THE WHARTON SCHOOL
University of Pennsylvania

The Management and Economics of the Pharmaceutical, Biotech & Medical Device Industries
HCMG 215/890
SPRING 2013

Mondays & Wednesdays
12:00 - 1:20 PM
JMHH 245

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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 7th, 9-11am)	40%
Term project	25%
Cases	20%
Class participation	15%

TERM PROJECTS
Students will work on a term project, in teams of five. 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 on **April 15th**. Please submit an electronic copy via Canvas and bring a hard copy to class.

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 Canvas. An electronic copy of your write-up must be submitted via Canvas by 5pm the day before the class in which the case is to be discussed. Please also bring a hard copy to class. Maximum length two pages (supporting material may be in an appendix). 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 are not expected to remember minutiae, e.g., specific dates, names, or minor statistics.

A.) All freely available readings and those accessible through Penn Libraries are posted in the files section of Canvas in lecture-specific folders. You can view or print the readings on your own from Canvas: https://wharton.instructure.com.
B.) All copyright protected readings require payment of a copyright fee. These must be ordered through Study.Net, which may be accessed using the link on the Canvas course site. Non-MBA students must pay this fee to Study.Net. For MBA students, it is already collected through tuition.
C.) You have the option to order a printed copy of the Study.Net course pack. Course packs are ordered via Study.net and picked up at Wharton Reprographics.

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.

The optional but recommended textbook, *Understanding Pharma: The Professional's Guide to How Pharmaceutical and Biotech Companies Really Work* 2nd Ed. by John Campbell, is on reserve in Lippincott Library.

CANVAS ACCESS
Students who have a Wharton account will automatically have access to Canvas 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 run into any issues, contact the Wharton courseware consultants at the WCIT office or online. Class handouts, updates to the syllabus and other materials will be posted on Canvas. Students auditing the class should email courseware@wharton.upenn.edu to request "observer" status for the course on Canvas.

CLASS PARTICIPATION
The quality and quantity of your in-class comments and questions are important. A component of your final course grade is allocated to your contribution to class discussion. Bring a name card to each class to help us learn your name and guarantee you receive credit for your contributions.

CLASS SCHEDULE AND READINGS

January 9: Introduction

- Standard & Poor's Industry Surveys: Pharmaceuticals, May 2012. If you are unfamiliar with the pharmaceutical industry we suggest the following reading order:
    1. "How the industry operates" (pp. 25-34)
    2. "Industry profile and trends" (pp. 11-24)
    3. "Current environment" (pp. 1-10)

OPTIONAL:

- S&P Pharmaceuticals 4. "How to analyze a pharmaceutical company" (pp.37-42)
- *Understanding Pharma,* John Campbell – Chapter 1: "Introduction to the Industry"

January 14: Global Pharma-Biotech Industry: Structure and Strategies

- S&P Industry Surveys: Biotechnology, August 2012. If you are unfamiliar with the biotechnology industry we suggest the following reading order:
    1. "How the industry operates" (pp. 18-26)
    2. "Industry profile and trends" (pp. 9-17)
    3. "Current environment" (pp. 1-8)
- EBI Biopharma Team "Top Biopharma Trends of 2011" IN VIVO Jan. 2012.

OPTIONAL

- Kaiser Family Foundation. "Follow the Pill: Understanding the US Commercial Pharmaceutical Supply Chain." March 2005.

January 16: 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.
- 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.
- Garnier, J-P. "Rebuilding the R&D Engine in Big Pharma." HBR May 2008.

OPTIONAL:

- *Understanding Pharma,* John Campbell – Chapter 4: "Discovery" and Chapter 5: "Drug Development"
- Berggren, R. et al. "Outlook for the next 5 years in drug innovation." Nature Reviews Drug Discovery June 2012.

January 21: Martin Luther King Day- NO CLASS

January 23: Pharmaceutical Marketing

- *Understanding Pharma,* John Campbell – Chapter 3: "Pharma and Biotech Costumers" and Chapter 8: "Marketing and Brand Management"
- Mittal, V. "Ensuring Big Pharma Doesn't Turn Specialty Markets into Primary Care." *In VIVO* March 2012.

