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

HCMG 215
Spring 2008
JMHH F60
Mon/Wed 12:00-1:20 p.m.

Syllabus Update 1/26/09

Professor Patricia M. Danzon
Office hours: Tuesday 1:30-2:30pm or by appt
Rm. 207 CPC
e-mail: danzon@wharton.upenn.edu

***Administrative Assistant**:* Jennifer Laverty
Rm. 108 CPC
Phone: 898-4268
e-mail: jlaverty@wharton.upenn.edu

***TA*:** Andrew Mulcahy
Office Hours: Wednesdays 2-3pm or by appt.
Rm. 4th Floor CPC (right off elevator)
e-mail: mulcahaw@wharton.upenn.edu

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

Course Pre-requisites
One course in Health Care (HCMG 101, 202, 203, 204, 211 or 212) or one course in Economics or equivalent experience with permission of instructor.

Grading

- Class participation 15%
- Cases 20%
- Exam 40%
- Term Project 25%

Term Projects
Students will work on a term project, in teams of 3-5. 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. A memo (approx. one page) outlining your topic and approach is due February 25th. The final write-up (max. 10 pages plus optional tables) is due April 15th.

Cases
Students should come to class prepared to discuss all the assigned cases (*shown in italics below*). Specific questions for each case will be posted on the webcafe. Each student should write up two cases (your choice). The case write-ups should be submitted to laverty@wharton.upenn.edu by 5pm the day before the class in which the case is to be discussed. Maximum length 2 pages.

WebCafe: All **c**lass materials will be posted on the webCafé, at **https://webcafe.wharton.upenn.edu/eRoom/hcmg/215-sp09-1**. All registered students are automatically set up as members. If you are not a Wharton student, you can get a Wharton account online at: http://accounts.wharton.upenn.edu. If you have questions about using webCafe, contact the Wharton webCafe Team at webcafe@wharton.upenn.edu.

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 and are not in the coursepack.

Other Resources: For a basic primer on the pharmaceutical industry, see J. Campbell, Understanding Pharma, Pharmaceutical Institute, available at Lippencott Library Reference Desk. 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 Industry Structure, Conduct and Performance: Pharma and Biotech

B1. S&P Industry Surveys: Biotechnology August 2008.

B2. "Follow the Pill: Understanding the US Commercial Pharmaceutical Supply Chain" Kaiser Family Foundation. March 2005

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.

** Congressional Budget Office, Research and Development in the Pharmaceutical Industry October 2006. Ch.1-3, Ch.6

January 28: Pharmaceutical Marketing

D1 Campbell, Ch. 3 Pharma Customers and "Ch. 7 Marketing and Brand Management in Understanding Pharma Pharmaceutical Institute 2005.

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.

** Van Brunt, "Biotech Patent Fights" Signals Magazine 2002

February 9: TBD

February 11: 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 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: 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.

February 23: Price and Reimbursement Regulation: An International Perspective

J1 Pharmaceuticals: Cost Containment, Pricing, Reimbursement, World Bank HNP Brief #7, August 2005

J2 Pearson SD, Rawlins MD. "Quality, Innovation, and Value for Money: NICE and the British National Health Service" JAMA November 23/30, 2005

J3 "France: 2009 Draft Social Security Finance Bill." PPR Nov. 2008.

J4 "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.

February 25: Biotech Financing: Venture capital and deals – Brenda Gavin, Managing Partner, Quaker Bioventures

K1 Brealy and Myers, "How Corporations Issue Securities" p. 405-416

K2 Robbins-Roth, "Initial Public Offerings" Ch. 18

K3 Boschwitz J. et al. "Making Licensing Pay" *In Vivo* May 2005

March 2: Medical Devices: Overview

H1. S&P Health Care Products and Supplies, September 2008

H2 Chai. "Medical device regulation in the US and the EU." Food and Drug Law Journal. V. 55.

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: Biotech Strategy: Sirtris Case

L1 *Sirtris Pharmaceuticals: Living Healthier, Longer. HBS 9-808-112*

L2 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 Vytorin 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. Chatterji et al. "Physician-Industry Collaboration in the Medical Device Industry." Health Affairs, November 2008

U2 Hahn et al. "The Need for Greater Price Transparency in the Medical Device Industry." Health Affairs, November 2008.

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: Pharmaceutical Marketing – Jan Malek, Director –IBSG Life Sciences, Cisco Systems

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