



Management and Economics of the Pharmaceutical & Biotech Industries

HCMG 863

Spring 2019

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Contact Information

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Teaching Assistants:

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Office Hours: By Appointment

Lectures

Class Meeting:

Monday and Wednesday, 10:30-11:50am, CPC Auditorium

Course Objectives

This course provides an overview of the management, economic and policy issues facing the pharmaceutical and biotechnology industries. The course perspective is global, with emphasis on the U.S. as the largest and most profitable market.

We focus on issues that differentiate these industries from most others, including:

- An R&D-intensive cost structure and rapid technological change; the role of biotechnology, genomics etc. in transforming the industry structure;
- A complex global market place in which customers include governments and third party payers, as well as physicians, pharmacists and individual consumers;
- Government regulation of every dimension of the business, including market access (safety and efficacy), pricing, manufacturing, and promotion;
- Continually evolving M&A strategies, including mergers, joint ventures, options-based deals and alliances;
- Global products and multinational firms, with growing tension between the needs and ability to pay in different market segments.

Course Format

- Lecture/presentation by instructor and industry guest speakers
- Case discussions
- Student presentations

Course Materials

Readings : All course readings are listed below and are required. The readings will be posted on the course website (cases are available through Study.Net).

Optional but recommended background reading is: “Understanding Pharma: the Professional’s Guide to How Pharmaceutical and Biotech Companies Really Work,” by John J. Campbell, 2018, 3rd edition. A copy of this book will also be available at the Lippincott Library reserve desk.

Course Website: The course website is located at <https://canvas.upenn.edu> . The syllabus, case questions, assignments, and readings will be posted on this website.

Grading

Case Write-ups	30%
Midterm Exam	30%
Term Project	30%
Class Participation	10%

1. **Two Case Write-ups (30%):** Students should come to class prepared to discuss all the assigned cases. Specific questions for each case will be posted on Canvas. Each student must write-up responses to the case questions for *two of the four cases* listed in the syllabus. You may work in teams to discuss the cases and responses. However, you must *independently write up the case*. The case write-up should be a maximum length of *two pages*. Your write-up is due via Canvas by *5:00 pm the day before the case is to be discussed*.
2. **Midterm Exam (30%):** There will be an in class midterm exam on *Wednesday, March 13*.
3. **Term Project (30%):** Students will work on a term project in teams of up to four students. A list of possible topics will be provided or you may select your own topic, subject to approval of the instructor. A one-page outline of the team’s project is due via Canvas at the *beginning of class on February 27*. The team’s final write-up (max. 10 pages plus optional tables) is due via Canvas at the *beginning of class on April 22*. The term project will be presented in class.
4. **Class Participation (10%):** The class participation grade will be assessed using a combination of a class sign-in sheet for attendance, periodic exercises, and speaker write-ups. Missing up to *two* classes will not affect your participation grade.

Classroom Guidelines and Policies

Attendance

Your on-time attendance for each class session is expected, as is your active participation. If you are unable to attend a class, please let me know in advance with a brief email.

Name Tents

Please display your name tent at each lecture including classes with guest speakers.

Laptops

Following Wharton's electronics policy, all phones, laptops, and other electronic devices must be turned off during class. Violations of this policy will lead to a lower participation grade. See: <https://www.nytimes.com/2017/11/22/business/laptops-not-during-lecture-or-meeting.html>

Academic Honesty

All students should familiarize themselves with the University's guidelines on citations, plagiarism and academic dishonesty, which are found at:

http://www.upenn.edu/academicintegrity/ai_codeofacademicintegrity.html

Any violations of this policy will result in significant consequences, including but not limited to, grade deductions and reporting to the University.

Course Schedule and Readings

Part I: Overview of Current Issues in the Pharmaceutical & Biotech Industries

Jan 16: Introduction and Course Overview

Readings:

- *Understanding Pharma*– Chapters 1 & 2 (Optional)
- Standard & Poor's Industry Surveys: Pharmaceuticals, June 2018 (pp. 4-39)
Recommended reading order:
 1. "How the industry operates" (pp. 30-39)
 2. "Industry trends" (pp. 14-29)
 3. "Industry financial metrics" (pp. 4-13)
- Frakt, A. "Something Happened to U.S. Drug Costs in the 1990s." New York Times, November 12, 2018

Jan 21: Martin Luther King, Jr. Day – No Class

Jan 23: Drug Discovery, Development, and Clinical Trials

Readings:

- *Understanding Pharma*– Chapters 4 & 5 (Optional)
- DiMasi, J, Grabowski, H., and R. Hansen (2016). "Innovation in the Pharmaceutical Industry: New Estimates of R&D costs." Journal of Health Economics. 47: 20-33.

- Scannell, J.W., Blanckley, A., Boldon, H. and Warrington, B. (2012). “Diagnosing the Decline in Pharmaceutical R&D efficiency.” *Nature Reviews Drug Discovery*, Volume 11.
- Parker, Ian (2013). “The Big Sleep,” *The New Yorker*, December 9, 2013.

Jan 28: Incentives for Innovation

Readings:

- **Case #1:** Organizing for Innovation at Glenmark (A)
- Grabowski, H. (2003) “Patents and New Product Development in the Pharmaceutical and Biotechnology Industry.” *The Georgetown Public Policy Review*.
- Kremer and Williams. (2010) “Incentivizing Innovation: Adding to the Tool Kit.” *Innovation Policy and the Economy*, 10(1):1–17.

