Management and Economics of the Pharmaceutical and Biotech Industries

HCMG 2150 / 899

Spring 2023

[Last Updated 10/29/22]

Contact Information

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Teaching Assistants:
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Lectures

Class Meeting:

Monday and Wednesday, 1:45-3:15pm, SHDH 1206

Course Description

This course explores the key phases of the pharmaceutical and biotechnology product lifecycle. The product journey begins in the lab where scientists explore a vast array of compounds against diseases (therapeutic targets). Compounds that perform best enter the capital-intensive clinical trial phase aimed at assessing the product's safety and efficacy. In parallel, regulatory agencies guide and govern these trials and ultimately decide which products are approved for use in patients.

Once approved, launched, and priced, products face many dynamic market forces including competitors trying to steal share, government and private payers placing downward pressure on price, regulatory agencies controlling what manufacturers can and cannot say about their products, generic manufacturers challenging existing patents, and finally patients and physicians who behave both rationally and irrationally when deciding which product to use. While the course perspective is global in nature, the emphasis is on the U.S., the largest and most profitable market.

In addition, we will delve into the world of biotech start-ups from creation and financing, to how they make decisions which compounds to advance. We will also explore how large pharma views the biotech industry to bolster their existing pipelines and drive shareholder value.

Through case studies, readings, guest speakers, and in-class exercises, students will learn concepts and analytical frameworks and acquire the tools and skills necessary to become the future leaders of the pharmaceutical and biotech industry.

Course Learning Objectives

The key learning objectives for this course are to understand:

- the general structure of the pharmaceutical and biotech industry, the economics that drive it, and the key trends impacting the industry and its public perception
- the different phases of clinical trials, what questions get answered at each phase, and key data that determines whether a drug advances to the next phase
- the forces (e.g., regulatory bodies, government, payers, competition, patients, physicians, etc.) and incentives that impact how pharmaceutical / biotech firms compete in the market
- the planning that goes into launching a pharmaceutical product in the U.S., specifically product, place, promotion, and price (i.e., the four P's of marketing)
- the role that private and government health insurers play in managing the price and use of pharmaceutical and biotech products
- the role of biotechnology / genomics etc. in transforming the industry structure, how biotech start-ups get funded, and what healthcare focused venture capital firms look for when making investment decisions

Course Format

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

Course Materials

Readings: The textbook and 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).

Required textbook: "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

Class Participation	**30%**
Midterm Exam	**25%**
Term Project Presentation	**30%**
Case Write-ups (7.5% for each write-up)	**15%**

1. **Two Case Write-ups:** A heavy emphasis is placed on case study analysis and discussion. Students should come to class prepared to discuss all the assigned cases. Discussion questions

for each case will be posted on Canvas. In addition, each student must write-up responses to the case questions for ***two of the five 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 mid-term exam on ***March 1*** which accounts for 25% of your final grade

3. **Term Project Presentation:** Students will work in teams on a term project presentation. 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 22.*** Presentation slides are due via Canvas at on ***April 16*** and will be shared with the class. Teams will make presentations in class on ***April 17-April 26***. All team members must participate in the presentation.

4. **Class Participation:** Class participation makes up a significant portion of the final grade. The class participation grade will be assessed using a combination of attending all classes (including guest speakers and final project presentations) and actively participating during in-class discussions, especially the five in-class case study discussions. There are always unforeseen circumstances throughout the semester than may cause you to miss class (i.e., illness, death in the family, religious holiday, etc.). Therefore, missing up to **three** classes during the semester 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. Students should remain in attendance for the duration of class.

Name Tents
Given the emphasis placed on class participation, name tents will be provided. 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 11: Introduction and Course Overview

Readings:

- *Understanding Pharma*– Chapters 1 & 2
- CFRA Industry Surveys: Pharmaceuticals, April 2022
  Recommended reading order:
  1. "How the industry operates" (pp. 35-38)
  2. "Industry Snapshot" (pp. 5-11)
- Frakt, A. "Something Happened to U.S. Drug Costs in the 1990s." New York Times, November 12, 2018.

