THE WHARTON SCHOOL
University of Pennsylvania

The Management and Economics of the Pharmaceutical, Biotech & Medical Device Industries
HCMG 215/899
SPRING 2014

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, 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 of different market segments.

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

GRADING

Final exam (May 9th, 9-11am)	40%
Term project	25%
Cases	20%
Class participation	15%

TERM PROJECTS
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. These projects will be

presented in class. The final write-up (max. 10 pages plus optional tables) is due in class on **April 16th**. 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. 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, not as group projects.

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 detailes of specific dates, companies, 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 readings 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.

Optional but recommended background readings:
Understanding Pharma: The Professional's Guide to How Pharmaceutical and Biotech Companies Really Work 2nd Ed. by John Campbell. On reserve in Lippincott Library.

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

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 15: Introduction

- Standard & Poor's Industry Surveys: Pharmaceuticals, July 2013.
  If you are unfamiliar with the pharmaceutical industry we suggest the following reading order:
  1. "How the industry operates" (pp. 28-37)
  2. "Industry profile and trends" (pp. 12-27)
  3. "Current environment" (pp. 1-11)

OPTIONAL:

- *Understanding Pharma*, John Campbell – Chapter 1: "Introduction to the Industry" (on Reserve at Lippincott).

January 20: Martin Luther King Day- NO CLASS

January 22: Global Pharma-Biotech Industry: Structure and Strategies

- S&P Industry Surveys: Biotechnology, August 2013.
  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 and trends" (pp. 10-18)
  3. "Current environment" (pp. 1-9)
- Morrison, C. "Biopharmaceutical Trends in 2012: Regulatory and Market Strides Paper over Existential Dilemmas" IN VIVO Jan. 2013.

January 27: R&D: Regulation, Costs and Returns

- 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, OUP.
- 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.

OPTIONAL:

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

January 29: Pharmaceutical Marketing

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

February 3: 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.

Febuary 5: 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]*
- Yong et al. 2013. "Evaluation and Use of Economic Data in Canada." *PharmacoEconomics* 31

- 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:

- Tarn et al. (2008) "Health Care Systems and Pharmacoeconomic Research in Asia Pacific Region" *Value in Health* 2:S137-155.
- 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).
- Drummond et al. "Key principles for the improved conduct of health technology assessments for resource allocation decisions." IJTAHC 24:3(2008), 244-258.

February 10: 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.

OPTIONAL:

- O'Keeffe, K. et al. "Making dollars and sense out of copay assistance." IN VIVO, July/Aug 2012.

February 12: Pricing and Reimbursement 2: Orphan and Rare Diseases – Brian Corvino, COO PharmaStrat

- *Case: Price and Market Access for Rare Disease Therapies. To be added to Canvas.*
- 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.*

February 17: Pricing and Reimbursement 3: 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).
- "Failure to Launch." Editorial in *Nature Biotechnology*, Jan 2013 (Vol. 31. No. 1).
- *Case: Gilead: Launching Truvada in Europe. Stanford Case OIT-94 8/27/09. [Study.Net]*

February 19: Biotech Financing and Strategy

- *Case: HBS 9-709-002 "Targanta Therapeutics: Hitting a Moving Target." July 2009. [Study.Net]*
- Lash, Alex. "Restructuring for Success: Shifting Biotech Strategies." IN VIVO, Jan 2012.
- Easton et al. "Launch or License: Taking your First Drug to Market" IN VIVO Dec. 2013

February 24: 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]*
- John Carroll, "VC ends '12 on a high note, outlook ranges from tough to terrific." *FierceBiotech*, January 18, 2013.
- Rockoff and Whalen. (2013) "Glaxo in Drug Discovery Deal" *Wall St. J. April 22 2013.*

February 26: Trends in Deals - Chris Morrison, Editor-in-Chief Biopharma, Elsevier

- 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.

