Management and Economics of the Pharmaceutical, Biotech & Medical Device Industries

HCMG 863

Spring 2017

[Last Updated 1/10/17]

Contact Information

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***Office Hours:* By Appointment**

Lectures

Class Meeting:

Tuesday and Thursday, 10:30-11:50am, Colonial Penn Center (CPC) Auditorium

Course Objectives

This course provides an overview of the management, economic and policy issues facing the pharmaceutical, biotechnology and medical device 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 required cases*** listed in the syllabus. You may work in teams (no more than 5 people) 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 (supporting material may be in an appendix). An electronic copy of your write-up must be submitted via Canvas by ***5:00 pm the day before the case is to be discussed***. Please also bring a hard copy to class.

2. **Midterm Exam (40%):** There will be an in class midterm exam on ***Thursday, February 23 .***

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 2.*** The team's final write-up (max. 10 pages plus optional tables) is due via Canvas at the ***beginning of class on April 13.*** 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 in class exercises and online questions. Missing up to two participation assessments will not affect your grade.

Classroom Guidelines and Policies – "Concert Rules"

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. 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
All phones, laptops, and other electronic devices should be turned off.

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 & Medical Device Industries

Jan 12: Introduction and Course Overview

Readings:
- *Understanding Pharma*– Chapters 1 & 2
- Standard & Poor's Industry Surveys: Pharmaceuticals, May 2016 (pp. 14-23, 35-53)
  Recommended reading order:
  1. "How the industry operates" (pp. 44-53)
  2. "Industry trends" (pp. 35-43)
  3. "Industry overview" (pp. 14-23)

Jan 17: 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.
- Parker, Ian (2013). "The Big Sleep," *The New Yorker,* December 9, 2013.

Jan 19: Incentives for Innovation

Readings:

- **Case:** Organizing for Innovation at Glenmark (A)
- 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 24: 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 26: 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.
- Raftery and Powell, "Health Technology Assessment in the UK" Lancet 2013:328.

Jan 31: 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 2: 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 7: 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.

- Wechsler, "Outrage Grows over Drug Pricing" *Pharmaceutical Executive* Nov. 2014.

Feb 9: 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 14: Generics and Biosimilars

- **Case:** Teva Pharmaceuticals, Ltd. **(background reading, not for write-up)**
- 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 16: Medical Devices: Overview

- Standard & Poor's Industry Surveys: Health Care Equipment and Supplies, October 2016 (pp. 12-17, 22-41)
  Recommended reading order:
  1. "How the industry operates" (pp. 36-41)
  2. "Industry trends" (pp. 22-35)
  3. "Industry overview" (pp. 12-17)
- Sorenson et al. (2013). "Evolving Reimbursement and Pricing Policies for Devices in Europe and the U.S. Should Encourage Greater Value." *Health Affairs* 32(4):788-796.

Feb 21: Review Session/Catch-up

Feb 23: Midterm Exam

Part II: Industry Perspectives

Guest Speaker Lectures [Speakers and Dates Subject to Change]

Feb 28: Data Analytics for Pharmaceuticals– Scott Johnson, Principal, Medicus Economics

Mar 2: Entrepreneurship in Pharma and Biotech– Maria Maccecchini, CEO and Founder, QR Pharma

Mar 7: Spring Break

Mar 9: Spring Break

Mar 14: Pharmaceutical Marketing – Sharon DeBacco, Vice President Product Promotion & Communication, Ironwood Pharmaceuticals

Mar 16: Investing in Pharma and Biotech – Joshua Schimmer, Managing Director, Piper Jaffray

Mar 21: Generic Drugs and the Pharmaceutical Market in India –Alok Sonig, Executive Vice President, Head of Dr. Reddy's, North America

Mar 23: Pharmaceutical Pricing and Reimbursement in Europe– Brian Corvino, COO & Jason Ward, Partner, Decision Resources Group

Mar 28: Pharmaceutical Markets in China – Donald Yin, Associate VP and Head, Global Health Outcomes, Merck

Mar 30: Valeant Case Study – Scott Hirsch, Head of Business Strategy, Valeant Pharmaceuticals

Apr 4: Corporate Strategy, M&A/L&A – Henry Gosebruch, CSO, AbbVie

Apr 6: Medication Adherence Strategies for Pharma – Andrea LaFountain, CEO, Mind Field Solutions

Apr 11: The Market for Vaccines – Sean McElligott, Director, Johnson & Johnson

Apr 13: Market Access – Speaker TBD

Part III: Student Presentations

Apr 18: Wrap-up/Student Presentations

Apr 20: Student Presentations

Apr 25: Student Presentations