THE WHARTON SCHOOL
University of Pennsylvania

The Management and Economics of the Pharmaceutical, Biotech & Medical Device Industries
HCMG 215
SPRING 2011

Monday/Wednesday; 12:00 – 1:30 PM
JMHH 240

Professor Patricia Danzon (danzon@wharton.upenn.edu)
Office Hours: By appointment (Colonial Penn Center 207)

Teaching Assistant: Andrew Mulcahy (mulcahaw@wharton.upenn.edu)
Office Hours: By appointment (Colonial Penn Center, 4th Floor)

Administrative Assistant: Jennifer Laverty (jlaverty@wharton.upenn.edu)
Office: Colonial Penn Center, Room G-1 (Basement Level)

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 and genomics 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 and complex deals and alliances;
- Global products and multinational firms, with growing tension between the needs and ability to pay of different market segments.

COURSE FORMAT

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

COURSE PRE-REQUISITES

One course in Health Care (HCMG 101, 202, 203, 204, 211 or 212) or one course in Economics or equivalent experience with permission of instructor.

GRADING

Final exam: 40% | Term project: 25% | Case write-ups: 20% | Participation: 15%

TERM PROJECTS

Students will work on a term project, in teams of 3-5. A list of possible topics will be provided or you may select your own topic, subject to approval of the instructor. These projects will be presented in class. A memo (approx. one page) outlining your topic and approach is due March 2. The final write-up (max. 10 pages plus optional tables) is due in class April 18th.

CASES

Students should come to class prepared to discuss all the assigned cases (*shown in italics below*). Each student must write up two cases (your choice). Specific questions for each case will be posted on webCafé. The case write-ups should be submitted to Andrew (mulcahaw@wharton.upenn.edu) by 5pm the day before the class in which the case is to be discussed. Maximum length 2 pages. Case write-ups are to be done individually.

READINGS

All course readings are required unless marked as optional on the syllabus. The main concepts/takeaways from readings will be discussed in class and are fair game for exam questions. You will not be tested on minutiae, e.g., specific dates, names, or minor statistics.

The course pack is available in two parts: Part I first includes readings through February 7 and Part II includes readings from February 9 through the end of the semester. Part II will be available for purchase in late January.

Every student enrolled in the class must pay the copyright fee on Study.net for Part I and Part II of the course pack. Study.net records how many/which students pay this fee. Once you pay the fee you have several options to access the course readings:

A.) All readings are posted on webCafé in lecture-specific folders. You can view or print the readings on your own from webCafé.
URL: https://webcafe.wharton.upenn.edu/eRoom/hcmg/215-sp11-1

B.) You can also view/print individual readings via Study.net. This is not recommended due to stability and quality issues at Study.net.
URL: http://www.study.net/r_mat.asp?crs_id=30018477

C.) You have the option to order a printed bulkpack. Bulkpacks are ordered via Study.net and picked up at Wharton Reprographics in SHDH.

The recommended reading order for each lecture is as indicated on the syllabus reading list below. Please keep in mind that reading updates and changes will be available only on webCafé. We will email the class whenever a change is made and will post an updated syllabus on webCafé.

WEBCAFÉ ACCESS

All students registered for the course require access to webCafé. Students who have a Wharton account will automatically have access the webCafé once they register for the class. Students who do not yet have a Wharton account can create one at **http://accounts.wharton.upenn.edu**. If you have problems, contact the webCafé consultants at the WCIT office or online. Class handouts and other materials will be posted on the webCafé.

CLASS SCHEDULE AND READINGS

January 12: Introduction

- Standard & Poor's *Industry Surveys: Pharmaceuticals*, November 2010. If you are unfamiliar with the pharmaceutical industry we suggest the following reading order:
    1. "How the industry operates" (pp. 18-29)
    2. "Industry profile" (pp. 8-17)
    3. "Current environment" (pp. 1-7)
    4. OPTIONAL: "How to analyze a pharmaceutical company" (pp. 30-35)