Jan 18: Drug Discovery, Development, and Clinical Trials

Readings:

- Case Companion (HBSP Product number: 7886-HTM-ENG) (an interactive introduction to case study analysis)
- *Understanding Pharma*—Chapter 4: Discovery (pp.73-84)

Jan 23: Drug Discovery, Development, and Clin. Trials (continued) & How to 'crack a case"

Readings:

- *Understanding Pharma*—Chapter 5: Drug Development (pp. 89-106)
- 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 25: Case Study Discussion #1 (to be or not to be a *research driven company*…..that is the question)

Readings:

- Organizing for Innovation at Glenmark (A)

Jan 30: Drug Development Optimization

Readings:

- Vertex Pharmaceuticals: R&D Portfolio Management (A) (pp. 12 – 15 & exhibit 7)

Guest Speaker:

- **How pharma / biotech decides which compounds to advance and which to cast aside**
    - o *Cody Powers, Principal and Head of Portfolio & Business Development Practice, ZS Associates*
    - o *Alex Schuth, Chief Operating and Financial Officer, Denali Therapeutics*

Feb 1: Case Study Discussion #2 (which products to keep and which to cast aside)

Readings:

- Vertex Pharmaceuticals: R&D Portfolio Management (A)

Feb 6: Case Study Discussion #3 (getting ready to launch)

Readings:

- *Understanding Pharma*– Chapter 8: Marketing and Brand Management (165-176)
- Schulze and Rengel. "What Matters Most in Commercial Success: First-in-Class or Best-in-Class?" *NRDD* June 2013.
- Product Team Cialis: Getting Ready to Market

Feb 8: Case Study Discussion #4 (relaunching a drug: is it worth it?)

Readings:

- MannKind Corporation: Take a Deep Breath, This Time Afrezza Will Work

Feb 13: Pricing & Reimbursement

Readings:

- Zaric, G. (2010). "Difficult Choices – An Introduction to Cost-Effectiveness Analysis." Ivey School of Business Note 910E07. July 2010. [available from Study.Net]
- 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.
- Lakdawalla, D. (2018) "Economics of the Pharmaceutical Industry." Journal of Economic Literature, 56(2). pp. 427-436.

Feb 15: Pricing & Reimbursement (Cont'd)

Readings:

- Kesselheim, et al. (2016). "The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform." JAMA, 316(8):858–871.
- Rockoff, J. "How Pfizer Set the Cost of Its New Drug at $9,850 a Month" Wall Street Journal. December 9, 2015.
- 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.
- Scannell, J.W. "Four Reasons Drugs are Expensive, of Which Two are False." Forbes. October, 13, 2015.

Feb 20: Case Study Discussion #5 (how to price a new drug?)

Readings:

- Merck: Pricing Gardasil

Feb 22: Orphan Drugs: Reimbursement and Pricing

Guest Speaker:

- Brian Corvino, Managing Director, Life Sciences and Health Care Practice, Deloitte

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 1: Midterm Exam (in-class)

Mar 6: No Class (Spring Beak)

Mar 8: No Class (Spring Break)

Mar 13: Trade and Distribution

Readings:

- *Understanding Pharma*—Chapter 12: Trade and Distribution (pp. 255-270)
- Kaiser Family Foundation. (2005). "Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain."

Part II: Industry Perspectives *(speakers and dates subject to change)*

Mar 15: Investing in Biotech Companies – Adam Koppel, MD, PhD, Managing Director, Life Sciences, Bain Capital

Mar 20: Inflation Reduction Act (IRA) of 2022: Impact on Drug Pricing and Innovation – Mark McClellan, MD, PhD, Professor of Business, Medicine, and Policy, and founding Director of the Duke-Margolis Center for Health Policy at Duke University

Mar 22: Inside the Black Box of PBM negotiations – Steve Miller, MD, Chief Clinical Officer, Cigna (formerly Express Scripts)

Mar 27: Innovation from External Sources – Debbie Baron, Senior Vice President of Worldwide Business Development, Pfizer, Inc.

Reading: Wang, N., Burr A., Powers, C. (October 17, 2022), "Why pharma needs to shift to an 'innovation constellation' investment strategy". (https://www.zs.com/insights/why-pharma-needs-an-innovation-constellation-investment-strategy)

Mar 29: **Innovation from External Sources** - Henry Gosebruch, Chief Strategy Officer, AbbVie

Apr 3: **Investing in Early-Stage Biotech Companies** – Cami Samuels, Partner, Venrock

Apr 5: **Starting a Biotech Company from the Ground Up** – John Crowley, Executive Chairman, Amicus Therapeutics

Apr 10: **Starting a Biotech Company from the Ground Up** – Maria L. Maccecchini Ph.D., Founder, President & CEO, Annovis

Apr 12: **What Makes for a Strong, Effective Biotech Leader: Lessons Learned from the Past 30 years** – Alex C. Sapir

Part III: Student Presentations

Apr 17: Student Presentations

Apr 19: Student Presentations

Apr 24: Student Presentations

Apr 26: Student Presentations / Wrap-up / Course Evaluations