THE WHARTON SCHOOL
University of Pennsylvania

The Management and Economics of the Pharmaceutical, Biotech & Medical Device Industries
HCMG 863
SPRING 2012

Monday/Wednesday; 3:00 – 4:30 PM
JMHH 350

Professor Patricia Danzon (danzon@wharton.upenn.edu)
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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

GRADING

Final exam (May 3rd - 9am)	40%
Term Project	25%
Cases	20%
Class participation	15%

TERM PROJECTS

Students will work on a term project, in teams of 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. The final write-up (max. 10 pages plus optional tables) is due in class April 16th.

CASES

Case questions will be posted on Canvas. All cases should be prepared for class discussion. Each team is responsible for one write up of each case (shown in italics below). Please email cases write-ups to Holly Cronin at hcronin@wharton.upenn.edu, by 5pm the day before the class in which the case is to be discussed. Case write-ups should not exceed 2 pages, excluding any supporting material.

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 are not expected to remember minutiae, e.g., specific dates, names, or minor statistics.

The course pack is available in two parts: Part I includes readings through February 13 and Part II includes readings from February 15 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 fees 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 available through Penn Libraries are posted in lecture-specific folders on Canvas within the Files menu. You can view or print the readings on your own from Canvas. **https://wharton.instructure.com/courses/183107**

B.) Cases and readings not available through Penn Libraries must be accessed via Study.net. **https://spike.wharton.upenn.edu/studynet/coursepack.cfm?CourseCode=2012A,HCMG863001**. A link to the Study.net course pack is available directly from the Canvas course home page.

C.) You have the option to order a printed bulkpack of the material on Study.net. 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 Canvas. We will email the class whenever a change is made and will post an updated syllabus on Canvas.

CANVAS ACCESS

All students registered for the course need access to Canvas. Students who have a Wharton account will automatically have access 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 consultants at the WCIT office or online. Class handouts and other materials will be posted on Canvas.

CLASS SCHEDULE AND READINGS

January 11: Introduction

- Standard & Poor's Industry Surveys: Pharmaceuticals, December 2011. If you are unfamiliar with the pharmaceutical industry we suggest the following reading order:
    1. "How the industry operates" (pp. 26-35)
    2. "Industry profile" (pp. 14-26)
    3. "Current environment" (pp. 1-13)
    4. OPTIONAL: "How to analyze a pharmaceutical company" (pp. 37-42)

January 16: Martin Luther King Day- NO CLASS

January 18: Global Pharma-Biotech Industry: Structure, Conduct and Performance

- S&P Industry Surveys: Biotechnology, August 2011. If you are unfamiliar with the biotechnology industry we suggest the following reading order:
    1. "How the industry operates" (pp. 19-27)
    2. "Industry profile" (pp. 10-19)
    3. "Current environment" (pp. 1-9)
- EBI Biopharma Team "A Look Back at 2010: In Search of New Biopharma Models" IN VIVO Jan. 2011.
- OPTIONAL: Kaiser Family Foundation. "Follow the Pill: Understanding the US Commercial Pharmaceutical Supply Chain." March 2005.

January 23: 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.
- "Mind the Gap: Different Views of Success May Drive Large Differences in Estimates of Pharma Value" IN VIVO Apr 2011.
- McCaughan, M. "Adapting to a Tiered Regulatory System." RPM Report Nov. 2007. *[Study.Net]*
- OPTIONAL: Sampat and Lichtenberg (2011). "What Are The Respective Roles Of The Public And Private Sectors In Pharmaceutical Innovation?" Health Affairs Feb 2011.
- OPTIONAL: Congressional Budget Office (2006). "Research and Development in the Pharmaceutical Industry." October 2006. *Chapters 1-3 and Chapter 6.*

January 25: Biotech Financing and Strategy

- *Case: PureTech Ventures HBS 9-712-419. [Study.Net]*
- Lash, A. "Your First Drug"s Approved And Launched... Now What?" IN VIVO Jul/Aug 2011.
- Licking, E. "Back to School: Big Pharmas Test New Models for Tapping Academia." IN VIVO Feb 2011.

January 30: Marketing and Commercialization: Humira and Gardasil Cases

NOTE: Read both cases, but choose only ONE for write up.

