THE WHARTON SCHOOL
University of Pennsylvania

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

HCMG 863
SPRING 2015
Tuesdays & Thursdays
10:30 – 11:50 AM
SHDH 211
Updated February 17, 2015

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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

Midterm	20%
Final exam(Friday May 8th, 12:00pm – 2:00pm)	20%
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 9.** 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. Specific questions for each case will be posted on Canvas. An electronic copy of your write-up must be submitted via Canvas by 9am on the day 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). Each 5 person team is responsible for one write-up of each case (shown in italics below), with proportionate adjustment for smaller groups.

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 details of specific dates, companies, minor statistics etc.

A.) Most of the readings are posted in the files section of Canvas in lecture-specific folders. You can view or print the readings from Canvas: https://canvas.upenn.edu.
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 Printing.

The recommended reading order for each lecture is as indicated on the syllabus reading list below. Any updates/changes to the readings will be posted on Canvas. We will send a Canvas announcement whenever a change is made and will post the 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
Registered students will automatically have access to Canvas. Class handouts, updates to the syllabus and other materials will be posted on Canvas. Students auditing the class should forward to courseware@wharton.upenn.edu any permission from the instructor or department to obtain "observer" status for the course on Canvas.

CLASS PARTICIPATION
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, December 2014.
  If you are unfamiliar with the pharmaceutical industry we suggest the following reading order:
  1. "How the industry operates" (pp. 23-31)
  2. "Industry profile and trends" (pp. 12-23)
  3. "Current environment" (pp. 1-11)

OPTIONAL:

- *Understanding Pharma*, John Campbell – Chapter 1: "Introduction to the Industry."

January 20: Global Pharma-Biotech Industry: Structure and Strategies

- S&P Industry Surveys: Biotechnology, September 2014.
  If you are unfamiliar with the biotechnology industry we suggest the following reading order:
  1. "How the industry operates" (pp. 21-30)
  2. "Industry profile and trends" (pp. 11-21)
  3. "Current environment" (pp. 1-10)
- Morrison, C. "Biopharma in 2013: A Rising Tide" IN VIVO Jan. 2014.

January 22: 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.
- Ringel et al. "Does Size Matter in Pharmaceutical R&D? If Not, What Does?" Nat. Reviews Drug Discovery December 2013.

OPTIONAL:

- *Understanding Pharma*, John Campbell – Chapter 4: "Discovery" and Chapter 5: "Drug Development."

January 27: 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]*
- Schulze and Rengel. "What Matters Most in Commercial Success: First-in-Class or Best-in-Class?" *NRDD* June 2013.

January 29: 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]*
- Raftery and Powell, "Health Technology Assessment in the UK" Lancet 2013:328.

February 3: Pricing and Reimbursement 1: Basic principles

- 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.

OPTIONAL:

- Robinson, "Specialty Pharmaceuticals: Policy Initiatives To Improve Assessment, Pricing, Prescription, And Use" *Health Affairs* 2013 33:10.

February 5: Pricing and Reimbursement 2: Regulated Markets ex-US

- Danzon, P. (2012). "Regulation of Price and Reimbursement" in Handbook on the BioPharmaceutical Industry. Eds. P. Danzon and S. Nicholson. Oxford University Press.
- Horn, Nink et al. "Early benefit assessment of new drugs in Germany – Results from 2011 to 2012" *Health Policy* 2014
- "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 10: Commercialization and Specialty Pharma – Tom Fezza, Principal, Global Strategy, Deloitte; and Christopher Brooke, VP Diabetes, Astra Zeneca.

February 12: Medical Devices: Overview

- 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)
- Donoghoe, N. et al. "Medical device growth in emerging markets: lessons from other industries." IN VIVO, June 2012.

February 17: Cancelled

February 19: Pricing and Reimbursement 3: Orphan Diseases – Brian Corvino, COO, Decision Resources

- *Case: Price and Market Access for Rare Disease Therapies*. On *Canvas*.
- Reardon, "Regulators adopt more orphan drugs." Nature 508 April 2014.
- 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 24: Corporate Strategy –M&A – David Gluckman, Co-Head, North America HC, Lazard

- Novartis-GSK deal (to be posted on Canvas). Not for write-up.
- Licking, E.F. "Sanofi-Genzyme: Emblematic of What Big Pharma's Buying Now." IN VIVO March 2011.

February 26: Data for Payers: Dealing with NICE – Scott Johnson, Principal, MedicusEconomics
Rescheduled from February 17.

