

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

HCMG 863
Spring 2009
JMHH F60
Mon/Wed 3:00-4:20 p.m.

Syllabus Update 1.26.09

Professor Patricia M. Danzon

Office hours: Tuesday 1:30-2:30pm or by appt

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Course Objectives: This course provides an overview of the management, economic and policy issues facing the pharmaceutical-biotechnology industries, with brief coverage of medical devices. We focus on functional areas where these industries differ significantly from other industries. These include: intensive R&D and rapid technological change; a complex global market place in which customers include physicians and third party payers, as well as individual consumers and sometimes pharmacists; complex and evolving M&A strategies, including alliances and joint ventures; and government regulation of every dimension of the business. The perspective is global but with emphasis on the U.S.

Readings: A coursepack of required readings is available from Wharton Reprographics in two parts. The readings listed below are required, except those marked ** which are optional. These optional readings are not in the coursepack.

Grading

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|-----------------------|-----|
| • Class participation | 15% |
| • Exam | 40% |
| • Case Studies | 20% |
| • Term Project | 25% |

Term Projects

Students will work on a term project, in teams of 5. A list of possible topics will be provided or you may choose a topic of particular interest to you, subject to approval. These projects will be presented in class. The final write-up (max. 10 pages plus optional tables) is due Wednesday April 15th.

Cases

Case questions will be posted on the WebCafe. 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

Jennifer Lavery at lavery@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.

WebCafe

All class materials will be posted at the WebCafe, at <https://webcafe.wharton.upenn.edu/eRoom/hcmg/863-sp09-1>. Registered students will automatically have access. In case of problems, contact the Wharton webCafe Team at webcafe@wharton.upenn.edu.

Other Resources: For a basic primer on the pharmaceutical industry, see J. Campbell, Understanding Pharma, Pharmaceutical Institute, available at Lippencott Reference. The Pharmaceutical Research Industry trade association, PhRMA, has useful industry overview materials, at www.phrma.org. For an insider account of the biotech industry, see Robbins Roth, From Alchemy to IPO.

Topics and Reading Assignments (denotes optional readings, not in the coursepack)**

January 14: Introduction

- A1. S&P Industry Surveys: Healthcare: Pharmaceuticals November, 2008.
- A2. "Prescription Drug Trends", Kaiser Family Foundation, September 2008

January 19: Martin Luther King Day- NO CLASS

January 21: Global Pharma-Biotech Industry: Structure, Conduct and Performance

- B1. S&P Industry Surveys: Biotechnology August 2008.
- B2. Windhover's Biopharma Team, "Reviewing 2007 to Forecast 2008" IN VIVO Jan. 2008.
- ** "Follow the Pill: Understanding the US Commercial Pharmaceutical Supply Chain" Kaiser Family Foundation. March 2005. www.KFF.org.

January 26: R&D (1): Regulation, Costs and Returns

- C1. DiMasi, JA and Grabowski, HG. "The Cost of Biopharmaceutical R D: is Biotech Different?" Managerial and Decision Economics 2007 28(4) pp. 469-479
- C2. McCaughan, M. "Adapting to a Tiered Regulatory System." RPM Report Nov. 2007.
- C3. Danzon and Towse, "The Economics of Gene Therapy and of Pharmacogenetics." Value in Health 2002 (1). (Skip the section on Gene Therapy).
- **Congressional Budget Office, Research and Development in the Pharmaceutical Industry October 2006. Ch.1-3, Ch.6

January 28: Marketing in the Old and New Worlds: Zantac and Humira Cases (choose one)

- E1. *INSEAD Case: Zantac*.
- E2. *Stanford Case: Abbott Laboratories and HUMIRA: Launching a Blockbuster Drug*.

February 2: Torcetrapib: A Case Study of (Failed) New Drug Development - Steve Yoder, MD MBA, Principal, Eastern Assoc., formerly team leader global product development at Pfizer

Readings are on Webcafe, not in the coursepack

Hensley and Winslow, "Blood Work: Pfizer makes \$800m. bid to reshape the health-care market." WSJ 4-8-2004

Rader, "Illuminating HDL – Is it Still a Viable Therapeutic Target?" NEJM Nov. 22 2007.

Morrison, "Best Laid Plans: Pfizer's Torcetrapib Tanks," IN VIVO Dec. 2006.

** Barter et al. "Effects of Torcetrapib in Patients at High Risk for Coronary Events." NEJM Nov. 22 2007.

February 4: Managing a Biotech Company – Jay Moorin, Partner, ProQuest Investments and formerly CEO, Magainin Pharmaceuticals.

F1. Van Brunt, J. "Biotech's Old Soldiers", Signals Magazine published 10/05/05

F2. Senior, M. "Change of Control: Why Getting it Right Matters Even More." IN VIVO March 2008.

February 9: NO CLASS

February 11: R&D Productivity Management – Dr. Thomas Hofstaetter, Senior VP, Corporate Business Development, Wyeth

D2. Huckman et al. "Wyeth Pharmaceuticals: Spurring Scientific Creativity with Metrics." HBS Case 2007-8 2007. *In Coursepack 1. Not for write-up.*

H1. Longman, R. "Pharma's Strategic Divide: Focus or Diversify?" IN VIVO Sept. 2008.

February 16: Washington Update: FDA and CMS - Mike McCaughan, Senior Editor, The RPM Report

I1. McCaughan, "Entering the World of REMS: Entereg Sets new Standards." RPM July 2008

I2. McCaughan, "Access and Evidence: Implications of the EPO Safety Debate" RPM October 2007.