January 17: Martin Luther King Day- NO CLASS

January 19: Global Pharma-Biotech Industry: Structure, Conduct and Performance

- S&P Industry Surveys: Biotechnology, August 2010. If you are unfamiliar with the biotechnology industry we suggest the following reading order:
    1. "How the industry operates" (pp. 17-25)
    2. "Industry profile" (pp. 9-17)
    3. "Current environment" (pp. 1-8)
- Aitken, Berndt et al (2009). "Prescription Drug Spending in the US: Looking Beyond the Turning Point" *Health Affairs* 28(1) 2009.
- Sehgal, C. (2010). "Change at Pfizer: Jeff Kindler (A)." Ivey School of Business Case 9B10M014. Version (A) 2010-01-27. (Not for write-up).
- OPTIONAL: Kaiser Family Foundation. "Follow the Pill: Understanding the US Commercial Pharmaceutical Supply Chain." March 2005.

January 24: R&D: Regulation, Costs and Returns

- DiMasi, J and H. Grabowski (2007). "The Cost of Biopharmaceutical R D: is Biotech Different?" *Managerial and Decision Economics* 2007 28(4) pp. 469-479.
- McCaughan, M. (2007). "Adapting to a Tiered Regulatory System." RPM Report Nov. 2007.
- Morrison, C. (2010). "Pharma: Serious about change?" IN VIVO Oct. 2010.
- OPTIONAL: Congressional Budget Office (2006). "Research and Development in the Pharmaceutical Industry." October 2006. *NOTE: Read Chapters 1-3 and Chapter 6.*
- OPTIONAL: Pettersson, A. et al (2009). "Pharma R&D: Doing the Same Thing That Didn't Work Before." IN VIVO April 2009

January 26: Cost-Effectiveness and Comparative Effectiveness Analysis

- Zaric, G. (2010). "Difficult Choices – An Introduction to Cost-Effectiveness Analysis." Ivey School of Business Note 910E07. July 2010.
- Ratner, M. (2009). "Advancing Comparative Effectiveness Research: An Interview with Sean Tunis." IN VIVO Sept. 2009.
- Chalkidou,K. and T. Walley (2010). "Using Comparative Effectiveness Research to Inform Policy and Practice in the UK NHS: Past, Present and Future." *Pharmacoeconomics* 28(10).

January 31: Pharmaceutical Marketing

- Campbell, J. (2005). *Understanding Pharma: A Primer on How Pharmaceutical Companies Really Work.* Pharmaceutical Institute, 2005. *Note: Read Chapter 3 (Pharma Customers) and Chapter 7 (Marketing and Brand Management) only.*

February 2 : Marketing and Commercialization: Metabical and Humira Cases

NOTE: Metabical and Humira cases eligible for write-up, but ***do not write up both.***

- *Case: Metabical: Pricing, Packaging & Demand Forecasting for a New Weight-Loss Drug.*
- *Case: Abbott Laboratories and HUMIRA: Launching a Blockbuster Drug*
- Mello, M. et al (2009). "Shifting terrain in the regulation of off-label promotion of pharmaceuticals." *NEJM* 360(15):1557-66. April 9, 2009.

February 7: Pricing, Reimbursement 1: Basic principles; Medicines Company Case

- *Case eligible for write-up: The Medicines Company. HBS: 9-502-076.*
- Berndt, E. (2002). "Pharmaceuticals in US Health Care: Determinants of Quantity and Price" *J. Econ. Perspectives* 16(4):45-66. Fall 2002.
- McCaughan, M. (2010). "Second-guessing FDA: CMS' expanding regulatory role." RPM Report, Sept. 2010.
- OPTIONAL: Outterson, K. and A. Kesselheim (2009). "How Medicare Could get Better Prices on Prescription Drugs." *Health Affairs* 28(5):w832-41. July 2009.

--- END OF PACK I, START PACK II ---

February 9: Pricing and Reimbursement 2: Reimbursement in the US - Brian Corvino, Partner, PharmaStrat Inc.

- Academy of Managed Care Pharmacy (2009). "AMCP Guide to Pharmaceutical Payment Methods 2009 Update." *J Managed Care Pharm* 15(6-a). August 2009. *NOTE: Executive Summary required, remainder is optional/to be skimmed.*
- McCaughan, M. (2010). "Straight talk about cancer drug coverage." RPM Report Dec. 2010.
- Baghdadi, R. (2010). "Dendreon vs. CMS: "Full Coverage or the CED Solution?", RPM Report November 2010.