Jan 30: Measuring Value: Cost Effectiveness and Comparative Effectiveness Analysis

Readings:

- Zaric, G. (2010). “Difficult Choices – An Introduction to Cost-Effectiveness Analysis.” Ivey School of Business Note 910E07. July 2010. [available from Study.Net]
- Williams, J. “Big Pharma’s Biggest Threat in Washington? It May Be this Obscure Research Firm.” *Washington Examiner*, December 11, 2018.

Feb 4: Marketing and Commercialization

Readings:

- **Case #2:** Cialis: Getting Ready to Market
- *Understanding Pharma*– Chapter 8 (pp. 156-173) (Optional)
- Schulze and Rengel. “What Matters Most in Commercial Success: First-in-Class or Best-in-Class?” *NRDD* June 2013.

Feb 6: Managed Markets: The Role of Insurers in Managing Pharmaceutical Use

Readings:

- *Understanding Pharma*– Chapter 10 (Optional)
- Kaiser Family Foundation. (2005). “Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain.”
- Frakt, A. (2017). “When a Drug Coupon Helps You but Hurts Fellow Citizens.” *New York Times*, September 25, 2017.

Feb 11: Medicare Part D

Readings:

- Hoadley, J., Cubanski, J. and P. Neuman. (2015). “Medicare's Part D Drug Benefit At 10 Years: Firmly Established But Still Evolving” *Health Affairs*. 34(10):1682-1687.
- Shih, C., Schwartz, J., and A. Coukell. “How Would Government Negotiation of Medicare Part D Drug Prices Work?” *Health Affairs Blog*. February 1, 2016.

Feb 13: Pricing and Reimbursement: U.S.

Readings:

- Danzon. "Pricing and Reimbursement for Biopharmaceuticals and Medical Devices in the USA" In: Anthony J. Culyer (ed.), Encyclopedia of Health Economics, Vol 3. San Diego: Elsevier; 2014. pp. 127-135.
- Rockoff, J. "How Pfizer Set the Cost of Its New Drug at \$9,850 a Month" Wall Street Journal. December 9, 2015.
- Scannell, J.W. "Four Reasons Drugs are Expensive, of Which Two are False." Forbes. October, 13, 2015.

Feb 18: Pricing and Reimbursement: U.S. (Cont'd)

Readings:

- **Case #3:** Merck: Pricing Gardasil
- Kesselheim, et al. (2016). "The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform." JAMA, 316(8):858–871.

Feb 20: Pricing and Reimbursement: International

Readings:

- **Case #4:** Gilead: Launching Truvada in Europe
- Danzon, P. (2012). "Regulation of Price and Reimbursement" in Handbook on the BioPharmaceutical Industry. Eds. P. Danzon and S. Nicholson. Oxford University Press. (Read pgs. 266-270 & 276-290)

Feb 25: Policy Issues: The Opioid Crisis

Readings:

- Pacula, R. and D. Powell. (2018). "A Supply-Side Perspective on the Opioid Crisis," Journal of Policy Analysis and Management, 37(2): 438-446.
- Saloner, B. and C. Barry (2018). "Ending the Opioid Epidemic Requires a Historic Investment in Medication-Assisted Treatment," Journal of Policy Analysis and Management, 37(2): 431-438.
- Ryan, H. et al. "You Want a Description of Hell? OxyContin's 12-hour Problem." Los Angeles Times. May 5, 2016.

Feb 27: Generics and Biosimilars

Readings:

- Grabowski et al. (2014). "Regulatory and Cost Barriers are Likely to Limit Biosimilar Development and Cost Savings." Health Affairs. 33(6).
- Alkire, M., "Unpacking Drug Price Spikes: Generics" Health Affairs Blog, March 21, 2016.

Mar 4: Spring Break – No Class

Mar 6: Spring Break – No Class

Mar 11: Review Session/Catch-up

Mar 13: Midterm Exam

Part II: Industry Perspectives

Guest Speaker Lectures [Speakers and Dates Subject to Change]

Mar 18: Entrepreneurship in Pharma: Application to Alzheimer's Disease– Maria Maccicchini, CEO and Founder, QR Pharma

Mar 20: The Market for Cancer Care – Sarbani Chaudhuri, Global Commercial Head- Lung Cancer, Pfizer

Mar 25: TBD

Mar 27: TBD

Apr 1: Orphan Drugs: Innovation and Pricing – Brian Corvino, Executive Vice President and Managing Partner, Decision Resources Group

Apr 3: Gene Therapies – Jeffrey Marrazzo, CEO and Co-Founder, Spark Therapeutics

Apr 8: Investing in Biopharma – Yaron Werber, Managing Director, Senior Biotechnology Analyst, Cowen

Apr 10: Innovation from External Sources, M&A/L&A – Henry Gosebruch, Chief Strategy Officer, AbbVie

Apr 15: Inside the Black Box of PBM Negotiations – Steve Miller, Chief Medical Officer, Express Scripts

Apr 17: Industry Responses to the Opioid Crisis – Mike Derkacz, CEO, Braeburn

Apr 22: Valeant Case Study – Scott Hirsch, Head of Business Strategy, Bausch Health (formerly Valeant)

Part III: Student Presentations

Apr 24: Student Presentations

Apr 29: Student Presentations

May 1: Wrap-up/Student Presentations