I3. Kelly, "Amgen's *Nplate* Has FDA Restrictions But may Escape Medicare Controls" RPM October 2008.

February 18: R&D(2): Management and Deals – Graham Brazier, VP and Head of Business Development, Bristol-Myers Squibb

D1. Boshwitz et al. "Know thy R&D Enemy: The Key to Fighting Attrition" In Vivo Jan. 2005. *In Coursepack Part 1.*

D3 Senior, "GSK's Risk Sharing Deals to Compete with in-House R&D." IN VIVO March 2006. *In Coursepack Part 1.*

D4 Longman, "Can Out-Partnering Help Vault Pfizer over the Second Cliff?" IN VIVO May 2008. *In Coursepack Part 2.*

February 23: Trends in Deals – Roger Longman, Managing Partner, Windhover Information; Editor, IN VIVO

- K1. Windhover's Biopharma Team. "The Trouble with Alliances." IN VIVO April 2008.
- K2. Longman, "Pharma's New Follow-On Strategy" IN VIVO Feb. 2008.
- K3. Longman, "After Roche/Genentech: Pharma's Focus on Efficiencies, Not Innovation." IN VIVO July 2008.

February 25: Pricing, PBMs and Pharmacoeconomics: Medicines Co. Case

- G1. *Case: The Medicines Company. HBS: 9-502-076*
- G2. Berndt, "Pharmaceuticals in US Health Care: Determinants of Quantity and Price" J. Econ. Perspectives Fall 2002.
- G3. Frank and Newhouse, "Negotiating Part D Drug Prices" Health Affairs Jan. 2008.

March 2: Price and Reimbursement Regulation: An International Perspective

- L1 Pharmaceuticals: Cost Containment, Pricing, Reimbursement, World Bank HNP Brief #7, August 2005
- L2 Pearson SD, Rawlins MD. "Quality, Innovation, and Value for Money: NICE and the British National Health Service" JAMA November 23/30, 2005
- L2 "France: 2009 Draft Social Security Finance Bill." PPR Nov. 2008.
- L3 "ECJ Delivers Mixed Verdict in Greek Parallel Trade Case." PPR Nov. 2008.
- ** Sood et al. "The Effect of Regulation On Pharmaceutical Revenues: Experience in Nineteen Countries." Health Affairs Dec. 2008.

March 4: - International Marketing - Nancy Lilly, Vice President, Global Marketing for New Product Planning and Marketing Analytics, Eli Lilly and Company

- N1. Danzon and Furukawa – "Prices and Availability of BioPharmaceuticals: An International Comparison" Health Affairs September 2006
- N2. "Canada: Creative Solutions to Shift in Cancer Care." PPR Oct. 2008.

March 9 and 11: Spring Break

March 16: The Generic Drug Industry – William Marth, CEO, TEVA USA

- O1. Padden and Jenkins, "Hatch Waxman Changes" National Law J. Feb 23, 2004 2p.
- O2. "Preliminary Results of European Commission Pharmaceutical Sector Inquiry." PPR Jan. 2009.
- O3. "Global and Local Perspectives On Biosimilar Developments." PPR Aug. 2008

**Case: Teva Pharmaceuticals, Ltd. HBS 9-707-441 Not for write-up.

March 18: Sirtris case

J1 *Sirtris Pharmaceuticals: Living Healthier, Longer. HBS 9-808-112*

J2 Jacquet, "Biopharma: Beyond the First Product." In Vivo June 2006

March 23: Asia and other Markets and Companies

P1. "BRIC Markets offer Growth Opportunities – But At What Price?" PPR October 2008.

P2. Licking, "Takeda's Global Ambition: IN VIVO June 2008

P3. "China: Strong Growth Potential in Private Health Care Insurance Market." PPR Dec. 2008.

March 25: Trends in Reimbursement and Comparative Effectiveness - Perry Bridger, Vice President, Avalere Health

R1. Rawson, "Comparative Effectiveness: The Next Gatekeeper to Commercial Success." RPM Sept. 2007 14-23.

R2. Rawson, "Why Pharma Should Embrace Comparative Effectiveness." RPM Feb. 2008.

R3. Baghadi, "Lucentis and the New Value System for Pharmaceuticals." RPM June 2007

March 30: Evolving Sales Force Strategies – Jaideep Bajaj, Managing Director, ZS Associates

S1 Rickwood, "Blow the Launch- Doom the Product." IN VIVO Oct. 2008

S2. Longman, "The Unsung Vytarin Victim: Primary-Care Marketing" IN VIVO Feb 2008.

April 1: Specialty Pharma – Ian Sanderson, Managing Director, Cowen and Co.

T Readings to be added.

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

U1. S&P Health Care Products and Supplies, September 2008

U2. Chai. "Medical device regulation in the US and the EU." Food and Drug Law Journal. V. 55.

April 8: Emerging Markets Producers: Dr. Reddy or Biocon case (choose one)

V1 *Dr. Reddy's Laboratories (A): Ivey Case 908M64*

V2. *Biocon: From Generics Manufacturing to Biopharmaceutical Innovation: Asia Case Research Center HKU657*

April 13: Biotech Strategy: Pharmaceutical Marketing – Jan Malek, Director –IBSG Life Sciences, Cisco Systems TBC

M1. Campbell, "Marketing and Brand Management," Ch. 7 in Understanding Pharma Pharmaceutical Institute 2005.

M2. Jones and Malek, “Unifying the Prescriber Influence Network.” Cisco Systems 2008.

April 15: TBD

April 20: Presentations

April 22: Presentations

April 27: Presentations