February 26-27: Midterm (2 hours between 2pm 2/26 and 5pm 2/27)

March 3: Pharma Markets in China – Don Yin, Asssociate VP and Head, Global Health Outcomes, Merck

- Xu, Leung et al. "Embracing China's Brave New Pharmaceutical World." *IN VIVO* July 2014.
- 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.
- Le Deu et al. (2012). "Healthcare in China: Entering uncharted waters". McKinsey &Co.

March 5: India's Pharmaceutical Market: I. Overview

- Subramanian et al. "Market Based Price Controls in India" *Pharmaceutical Executive* April 2014.
- Roderick, P. and Pollock, A.M. "India's patent laws under pressure." Lancet September 2012.
- Roderick, Mahajan et al. "India Should Introdruce a New Drugs Act." Lancet January 2014.

March 10 and 12: Spring Break

March 17: LATAM Pharmaceutical Markets: Brazil and Chile Dr. Leandro Reis, ANS, Brazil (TBC)

- Danzon and Furukawa, *Cross-National Evidence on Generic Pharmaceuticals* NBER 17226 July 2011
- "*Chile: Pharma's Changing Landscape."* 2014. PharmaBoardroom.com
- *Case: Farmacias Similares.* HBS 9-307-092..*[Study.Net] (to be discussed in class on 3/19).*

March 19: India, Glenmark Case; Mexico, Farmacias Similares Case discussion

- *Case: Organizing for Innovation at Glenmark (A) ISB 028[Study.Net]*
- Comer, B. "FDA Abroad: Is FDA Capable of Sufficiently Overseeing Global Drug Imports?" *Pharmaceutical Executive*. July 2014.

March 24: Sales Force Strategies – Jaideep Bajaj, Managing Director, ZS Associates

- *Understanding Pharma*, John Campbell – Chapter 9: "Sales."
- Wilcox, I. "The Devil beyond the Detailing." *Pharmaceutical Executive* Nov. 2014.
- Wright, "Matching Resources to Opportunities: How Differential Resourcing can Transform the Pharmaceutical Sales Model." ZS Associates 2009.

March 26: Distributors and Supply Chain – Nate Massari, Charles Cycon and Larry Marsh, Amerisource Bergen

- *"2014-15 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors"* by Adam Fein --- Chapter 6 on 'Forces of Change in Drug Distribution'
- McKesson Specialty Health, "Real-World data boosts market access and enhances product differentiation" *Pharmaceutical Executive*

March 31: The Generic and Biosimilar Sectors – Siggi Olafsson, President and CEO, Global Generics, Teva

- *Case: Teva Pharmaceuticals, Ltd. HBS 9-707-441* (Not for write-up).*[Study.Net]*
- Grabowski et al. "*Regulatory and Cost Barriers are Likely to Limit Biosimilar Development and Cost Savings. "* Health Affairs 33(6) 2014.
- Wechsler. "Brand Generic Wars Heat Up." *Pharmaceutical Executive* Oct. 2013.

April 2: Venture Capital and Private Equity Financing – Ali Behbahani, Partner NEA Associates

- Papp, T. (2010). "The Rise of Option Agreements." Nat Rev Drug Disc (9):422. June 2010.
- Easton et al. "Launch or License: Taking your First Drug to Market" IN VIVO Dec. 2013

April 7: 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). *[Study.Net]*
- McCaughan, M. "Secondary uses of Sentinel." The RPM Report, March 2012 (Vol. 8, No. 3). *[Study.Net]*
- Frank et al. "Era of Faster FDA Drug Approvals has also seen Increased Black Box Warnings and Withdrawals." *Health Affairs.* 33 (8) 2014.

- Wechsler. “FDA Pursues Delicate Balancing Act.” *Pharmaceutical Executive* Dec. 2013.

April 9: Investing in biotech & pharma: How to analyze stocks in a highly specialized sector of the market- Mark Schoenebaum, MD, Senior Managing Director, Head of HC Research, Evercore ISI

April 14: Corporate Strategy/Vaccines- Liz Anderson, former VP Infectious Diseases and Vaccines, Janssen

- *Case: Novartis: Leading a Global Enterprise*- HBS 9-413-096 *[Study.Net]*
- *Case: Sanofi-Pasteur: The Dengue Vaccine* HBS 9-514-074).*[Study.Net]*
- Noor and Kleinrock. “Pharma 50 Insight: The Accelerating Growth of Specialty Markets.” *Pharmaceutical Executive*. June 2014.

April 16: 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 21 and 23: Presentations

April 28: Review /Make-Up Final