Management and Economics of the Pharmaceutical & Biotech Industries

HCMG 8630

Spring 2024

[Last Updated 1/10/24]

Contact Information

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Office Hours: **Mondays 3:15-4:15 pm, Colonial Penn Center 303, or by appointment**

Teaching Assistants:
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Office Hours: **By appointment**

Lectures

Class Meeting:

Monday and Wednesday, 10:15-11:45am, 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, other readings through Course Materials @ Penn Libraries).

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.

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	**25%**
Term Project Presentation	**30%**
Class Participation	**15%**

1. **Two Case Write-ups:** Students should come to class prepared to discuss all the assigned cases. Discussion questions for each case will be posted on Canvas. Each student must write-up responses to the case questions for ***two of the three cases*** listed in the syllabus. You may work individually or in teams to discuss the cases and responses. 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:** There will be an in class midterm exam on ***February 26.***

3. **Term Project Presentation:** Students will work on a term project presentation in teams. 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 21.*** Presentation slides are due via Canvas at ***2:00 pm on April 9*** and will be shared with the class**.** Teams will make presentations in class on ***April 10-April 17***. All team members must participate in the presentation.

4. **Class Participation:** The class participation grade will be assessed using a combination of attendance and guest speaker write-ups. Missing up to **two** classes for the semester will not affect your participation grade. There are ***three*** guest speaker write-ups. You can choose to do write-ups for any 3 guest speakers. Go to "Quizzes" on Canvas to submit your write-ups. These are ***due four days after the guest lecture at 5:00 pm***.

Classroom Guidelines and Policies

Attendance
Your on-time attendance for each class session is expected, as is your active participation.

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.

Generative AI
You may use generative AI programs (e.g., tools like ChatGPT) to help generate ideas and brainstorm. However, you should note that the material generated by these programs may be inaccurate, incomplete, or otherwise problematic. Beware that use may also stifle your own independent thinking and creativity. You may not submit any work generated by an AI program as your own. If you include material generated by an AI program, it should be cited like any other reference material (with due consideration for the quality of the reference, which may be poor). Any plagiarism or other form of cheating will be dealt with severely under relevant Penn policies.

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 17: Introduction and Course Overview

Readings:

- *Understanding Pharma*– Chapters 1 & 2 (Optional)
- CFRA Industry Surveys: Pharmaceuticals, October 2023 (pp. 5-41)
  Recommended reading order:
  1. "How the industry operates" (pp. 33-41)
  2. "Industry trends" (pp. 9-32)
  3. "Industry Snapshot" (pp. 5-8)
- Frakt, A. "Something Happened to U.S. Drug Costs in the 1990s." New York Times, November 12, 2018

Jan 22: Drug Discovery, Development, and Clinical Trials

Readings:

- *Understanding Pharma*—Chapter 4 (Optional)
- *Understanding Pharma*—Chapter 5 (Required, pp. 89-112)
- 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.
- Parker, Ian (2013). "The Big Sleep," The New Yorker, December 9, 2013.

Jan 24: Drug Discovery, Development, and Clinical Trials (Cont'd)

Readings:

- 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.

Jan 29: 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.
- Lakdawalla, D. (2018) "Economics of the Pharmaceutical Industry." Journal of Economic Literature, 56(2). (Optional)

Jan 31: 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 5: Marketing and Commercialization

Readings:

- **Case #2:** Cialis: Getting Ready to Market
- *Understanding Pharma*– Chapter 8 (Required, pp. 163-180)
- Schulze and Rengel. "What Matters Most in Commercial Success: First-in-Class or Best-in-Class?" *NRDD* June 2013.

Feb 7: 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 12: 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.

Feb 14: Pricing and Reimbursement: Overview

Readings:

- **Case #3:** Merck: Pricing Gardasil
- 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 19: Pricing and Reimbursement: Inflation Reduction Act

Readings:

- Cubanski, J. "Explaining the Prescription Drug Provisions in the Inflation Reduction Act. September 22, 2022
- Walker, L. and D, Gorenstein. "What's a Fair Price for a Prescription Drug? Medicare's About to Weigh In," NPR. July 28, 2023.
- Cubanski, J. "FAQs about the Inflation Reduction Act's Medicare Drug Price Negotiation Program." August 8, 2023 (Optional)
- Rome, B. et al. (2023). "Simulated Medicare Drug Price Negotiation Under the Inflation Reduction Act of 2022." JAMA Health Forum. (Optional)

Feb 21: 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.

Feb 26: Midterm Exam

Feb 28: No Class – MBA Core Exams

Mar 4: No Class – Spring Break

Mar 6: No Class – Spring Break

Part II: Industry Perspectives

Guest Speaker Lectures [Speakers and Dates Subject to Change]

Mar 11: Ethical Issues in Biopharma – Holly Fernandez Lynch, JD, Assistant Professor of Medical Ethics and Health Policy, Perelman School of Medicine, University of Pennsylvania

Mar 13: Vaccine Development and Distribution – Sean McElligott, Executive Director and Head, U.S. Health Economics Outcomes Research, Novartis

Mar 18: Inside the Black Box of PBM Negotiations – Steve Miller, MD, formerly Chief Clinical Officer, Cigna and Express Scripts

Mar 20: Orphan Drugs: Reimbursement and Pricing-- Brian Corvino, Principal, Life Sciences and Health Care Practice, Deloitte

Mar 25: Building a Biotech Company from the Ground Up – Emily Minkow, Venture Partner, RA Ventures (formerly Chief Business Officer, Prevail Pharmaceuticals)

Mar 27: Obesity Drug Innovation – John Steele, MSc, Vice President of Corporate Affairs, Diabetes and Obesity, Eli Lilly

Apr 1: The Generic and Biosimilar Industry – Alok Sonig, Executive Vice President and Group President, Pharmaceuticals, Baxter

Apr 3: Investing in Biopharma – Adam Koppel, MD, PhD, Partner and Managing Director, Life Sciences, Bain Capital

Apr 8: Innovation from External Sources – Henry Gosebruch, CEO, Neumora (formerly Chief Strategy Officer, AbbVie)

Part III: Student Presentations

Apr 10: Student Presentations

Apr 15: Student Presentations

Apr 17: Wrap-up/Student Presentations