March 3: Effects of health system change/ACA on the biopharma industry – Dan Mendelson, Founder and CEO, Avalere

- Robinson, J. 2012. "Providers' Payment and Delivery System Reforms …" *Health Affairs* Sept. 2012.
- KFF.org. 2013. "Medicare Part D Trends."
- Cha, 2013. "AIDS advocates say some drug coverage is inadequate in exchanges." *Washington Post* Dec. 2013.

March 5: Corporate Strategy –M&A – David Gluckman, Co-Head, North America HC, Lazard

- Amgen-Onyx Case (to be posted on Canvas)
- 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.

March 10 and 12: Spring Break

March 17: Academic Alliances and Personalized Medicine– Dana Hammil, Director of Alliance Management, UPenn, and Simon Bateman, Exec. Director Alliance Management, Novartis Oncology

- Porter et al. "Chimeric Antigen Receptor-Modified T Cells in CLL" NEJM August 25, 2011. SKIM AS BACKGROUND for discussion of the UPenn-Novartis Alliance. DETAILS NOT REQUIRED
- 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

March 19: Pharma Markets in China – Yehong Zhang, General Manager Greater China, Aetna (TBC)

- Cheng, T-M. (2012). "Early results of China's historic health reforms: The view from Minister Chen Zhu." *Health Affairs* 31(11) 2636-2544.
- 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 24: Washington Update: FDA & CMS - Mike McCaughan, Senior Editor, RPM Report (TBC)t

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

March 26: China Pharma Case: Hisun Pharmaceuticals – Itay Efraty, Hisun USA (TBC)

- Le Deu et al. (2012). "Healthcare in China: Entering uncharted waters". McKinsey &Co.

March 31: Sales Force Strategies – Jaideep Bajaj, Managing Director, ZS Associates (TBC)

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

April 2: Investing in biotech & pharma: How to analyze stocks in a highly specialized sector of the market - Mark Schoenebaum, MD, Senior Managing Director, Head of Health Care Research, ISI

April 7: Medical Devices: Overview – Michel Orsinger, Worldwide Chairman, Depuy Synthes (J&J)

- S&P Industry Surveys: Health Care Products and Supplies, August 2013.
  NOTE: We recommend the following sections and reading order:
  1. "How the industry operates" (pp. 44-51)
  2. "Industry profile" (p. 22-43)
  3. "Current environment" (pp. 1-22)
- Stuart, M. "The Medical Device Industry Stays the Course in 2012." IN VIVO Jan. 2013.
- Donoghoe, N. et al. "Medical device growth in emerging markets: lessons from other industries." IN VIVO, June 2012.

April 9: Medical Device Start Ups – David Anderson, President and CEO, Gentis, Inc.

- Posner, S.A. & Speers, M.S. "Commercialization alternatives in the new medtech world." IN VIVO, Sept 2012.
- Sorenson et al.. (2013). "Evolving Reimbursement and Pricing Policies for Devices in Europe and the US Should Encourage Greater Value." *Health Affairs* 32(4):788-796.

April 14: The Generic Drug Industry – William Marth, former CEO, TEVA USA, TBC

- *Case: Teva Pharmaceuticals, Ltd. HBS 9-707-441 (Not for write-up). [Study.Net]*
- Pozen, R. and E. Leonard. "Note on Generic Drugs in the European Union." HBS Note May 28, 2009. *[Study.Net]*
- McCaughan, M. "Biosimilarity vs. 'cognitive dissonance': the ongoing challenges to new FDA pathway." The RPM Report, Oct 2012 (Vol. 8, No. 9). *[Study.Net]*

April 16: India's Pharmaceutical Market and Firms: Glenmark Case

- *Case: Organizing for Innovation at Glenmark (A) ISB 028 [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 21: Pharmaceutical Markets in Brazil and Mexico – Andrea Puig, Regional Senior Manager, LatAm, Janssen Pharmaceuticals

- 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 23 and 28: Presentations