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

<table>
<thead>
<tr>
<th>Component</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Final exam (May 3rd - 9am)</td>
<td>40%</td>
</tr>
<tr>
<td>Term Project</td>
<td>25%</td>
</tr>
<tr>
<td>Cases</td>
<td>20%</td>
</tr>
<tr>
<td>Class participation</td>
<td>15%</td>
</tr>
</tbody>
</table>
TERM PROJECTS
Students will work on a term project, in teams of 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. The final write-up (max. 10 pages plus optional tables) is due in class April 16th.

CASES
Case questions will be posted on Canvas. 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 Holly Cronin at hcronin@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.

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.

The course pack is available in two parts: Part I includes readings through February 13 and Part II includes readings from February 15 through the end of the semester. Part II will be available for purchase in late January.

Every student enrolled in the class must pay the copyright fees on Study.net for Part I and Part II of the course pack. Study.net records how many/which students pay this fee. Once you pay the fee you have several options to access the course readings:

A.) All readings available through Penn Libraries are posted in lecture-specific folders on Canvas within the Files menu. You can view or print the readings on your own from Canvas. https://wharton.instructure.com/courses/183107

B.) Cases and readings not available through Penn Libraries must be accessed via Study.net. https://spike.wharton.upenn.edu/studynet/coursepack.cfm?CourseCode=2012A,HCMG863001. A link to the Study.net course pack is available directly from the Canvas course home page.

C.) You have the option to order a printed bulkpack of the material on Study.net. Bulkpacks are ordered via Study.net and picked up at Wharton Reprographics in SHDH.

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
All students registered for the course need access to Canvas. Students who have a Wharton account will automatically have access 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 have problems, contact the consultants at the WCIT office or online. Class handouts and other materials will be posted on Canvas.
CLASS SCHEDULE AND READINGS

January 11: Introduction

- Standard & Poor’s Industry Surveys: Pharmaceuticals, December 2011. If you are unfamiliar with the pharmaceutical industry we suggest the following reading order:
  1. “How the industry operates” (pp. 26-35)
  2. “Industry profile” (pp. 14-26)
  3. “Current environment” (pp. 1-13)
  4. OPTIONAL: “How to analyze a pharmaceutical company” (pp. 37-42)

January 16: Martin Luther King Day - NO CLASS

January 18: Global Pharma-Biotech Industry: Structure, Conduct and Performance

- S&P Industry Surveys: Biotechnology, August 2011. 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” (pp. 10-19)
  3. “Current environment” (pp. 1-9)


January 23: R&D: Regulation, Costs and Returns


- "Mind the Gap: Different Views of Success May Drive Large Differences in Estimates of Pharma Value” IN VIVO Apr 2011.


January 25: Biotech Financing and Strategy

- Case: PureTech Ventures HBS 9-712-419. [Study.Net]

- Lash, A. "Your First Drug”s Approved And Launched... Now What?” IN VIVO Jul/Aug 2011.

January 30: 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]

February 1: Pricing and Reimbursement: Basic principles and the US

- “Dendreon vs. CMS: Full Coverage or the CED Solution?” RPM Report November 2010. [Study.Net]

February 6: Cost-Effectiveness and Comparative Effectiveness Analysis


February 8: Pricing and Reimbursement in Regulated Markets ex-US: Truvada Case

- Danzon et al. “Setting Cost-Effectiveness Thresholds As A Means To Achieve Appropriate Drug Prices In Rich And Poor Countries.” Health Affairs Aug 2011.


--- END OF PACK I, START PACK II ---

**February 15: R&D Productivity Management – John Keller PhD, VP Corporate Development and Strategy, Shionogi, Inc.**

- Senior, M. “Putting the Pieces Together Again: GSK Creates End-to-End Business Units.” IN VIVO Jan 2011.

**February 20: Medical Devices: Overview**

- S&P Industry Surveys: Health Care Products and Supplies, August 2011. NOTE: We recommend the following sections and reading order:
  1. “How the industry operates” (pp. 33-37)
  2. “Industry profile” (p. 17-33)
  3. “Current environment” (pp. 1-16)

**February 22: Trends in Deals - Chris Morrison, Elsevier , Editor-in-Chief, Biopharma**


**February 27: Personalized Medicine, Diagnostics and Therapeutic Vaccines - Dr. Steve Nichtberger, formerly President and CEO, Tengion**

- Case: Tengion: Bringing Regenerative Medicine to Life. [Study.Net]
February 29: Working with Payers - Roger Longman, CEO Value and Innovation, formerly Managing Director, Pharma, Elsevier Business Intelligence

- See recent posts on www.valueandinnovation.net/blog.

March 5 and 7: Spring Break – NO CLASS


- “Kanghui: A New Strategic Opens The Door To Orthopedics In China.” IN VIVO Oct 2011.

March 14: Washington Update: FDA & CMS - Mike McCaughan, Senior Editor, RPM Report


March 19: Biotech Strategy to Create Value - Lorence Kim MD, Managing Director, Goldman Sachs


March 21: Building a Blockbuster Brand: The Launch of Victoza - Heather Millage, Corporate VP Novo Nordisk

- Case: Launching Victoza. Proprietary Novo Nordisk case, used with permission.
March 26: Evolving Sales Force Strategies - Jaideep Bajaj PhD, Managing Director, ZS Associates

- ZS Report TBD.

March 28: Medical Device Start-Ups - David Anderson, President and CEO, Gentis Inc. (TBC)


April 2: The Generic Drug Industry - William Marth, CEO, TEVA USA

- OPTIONAL: Case: Teva Pharmaceuticals, Ltd. HBS 9-707-441 (Not for write-up). [Study.Net]

April 4: Corporate Strategy - M&A – David Gluckman, CoHead, North America HC, Lazard


April 9: Global Markets for Medical Devices – Ruchika Singhal, Medtronic

- Readings TBD

April 11: India’s Pharmaceutical Market: Dr. Reddy Case (speaker TBC)

- Case for write-up: Dr. Reddy’s Laboratories (A): Ivey Case 908M64. [Study.Net]
April 16: Pharmaceutical Markets in Brazil and Mexico - TBD


April 18: Presentations

April 23: Presentations