January 28: 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*:913-914. December 2010.

January 30: Measuring Value: 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]*
- Klasmeier, C. "Congress should clarify the circumstances under which drug makers can communicate results on comparative effectiveness." *Health Affairs* October 2012, 2220-4.
- Epstein, R. "The hypothetical migraine drug comparative effectiveness study: A payer's recommendation for obtaining more useful results." *Health Affairs* October 2012, 2225-9.

OPTIONAL:

- 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).

February 4: Pricing and Reimbursement 1: Basic principles

- Gregson, Sparrowhawk, Mauskopf and Paul "Pricing Medicines: Theory and Practices, Challenges and Opportunities" *Nature (Vol 4)* February 2005
- Danzon and Taylor. "Drug Pricing and Value in Oncology." *The Oncologist*. 2010:15(suppl 1):24-31.
- O'Keeffe, K. et al. "Making dollars and sense out of copay assistance." IN VIVO, July/Aug 2012

February 6: Pricing and Reimbursement 2: Regulated Markets ex-US

- Danzon, P. (2012). "Regulation of Pricing and Reimbursement" in Handbook on the BioPharmaceutical Industry. Eds. P. Danzon and S. Nicholson. Oxford University Press.
- Senior, M. "Germany's pricing revolution: why the world should be watching." IN VIVO, Feb 2012 (Vol. 30, No. 2).

February 11: Pricing and Reimbursement 3: Truvada Case; Biosimilars

- *Case: Gilead: Launching Truvada in Europe. Stanford Case OIT-94 8/27/09.*
- Moran, N. (2008). "Fractured European market undermines biosimilar launches." *Nat Rev Drug Disc* 26(1):5-6 January 2008.
- McCaughan, M. "Biosimilarity vs. 'cognitive dissonance': the ongoing challenges to new FDA pathway." The RPM Report, Oct 2012 (Vol. 8, No. 9).

February 13: Biotech Financing and Strategy

- Case: HBS 9-709-002 "Targanta Therapeutics: Hitting a Moving Target." July 2009
- Lash, Alex. "Restructuring for Success: Shifting Biotech Strategies." IN VIVO, Jan 2012
- Lash, A. "Your First Drug"s Approved And Launched... Now What?" IN VIVO Jul/Aug 2011.

February 18: Medical Devices: Overview

- S&P Industry Surveys: Health Care Products and Supplies, August 2012. *NOTE: We recommend the following sections and reading order:*
    1. "How the industry operates" (pp. 37-43)
    2. "Industry profile" (p. 18-36)
    3. "Current environment" (pp. 1-17).
- Robinson, J.C. "Providers' payment and delivery system reforms hold both threats and opportunities for the drug and device industries." Health Affairs, Sept 2012
- Posner, S.A. & Speers, M.S. "Commercialization alternatives in the new medtech world." IN VIVO, Sept 2012.

February 20: Trends in Deals - Chris Morrison, Elsevier, IN VIVO Editor-in-Chief, Biopharma

- Morrison, C. "IND Over POC: The New Sweet Spot for Biopharma Dealmaking?" IN VIVO Oct 2011.
- Merrill, J. "The Orphan Drug Boom: Gold Rush or Flash in the Pan?" IN VIVO Nov. 2012
- Papp, T. (2010). "The Rise of Option Agreements." Nat Rev Drug Disc (9):422. June 2010.

February 25: Personalized Medicine and Companion Diagnostics – Dr. Carl June TBC

- Davis et al. "The microeconomics of personalized medicine: today's challenge and tomorrow's promise." *Nat Rev Drug Disc* 8:279-86. April 2009.
- Pambianco et al. "Utility before profitability: The evolving evidence paradigm for molecular diagnostics." IN VIVO Sept. 2012
- Singer, D.R.J, & Marsh, A. "Challenges and solutions for personalized medicines." Health Policy and Technology, March 2012 (Vol. 1, Iss. 1).

