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](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.


**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](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:
    1. S&P Pharmaceuticals 4. “How to analyze a pharmaceutical company” (pp. 37-42)
    2. 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)
  - Optional:

January 16: R&D: Regulation, Costs and Returns
  - Optional:
    1. Understanding Pharma, John Campbell – Chapter 4: “Discovery” and Chapter 5: “Drug Development”

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.
January 30: Measuring Value: Cost-Effectiveness and Comparative Effectiveness Analysis

- Klasmeier, C. “Congress should clarify the circumstances under which drug makers can communicate results on comparative effectiveness.” Health Affairs October 2012, 2220-4.

OPTIONAL:

February 4: Pricing and Reimbursement 1: Basic principles


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

- 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

- 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, 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
February 20: Trends in Deals - Chris Morrison, Elsevier, IN VIVO Editor-in-Chief, Biopharma
  o Merrill, J. “The Orphan Drug Boom: Gold Rush or Flash in the Pan?” IN VIVO Nov. 2012.

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

February 27: Venture Capital – Brenda Gavin, Managing Partner, Quaker Bioventures
  o Brealey and Myers, “How Corporations Issue Securities” from Principles of Corporate Finance, p. 405-416. [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
  o 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
  o McCaughan, M. “FDAAA impact analysis (year 4): the REMS retreat continues – for now.” The RPM Report, July/Aug 2012 (Vol. 8, No. 7).
  o McCaughan, M. “Secondary uses of Sentinel.” The RPM Report, March 2012 (Vol. 8, No. 3).

March 18: Strategies in Emerging Markets to Create Value
  o Ivey W 11276. “Oral Insulin: Breakthrough Innovation at Biocon” 2011
  o 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
  o Case: Launching Victoza. Proprietary Novo Nordisk case, used with permission.
  o 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.
March 25: Sales Force Strategies – Jaideep Bajaj, Managing Director, ZS Associates
  o ZS Reports TBD.
  o Understanding Pharma, John Campbell – Chapter 9: “Sales”

March 27: India’s Pharmaceutical Market: Dr. Reddy Case (TBC)
  o Case: “Daiichi Sankyo’s Acquisition of Ranbaxy - Cultural Issues in Integrating Business Models and Organisations.” AsiaCase.com ABCC-2011-006
  o Case for write-up: Dr. Reddy’s Laboratories (A): Ivey Case 908M64. [Study.Net]
  o Witty, “New Strategies for Innovation in Global Health: A Pharmaceutical Industry Perspective.”
    Health Affairs 30(1) 2011.

April 1: Pharmaceutical Markets in Brazil and Mexico
    http://www.businessresearch.eiu.com/broadening-healthcare-access-brazil-through-innovation.html
  o Danzon and Furukawa, Cross-National Evidence on Generic Pharmaceuticals NBER 17226 July 2011

April 3: Global Markets for Medical Devices – Ruchika Singhal, Medtronic
  o Donoghoe, N. et al. “Medical device growth in emerging markets: lessons from other industries.”
    IN VIVO, June 2012 (Vol. 30, No. 6).
  o “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
  o Merrill, J. “Opening the door to biosimilars in the US.” IN VIVO Sept. 2010.
  o Rawson, K. “FDA’s latest PR push: protecting the reputation of generic drugs.” The RPM Report, May 2012 (Vol. 8, No. 5).
  o 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

April 15: Presentations

April 17: Presentations

April 22: Presentations