- *Case: Abbott Laboratories and HUMIRA: Launching a Blockbuster Drug. [Study.Net]*
- *Case Merck: Pricing Gardasil Kellogg KEL 400. [Study.Net]*
- Kresse, H. and M. Shah (2010). "Strategic trends in the vaccine market." *Nat Rev Drug Disc* 9:913-914. December 2010.
- "Off-Label Changes Coming? Sorrell Ruling Prompts New Legal Challenges" RPM Report Nov 2011. *[Study.Net]*

February 1: Pricing and Reimbursement: Basic principles and the US

- Danzon and Taylor "Drug Pricing and Value in Oncology." *The Oncologist*. 2010:15(suppl 1):24-31.
- 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. "Straight Talk About (CMS) Cancer Drug Coverage." RPM Report Jan 2011. *[Study.Net]*
- "Dendreon vs. CMS: Full Coverage or the CED Solution?" RPM Report November 2010. *[Study.Net]*

February 6: 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. *[Study.Net]*
- 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).
- "Comparative Effectiveness Research: Who Will Do The Studies?" Health Affairs Nov 2010.

February 8: Pricing and Reimbursement in Regulated Markets ex-US: Truvada Case

- *Case for write-up: Gilead: Launching Truvada in Europe. Stanford Case OIT-94 8/27/09. [Study.Net]*
- OECD (2009). "Chapter 4: Ensuring Efficiency in Pharmaceutical Expenditures." From *Achieving Value for Money in Health Care,* 2009.
- Danzon et al. "Setting Cost-Effectiveness Thresholds As A Means To Achieve Appropriate Drug Prices In Rich And Poor Countries." *Health Affairs* Aug 2011.

February 13: Working with Payers ex-US: Case Studies - Farhad Riahi MD MBA, Head, Health Care Systems, Novartis

- Senior, M. (2009). "Pricing Experiments: Pharmas get Creative in Germany" IN VIVO 7/09 and "The New German Reimbursement System" http://www.valueandinnovation.net/2012/01/the-new-german-reimbursement-system-nothings-a-slam-dunk/.
- PPR (2010). "Pricing and Reimbursement of Reformulations: European Case Studies."
- Moran, N. (2008). "Fractured European market undermines biosimilar launches." *Nat Rev Drug Disc* 26(1):5-6 January 2008.
- Morel et al. "The Level of Income Appears to Have No Consistent Bearing on Pharmaceutical Prices Across Countries." *Health Affairs* Aug 2011.

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

February 15: R&D Productivity Management – John Keller PhD, VP Corporate Development and Strategy, Shionogi, Inc.

- Huckman et al (2010). "Wyeth Pharmaceuticals: Spurring Scientific Creativity with Metrics." HBS Case 2007-8 2007, Rev. April 6, 2010. *Read for discussion.* (Not for write-up). *[Study.Net]*
- Senior, M. "Putting the Pieces Together Again: GSK Creates End-to-End Business Units." IN VIVO Jan 2011.
- Behnke. "Changing Pharma"s Innovation DNA." IN VIVO Feb 2011.

February 20: Medical Devices: Overview

- S&P Industry Surveys: Health Care Products and Supplies, August 2011. *NOTE: We recommend the following sections and reading order:*
    1. "How the industry operates" (pp. 33-37)
    2. "Industry profile" (p. 17-33)
    3. "Current environment" (pp. 1-16)
- Chai, J. (2000). "Medical device regulation in the US and the EU." *Food and Drug Law Journal*. 55:57-80.

February 22: Trends in Deals - Chris Morrison, Elsevier , Editor-in-Chief, Biopharma

- Morrison, C. "Merck's Capital Idea: Industry's Latest Push To Strengthen VC Ties." IN VIVO Sep 2011.
- Morrison, C. "IND Over POC: The New Sweet Spot for Biopharma Dealmaking?" IN VIVO Oct 2011.

February 27: Personalized Medicine, Diagnostics and Therapeutic Vaccines - Dr. Steve Nichtberger, formerly President and CEO, Tengion

- *Case: Tengion: Bringing Regenerative Medicine to Life. [Study.Net]*
- Davis et al. "The microeconomics of personalized medicine: today's challenge and tomorrow's promise." *Nat Rev Drug Disc* 8:279-86. April 2009.
- Ratner. "Personalized Medicine in 2010: Welcome to the Establishment." IN VIVO Jan 2011.
- Ratner. "Is Diagnostics the New Biotech And Will Pharma Embrace It?" IN VIVO Sep 2011.