February 27: Venture Capital – Brenda Gavin, Managing Partner, Quaker Bioventures

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

March 4 and 6: Spring Break

March 11: Pharma and Device Strategies in Emerging Markets: China – James Deng, VP and Head, 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.
- Li, Y. et al. (2012). "Overprescribing in China, driven by financial incentives, results in very high use of antibiotics, injections, and corticosteroids." Health Affairs, 31(5), 1075-1082.

March 13: Washington Update: FDA & CMS - Mike McCaughan, Senior Editor, RPM Report

- McCaughan, M. "FDAAA impact analysis (year 4): the REMS retreat continues – for now." The RPM Report, July/Aug 2012 (Vol. 8, No. 7).
- McCaughan, M. "Secondary uses of Sentinel." The RPM Report, March 2012 (Vol. 8, No. 3).
- McCaughan, M. "Targeted Cancer Therapies in Context: FDA's Pazdur on Companion Diagnostics" The RPM Report, Nov 2012).

March 18: Strategies in Emerging Markets to Create Value

- Ivey W 11276. "Oral Insulin: Breakthrough Innovation at Biocon" 2011
- Diller, W. "Pharma's Aim: Tap Innovation in Emerging Markets To Fix Woes at Home."

March 20: Building a Blockbuster Brand: The Launch of Victoza – Heather Millage, Corporate VP Novo Nordisk

- *Case: Launching Victoza*. Proprietary Novo Nordisk case, used with permission.
- Academy of Managed Care Pharmacy. "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.*
- Cassese, M. & Touchot, N. "A call for action: pharma strategies for development of payor evidence programs." IN VIVO, Feb 2012 (Vol. 30, No. 2).

March 25: Sales Force Strategies – Jaideep Bajaj, Managing Director, ZS Associates

- ZS Reports TBD.
- *Understanding Pharma*, John Campbell – Chapter 9: "Sales"
- Edmunds, R. (2009). "Transforming Pharma's Commercial Capabilities to Drive Maximum Value." IN VIVO May 2009.

March 27: India's Pharmaceutical Market; Dr. Reddy Case (TBC)

- Case: "Daiichi Sankyo's Acquisition of Ranbaxy- Cultural Issues in Integrating Business Models and Organisations." AsiaCase.com ABCC-2011-006
- *Case for write-up: Dr. Reddy's Laboratories (A): Ivey Case 908M64. [Study.Net]*
- Witty, "New Strategies for Innovation in Global Health: A Pharmaceutical Industry Perspective." *Health Affairs* 30(1) 2011.
- Roderick, P. and Pollock, A.M. "India's patent laws under pressure." Lancet September 2012.

April 1: Pharmaceutical Markets in Brazil and Mexico

- Branco, D. "Healthcare in Brazil." Economist Intelligence Unit Nov. 2010. http://www.businessresearch.eiu.com/broadening-healthcare-access-brazil-through-innovation.html
- Danzon and Furukawa, *Cross-National Evidence on Generic Pharmaceuticals* NBER 17226 July 2011

April 3: Global Markets for Medical Devices – Ruchika Singhal, Medtronic

- Donoghoe, N. et al. "Medical device growth in emerging markets: lessons from other industries." IN VIVO, June 2012 (Vol. 30, No. 6).
- "Kanghui: A New Strategic Opens The Door To Orthopedics In China." IN VIVO Oct 2011.

April 8: The Generic Drug Industry – William Marth, former CEO, TEVA USA

- Pozen, R. and E. Leonard. "Note on Generic Drugs in the European Union." HBS Note May 28, 2009. *[Study.Net]*
- Merrill, J. "Opening the door to biosimilars in the US." IN VIVO Sept. 2010.
- Rawson, K. "FDA's latest PR push: protecting the reputation of generic drugs." The RPM Report, May 2012 (Vol. 8, No. 5).
- OPTIONAL: Case: Teva Pharmaceuticals, Ltd. HBS 9-707-441 (Not for write-up). *[Study.Net]*

April 10: Corporate Strategy - M&A – David Gluckman, Co-Head, 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.

April 15: Presentations

April 17: Presentations

April 22: Presentations