February 14 : Pricing and Reimbursement 3: Regulation ex-US

- OECD (2009). "Chapter 4: Ensuring Efficiency in Pharmaceutical Expenditures." From *Achieving Value for Money in Health Care,* 2009.
- Senior, M. (2009). "Pricing Experiments: Pharmas get Creative in Germany" IN VIVO July 2009.
- PPR (2010). "Pricing and Reimbursement of Reformulations: European Case Studies." Pharma Pricing Review January 2010.
- Clement, F. et al (2009). "Using Effectiveness and Cost-Effectiveness to Make Drug Coverage Decisions: A Comparison of Britain, Australia and Canada." JAMA 302(13):1437-1443.

February 16: Biotech Financing: Venture capital and deals – Brenda Gavin, Managing Partner, Quaker Bioventures

- Brealey and Myers, "How Corporations Issue Securities" from *Principles of Corporate Finance*, p. 405-416
- Robbins-Roth, "Initial Public Offerings" from *From Alchemy to IPO: The Business of Biotechnology.* Basic Books, May 2000.

February 21: March 2: Biosimilars; Truvada Case

- *Case eligible for write-up: Gilead: Launching Truvada in Europe. Stanford Case.*
- Moran, N. (2008). "Fractured European market undermines biosimilar launches." *Nat Rev Drug Disc* 26(1):5-6 January 2008.
- Rawson, K. (2010). "FDA's Balancing Act: Early Hints at a Biosimilars Approval Pathway." RPM Report November 2010
- OPTIONAL: Danzon, P. and M. Furukawa (2006). "Prices and Availability of Biopharmaceuticals: An International Comparison." *Health Affairs* 25(5):1353. 2006.

February 23: Trends in Deals - Chris Morrison, Elsevier, Editor-in-Chief, Biopharma

- Morrison, C. and E. Licking (2010). "Pharma: Serious about Change?" IN VIVO Oct. 2010.
- Morrison, C. and R. Longman (2009). "Dealmaking When Pharma's the Only Game in Town." IN VIVO September 2009.

February 28: Washington Update: FDA and CMS - Mike McCaughan, Senior Editor, The RPM Report

- McCaughan, M. (2010). "Health care reform: For biopharmas there is much to like." IN VIVO April 2010.
- McCaughan, M. (2007). "Access and Evidence: Implications of the EPO Safety Debate" RPM Report October 2007.
- McCaughan, M. (2010). "REMS 2.0: FDA refining new drug safety tools." RPM Report November 2010.
- McCaughan, M. (2009). " Genomics Revolution Meets Regulatory Evolution: Why Personalized Medicine is Taking So Long" RPM Report October 2009.

March 2: Working with Payers

- Gupta, A. et al (2010). "Increasing the odds of new pharma product access: engage payors during product development." IN VIVO September 2010.
- Hamermesh, R. et al (2010). "Managing Drugs on the Forefront of Personalized Medicine: The Erbitux and Vectibix story. HBS Note. March 2010.
- Hamermesh, R. et al (2010). "Plavix: Drugs in the Age of Personalized Medicine." HBS Note. November 2010.

March 7 and 9: Spring Break

March 14: Managing a Biotech Company/Managing People – Jay Moorin, Managing Partner, ProQuest Investments and formerly CEO, Magainin Pharmaceuticals.

- Jacquet, P. and J. Hodgson (2006). "Biopharma: Beyond the First Product." IN VIVO June 2006.
- Booth, B. (2009). "Beyond the Biotech IPO: A Brave New World." *Nature Biotech* 27(8):705-709. August 2009.

March 16: Biotech strategy : IP and Deals

- *Case eligible for write-up: Alnylam Pharmaceuticals: Building Value from the IP Estate (HBS).*
- Mehta, A. et al (2009). "New Frontiers In Pharma R&D Investment." IN VIVO Nov. 2009.