February 29: Working with Payers - Roger Longman, CEO Value and Innovation, formerly Managing Director, Pharma, Elsevier Business Intelligence

- See recent posts on www.valueandinnovation.net/blog.
- Wang and Svoboda. "New Blueprint for Market Access Architecture." RPM Report Dec 2011. *[Study.Net]*
- Hamermesh, R. et al (2010). "Managing Drugs on the Forefront of Personalized Medicine: The Erbitux and Vectibix story." HBS Note. March 2010. *[Study.Net]*

March 5 and 7: Spring Break – NO CLASS

March 12: Pharma and Device Strategies in Emerging Markets: China - James Deng, VP Greater China, Becton Dickinson

- Zhang et al. "Building An Oncology Drug Business In China: Balancing Access And Pricing Freedom." IN VIVO Dec 2010.
- Gunda et al. "Key Considerations for Launching Pharmaceutical Products in Emerging Markets." IN VIVO Jul/Aug 2011.
- "Kanghui: A New Strategic Opens The Door To Orthopedics In China." IN VIVO Oct 2011.

March 14: Washington Update: FDA & CMS - Mike McCaughan, Senior Editor, RPM Report

- McCaughan, M. "Access and Evidence: Implications of the EPO Safety Debate." RPM Report October 2007. *[Study.Net]*
- McCaughan, M. "Dollars for Donuts Deal Revisited: What Pharma Got." RPM Report Oct 2011. *[Study.Net]*
- McCaughan, M. "Genomics Revolution Meets Regulatory Evolution: Why Personalized Medicine is Taking So Long." RPM Report October 2009. *[Study.Net]*
- McCaughan, M. "FDA and the R&D Crisis: Time to Stop the Blame Game." RPM Report Jul/Aug 2011. *[Study.Net]*
- McCaughan, M. "The Era of Drug Efficacy." RPM Report Apr 2011. *[Study.Net]*

March 19: Biotech Strategy to Create Value - Lorence Kim MD, Managing Director, Goldman Sachs

- "Bridging the Gap Between Sell- And Buy-Sides In Biopharma Business Development." IN VIVO Oct 2011.

March 21: Building a Blockbuster Brand: The Launch of Victoza - Heather Millage, Corporate VP Novo Nordisk

- *Case: Launching Victoza*. Proprietary Novo Nordisk case, used with permission.
- CBO "Potential Effects of a Ban on Direct-to-Consumer Advertising of New Prescription Drugs." May 2011.

March 26: Evolving Sales Force Strategies - Jaideep Bajaj PhD, 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.
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March 28: Medical Device Start-Ups - David Anderson, President and CEO, Gentis Inc. (TBC)

- Bylander, "Much ado About Nothing: Weighing the Impact of the Institute of Medicine 510k Report" IN VIVO Sept.11.
- Salemi, T. (2009). "Have Device VCs bet too Big?" IN VIVO Sept. 2009.

April 2: 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. *[Study.Net]*
- PPR (2009). "Preliminary Results of European Commission Pharmaceutical Sector Inquiry." Pharma Pricing Review Jan. 2009. *[Study.Net]*
- Merrill, J. (2010). "Opening the door to biosimilars in the US." IN VIVO Sept. 2010.
- OPTIONAL: Case: Teva Pharmaceuticals, Ltd. HBS 9-707-441 (Not for write-up). *[Study.Net]*

April 4: Corporate Strategy - M&A – David Gluckman, CoHead, North America HC, Lazard

- Baldwin, C. et al (2010). "Roche's Acquisition of Genentech." HBS Case. (Not for write-up). *[Study.Net]*
- Licking, E.F. "Sanofi-Genzyme: Emblematic of What Big Pharma's Buying Now" IN VIVO March 2011.
- Papp, T. (2010). "The Rise of Option Agreements." Nat Rev Drug Disc (9):422. June 2010.
- "The Public Policy Implications of the Abbott Split." RPM Report Dec 2011. *[Study.Net]*

April 9: Global Markets for Medical Devices – Ruchika Singhal, Medtronic

- Readings TBD

April 11: India's Pharmaceutical Market: Dr. Reddy Case (speaker TBC)

- *Case for write-up: Dr. Reddy's Laboratories (A): Ivey Case 908M64. [Study.Net]*
- Coukell, A. "The Challenge of Controlling Global Production." RPM Report Sept. 2011. *[Study.Net]*
- Witty, "New Strategies for Innovation in Global Health: A Pharmaceutical Industry Perspective." *Health Affairs* 30(1) 2011.

April 16: Pharmaceutical Markets in Brazil and Mexico - TBD

- Branco, D. "Healthcare in Brazil." Economist Intelligence Unit Nov. 2010. http://www.businessresearch.eiu.com/broadening-healthcare-access-brazil-through-innovation.html

April 18: Presentations

April 23: Presentations