Management and Economics of the Pharmaceutical & Biotech Industries

HCMG 215/899

Spring 2018

[Last Updated 1/3/18]

Contact Information

Professor: Abby Alpert
***Office*: Colonial Penn Center 303**
Email: alpertab@wharton.upenn.edu
***Office Hours:* Tuesday & Thursday 3:00-4:00 pm, or by appointment**

Teaching Assistant: Sarah Dykstra
Email: sdykstra@wharton.upenn.edu
***Office Hours:* By Appointment**

Lectures

Class Meeting:

Tuesday and Thursday, 1:30-2:50pm, SHDH 1206

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 : The *required* textbook for this class is "Understanding Pharma: the Professional's Guide to How Pharmaceutical and Biotech Companies Really Work," by John J. Campbell, 2nd edition.

Additional readings are listed below and will be posted on the course website (cases are available through Study.Net).

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	**20%**
Midterm Exam	**40%**
Term Project	**30%**
Class Participation	**10%**

1. **Two Case Write-ups (20%):** 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 (40%):** There will be an in class midterm exam on ***Tuesday, February 27.***

3. **Term Project (30%):** Students will work on a term project in teams of up to five 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 March 1.*** The team's final write-up (max. 10 pages plus optional tables) is due via Canvas at the ***beginning of class on April 12.*** 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 and periodic online exercises. Missing one or two classes will not lower your participation grade. Beyond these two classes, I will only excuse absences for which I receive an email from the College (or relevant Department) Office.

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.

Laptops
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
- Standard & Poor's Industry Surveys: Pharmaceuticals, June 2017 (pp. 7-45)
  Recommended reading order:
  1. "How the industry operates" (pp. 35-45)
  2. "Industry trends" (pp. 23-34)
  3. "Industry overview" (pp. 7-22)

Jan 16: Drug Discovery, Development, and Clinical Trials

Readings:

- *Understanding Pharma*– Chapters 4 & 5
- DiMasi, J and H. Grabowski (2012). "R&D Costs and Returns to New Drug Development" Ch. 2 in Handbook on the Economics of the Pharmaceutical Industry, eds. Danzon and Nicholson.
- Carpenter, Daniel (2004). "The Political Economy of FDA Drug Review: Processing, Politics, and Lessons for Policy." Health Affairs, 23(1):52–63.
- 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 18: Incentives for Innovation

Readings:

- **Case:** 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 23: Marketing and Commercialization

Readings:

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

Jan 25: 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.
- Garthwaite and Duggan (2012). "Empirical Evidence on the Value of Pharmaceuticals." The Oxford Handbook of the Economics of the Biopharmaceutical Industry, pages 463–492.

Jan 30: Measuring the Value of Pharmaceuticals in Practice

- **Guest speaker:** Scott Johnson, Principal, Medicus Economics

Feb 1: Managed Markets: The Role of Insurers in Managing Pharmaceutical Use

Readings:

- *Understanding Pharma*– Chapter 10
- Kaiser Family Foundation. 2005. "Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain."
- Koons, C. and R. Langreth. "That Drug Coupon Isn't Really Clipping Costs" Bloomberg Businessweek, December 23, 2015.

Feb 6: 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 8: Pricing and Reimbursement: U.S.

Readings:

- **Case:** 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.
- Kesselheim, et al. (2016). "The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform." JAMA, 316(8):858–871.
- Scannell, J.W. "Four Reasons Drugs are Expensive, of Which Two are False." Forbes. October, 13, 2015.

Feb 13: Pricing and Reimbursement: International

- **Case:** 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.
- "Failure to Launch." Editorial in Nature Biotechnology, Jan 2013 (Vol. 31. No. 1).

Feb 15: Generics and Biosimilars

- Wechsler. "Brand Generic Wars Heat Up." Pharmaceutical Executive Oct. 2013
- 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 20: Pharmaceuticals vs. Medical Devices

- Standard & Poor's Industry Surveys: Health Care Equipment and Supplies, October 2017 (pp. 5-34)
  Recommended reading order:
  1. "How the industry operates" (pp. 29-34)
  2. "Industry trends" (pp. 15-28)
  3. "Industry overview" (pp. 5-14)

Feb 22: Review Session/Catch-up

Feb 27: Midterm Exam

Part II: Industry Perspectives

Guest Speaker Lectures [Speakers and Dates Subject to Change]

Mar 1: Entrepreneurship in Pharma and Biotech: Application to Alzheimer's Disease– Maria Maccecchini, CEO and Founder, QR Pharma

Mar 6: Spring Break

Mar 8: Spring Break

Mar 13: Pharmaceutical Pricing and Reimbursement in Europe – Volker Janssen, Senior Partner, Simon-Kucher & Partners

Mar 15: Innovation from External Sources, M&A/L&A – Henry Gosebruch, Chief Strategy Officer, AbbVie

Mar 20: Pharmaceutical Markets in Asia – Donald Yin, Associate VP and Head, Global Health Outcomes, Merck

Mar 22: TBD

Mar 27: Inside the Black Box of PBM Negotiations – Steve Miller, Chief Medical Officer, Express Scripts

Mar 29: Gene Therapies – Jeffrey Marrazzo, CEO and Co-Founder, Spark Therapeutics

Apr 3: The Generic Drug Industry –Alok Sonig, Executive Vice President, Head of Dr. Reddy's, North America

Apr 5: Artificial Intelligence for Pharma R&D – Niven Narain, CEO and Co-Founder, BERG

Apr 10: TBD

Apr 12: Valeant Case Study – Scott Hirsch, Head of Business Strategy, Valeant Pharmaceuticals

Part III: Student Presentations

Apr 17: Wrap-up/Student Presentations

Apr 19: Student Presentations

Apr 24: Student Presentations