March 21: Vaccines and Vaccine Pricing: Juan Gil, Director of Marketing, Merck Vaccines TBC - Gardasil Case

- *Case eligible for write-up: Merck: Pricing Gardasil Kellogg KEL 400*
- Silverman, E. (2009). "The Vaccine Market Grows Up: They're not Just for Kids Anymore." IN VIVO July 2009.
- Kresse, H. and M. Shah (2010). "Strategic trends in the vaccine market." *Nat Rev Drug Disc* 9:913-914. December 2010.
- OPTIONAL: Danzon, P. et al (2005). "Vaccine Supply: A Cross-National Perspective." *Health Affairs* 24(3):706. May/June 2005.

March 23: Corporate Strategy – M&A -- Steve Sands, Vice Chair and Global Co-Head, HC Investment Banking, Lazard TBC

- Baldwin, C. et al (2010). "Roche's Acquisition of Genentech" HBS Case. (Not for write-up).
- Longman, R. (2009). "Merck buys Schering-Plough….and Time." IN VIVO March 2009.
- Diller, W. (2009). "Pfizer's Ambitions in the Off-Patent World." IN VIVO March 2009.
- Papp, T. (2010). "The Rise of Option Agreements." *Nat Rev Drug Disc* (9):422. June 2010.

March 28: India's Pharmaceutical Industry: Vishwas Seshadri, Celgene; Dr. Reddy Case

- *Case eligible for write-up: Dr. Reddy's Laboratories (A): Ivey Case 908M64*
- Oortwijn, W. et al (2010). "The role of health technology assessment on pharmaceutical reimbursement in selected middle-income countries." *Health Policy* 95(2010):174-184.

March 30: Medical Devices: Overview

- S&P Industry Surveys: Health Care Products and Supplies, August 2010. *NOTE: We recommend the following sections and reading order:*
  1. "How the industry operates" (pp. 30-37)
  2. "Industry profile" (p. 16-29)
  3. "Current environment" (pp. 1-15).
- Chai, J. (2000). "Medical device regulation in the US and the EU." *Food and Drug Law Journal*. 55:57-80.

April 4: Pharma and Device Strategies in Emerging Markets -- TBC

- Wong, J. et al (2009). "China's Health Care Reform: Bull Run for Medtech Starts in the Year of the Ox." IN VIVO Nov. 2009.
- Sun, Q. et al (2008). "Pharmaceutical Policy in China." *Health Affairs* 27(4):1042-50. July/August 2008.
- Diller, W. (2009). "Emerging Pharma Markets: Adapt, Diversify and Persist." IN VIVO 6.09.
- Witty, "New Strategies for Innovation in Global Health: A Pharmaceutical Industry Perspective." *Health Affairs* 30(1) 2011.
- OPTIONAL: Licking, E. (2010). "The Importance of Emerging Markets" IN VIVO October 2010.
- OPTIONAL: Li, Y. et al. "Viagra in China: A Prolonged Battle over IP Rights." Columbia Case (Not for write up).

April 6: Medical Device Start-Ups – David Anderson, President and CEO, Gentis Inc. TBC

- Filmore, D. and S. Levin (2009). "HC Reform Targets Medical Devices." IN VIVO May 2009.
- Salemi, T. (2009). "Have Device VCs bet too Big?" IN VIVO Sept. 2009.

April 11: Evolving Sales Force Strategies – Jaideep Bajaj, Managing Director, ZS Associates

- Rickwood, S. (2008). "Blow the Launch- Doom the Product." IN VIVO Oct. 2008.
- Edmunds, R. (2009). "Transforming Pharma's Commercial Capabilities to Drive Maximum Value." IN VIVO May 2009.
- ZS Report TBD

April 13: The Generic Drug Industry – William Marth, CEO, TEVA USA

- Padden, M. and T. Jenkins (2004). "Hatch Waxman Changes." *National Law J.* Feb 23, 2004.
- Pozen, R. and E. Leonard (2009). "Note on Generic Drugs in the European Union." HBS Note May 28, 2009.
- PPR (2009). "Preliminary Results of European Commission Pharmaceutical Sector Inquiry." Pharma Pricing Review Jan. 2009.
- Merrill, J. (2010). "Opening the door to biosimilars in the US." IN VIVO Sept. 2010.
- OPTIONAL: Teva Pharmaceuticals, Ltd. HBS Case 9-707-441 (Not for write-up).

April 18: Presentations

April 20: Presentations

April 25: Presentations

Final exam: Thursday, May 5, 9-11am