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
- Final exam (May 13, 9-11am) 40%
- 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 16th. 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.) 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.
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 Reprographics.

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:


CANVAS ACCESS
Registered students who have a Wharton account will automatically have access to Canvas. Students who do not yet have a Wharton account can create one at 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 15: Introduction
- Standard & Poor’s Industry Surveys: Pharmaceuticals, July 2013.
  If you are unfamiliar with the pharmaceutical industry we suggest the following reading order:
  1. “How the industry operates” (pp. 28-37)
  2. “Industry profile and trends” (pp. 12-27)
  3. “Current environment” (pp. 1-11)

OPTIONAL:
- Understanding Pharma, John Campbell – Chapter 1: “Introduction to the Industry” (on Reserve at Lippincott).

January 20: Martin Luther King Day- NO CLASS

January 22: Global Pharma-Biotech Industry: Structure and Strategies
  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 and trends” (pp. 10-18)
  3. “Current environment” (pp. 1-9)

January 27: R&D: Regulation, Costs and Returns

OPTIONAL:
- Understanding Pharma, John Campbell – Chapter 4: “Discovery” and Chapter 5: “Drug Development” (on Reserve at Lippincott).

January 29: 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 3: R&D Productivity Management – John Keller PhD, CEO and President, Shionogi, Inc.
- Senior, M. “Putting the Pieces Together Again: GSK Creates End-to-End Business Units.” IN VIVO Jan 2011.

February 5: Measuring Value: Cost-Effectiveness and Comparative Effectiveness Analysis
February 10: Pricing and Reimbursement 1: Basic principles

February 12: Pricing and Reimbursement 2: Orphan and Rare Diseases – Brian Corvino, COO PharmaStrat
- Case: Price and Market Access for Rare Disease Therapies. To be added to Canvas.

February 17: Pricing and Reimbursement 3: 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 19: Biotech Financing and Strategy

February 24: TBD

February 26: Trends in Deals - Chris Morrison, Editor-in-Chief, Biopharma, Elsevier
- Merrill, J. “The Orphan Drug Boom: Gold Rush or Flash in the Pan?” IN VIVO Nov. 2012

March 3: Effects of health system change/ACA on the biopharma industry – Dan Mendelson, Founder and CEO, Avalere

March 5: Corporate Strategy –M&A – David Gluckman, Co-Head, North America HC, Lazard
- Amgen-Onyx Case (to be posted on Canvas)
March 10 and 12: Spring Break

March 17: Academic Alliances and Personalized Medicine— Dana Hammil, Director of Alliance Management, UPenn, and Simon Bateman, Exec. Director Alliance Management, Novartis Oncology

March 19: Pharma Markets in China – Yehong Zhang, General Manager Greater China, Aetna (TBC)
  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 24: Washington Update: FDA & CMS - Mike McCaughan, Senior Editor, RPM Report (TBC)

March 26: China Pharma Case: Hisun Pharmaceuticals – Itay Efraty, Hisun USA (TBC)

March 31: Sales Force Strategies – Jaideep Bajaj, Managing Director, ZS Associates (TBC)
  o ZS Reports (to be posted).
  o Understanding Pharma, John Campbell – Chapter 9: “Sales.”

April 2: Investing in biotech & pharma: How to analyze stocks in a highly specialized sector of the market - Mark Schoenebaum, MD, Senior Managing Director, Head of Health Care Research, ISI

April 7: Medical Devices: Overview – Michel Orsinger, Worldwide Chairman, Depuy Synthes (J&J) (TBC)
    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)

April 9: Medical Device Start Ups – David Anderson, President and CEO, Gentis, Inc. (TBC)
April 14: The Generic Drug Industry – William Marth, former CEO, TEVA USA (TBC)
  o Case: Teva Pharmaceuticals, Ltd. HBS 9-707-441 (Not for write-up). [Study.Net]
  o McCaughan, M. “Biosimilarity vs. ‘cognitive dissonance’: the ongoing challenges to new FDA pathway.”
    The RPM Report, Oct 2012 (Vol. 8, No. 9). [Study.Net]

April 16: India’s Pharmaceutical Market and Firms: Glenmark Case
  o Case: Organizing for Innovation at Glenmark (A) ISB 028 [Study.Net]

April 21: Pharmaceutical Markets in Brazil and Mexico – Andrea Puig, Regional Senior Manager, LatAm, Janssen Pharmaceuticals (TBC)
    http://www.businessresearch.eiu.com/broadening-healthcare-access-brazil-through-innovation.html

April 23 and 28: Presentations