 or email deanofstudents@echo.rutgers.edu]

[Rutgers University-Newark Dean of Students phone (973)353-5063 or email DeanofStudents@newark.rutgers.edu]

If you have experienced any form of ***gender or sex-based discrimination or harassment***, including sexual assault, sexual harassment, relationship violence, or stalking, the Office for Violence Prevention and Victim Assistance provides help and support. More information can be found at http://vpva.rutgers.edu/.

[Rutgers University-New Brunswick incident report link: http://studentconduct.rutgers.edu/concern/. You may contact the Office for Violence Prevention and Victim Assistance at (848)932-1181]

[Rutgers University-Newark incident report link: https://cm.maxient.com/reportingform.php?RutgersUniv&layout_id=7 . You may also contact the Office of Title IX and ADA Compliance at (973)353-1906 or email at TitleIX@newark.rutgers.edu. If you wish to speak with a staff member who is confidential and does **not** have a reporting responsibility, you may contact the Office for Violence Prevention and Victim Assistance at (973)353-1918 or email run.vpva@rutgers.edu]

If students who have experienced a temporary condition or injury that is adversely affecting their ability to fully participate, you should submit a request via https://temporaryconditions.rutgers.edu .

If you are a military ***veteran*** or are on active military duty, you can obtain support through the Office of Veteran and Military Programs and Services. http://veterans.rutgers.edu/

If you are in need of ***mental health*** services, please use our readily available services.

[Rutgers University-Newark Counseling Center: http://counseling.newark.rutgers.edu/]

[Rutgers Counseling and Psychological Services–New Brunswick: http://rhscaps.rutgers.edu/]

If you are in need of ***physical health*** services, please use our readily available services.

[Rutgers Health Services – Newark: http://health.newark.rutgers.edu/]

[Rutgers Health Services – New Brunswick: http://health.rutgers.edu/]

If you are in need of ***legal*** services, please use our readily available services: http://rusls.rutgers.edu/

Students experiencing difficulty in courses due to ***English as a second language (ESL)*** should contact the Program in American Language Studies for supports.

[Rutgers–Newark: PALS@newark.rutgers.edu]

[Rutgers–New Brunswick: eslpals@english.rutgers.edu]

If you are in need of additional ***academic assistance***, please use our readily available services.

[Rutgers University-Newark Learning Center: http://www.ncas.rutgers.edu/rlc

[Rutgers University-Newark Writing Center: http://www.ncas.rutgers.edu/writingcenter]

[Rutgers University-New Brunswick Learning Center: https://rlc.rutgers.edu/]

[Optional items that many faculty include:

- Students must sign, date, and return a statement declaring that they understand the RU Academic Integrity Policy.

- Students must sign, date, and return a statement declaring that they understand this syllabus.]