COURSE DESCRIPTION

Successful managers of pharmaceutical firms function in a multifaceted, ever-changing environment of diverse challenges. These challenges come from government and from society. These challenges are legal, regulatory, and ethical. They are increasingly international. This course will help aspiring executives in pharmaceutical firms to develop the knowledge, skills and ethical compass to succeed in this environment. The topics covered include research ethics, bioethics, intellectual property, healthcare reform, and drug marketing. The course uses Harvard Business School cases that give students opportunities to learn by making executive-level decisions in real-world business contexts.

Students will be expected to (1) participate actively in the case studies and class discussions; (2) complete two group presentations; and (4) complete three written assignments of approximately 3-5 pages in length.

COURSE MATERIALS

Textbooks and Other Readings

You will need ASAP to purchase a set of Harvard Business School cases that will be available on the Harvard Business School Online website. The course link is here: https://cb.hbsp.harvard.edu/cbnp/access/20430106. If you have not yet registered with HBS Online, you should do so ASAP. Other cases and class materials will be distributed in class or through the Blackboard website. If you do not already have one you will also need to purchase a Triton clicker at the campus bookstore in order to participate in class discussions and polls.

Some readings will be distributed from Michael A. Santoro and Thomas M. Gorrie (eds.), Ethics and the Pharmaceutical Industry (Cambridge University Press, 2005). It is not required to purchase this text.

Course Website

Students should check Blackboard a few times a week for announcements and additional readings.
CLASS PARTICIPATION

The development of verbal skills is given a high priority in this course. The classroom should be considered a laboratory in which you can test your ability to convince your peers of the correctness of your approach to complex problems, and of your ability to achieve the desired results through the use of that approach. Some of the things that have an impact on effective class participation are the following:

1. Is the participant a good listener?
2. Are the points that are made relevant to the discussion? Are they linked to the comments of others?
3. Do the comments show evidence of analysis of the readings?
4. Does the participant distinguish among different kinds of data, such as facts, opinions, beliefs, and concepts?

OTHER ADMINISTRATIVE DETAILS

Because faculty members tend to have somewhat different expectations as to class behavior, we would like to outline a few of my expectations concerning such matters.

1. Attendance in every class is important. In the event that for some unavoidable reason you have to miss a class, we would appreciate it if you would let us know in advance of class by means of an e-mail message. Also, if you do miss a class, it is your responsibility to find out from your classmates what materials were covered, what additional assignments were made, and what items may have been distributed in class.

2. As a courtesy to your classmates and to me, you are expected to be in class, ready to roll, on time. Anyone coming in late will be a prime candidate for a cold call.

3. Since we frequently call on individuals whose hands are not raised, you should let us know before the start of the class if some emergency has made it impossible for you to be prepared adequately for that class.

4. Given the importance of class participation, we will seek to learn your names as quickly as possible. To facilitate that, we ask you to use a name card throughout the course.
CLASS SCHEDULE

Unit I. Ethics Drug Research: Medicine, Science, and Business

September 4—Introduction

September 11—Medicine, Science and Business


September 18—Patients and Research

*Genzyme's Gaucher Initiative: Global Risk and Responsibility*

*Myelin Repair Foundation: Accelerating Drug Discovery Through Collaboration*

September 25—The Pharm Industry and the Health Care System

*Johnson & Johnson’s Response to Tylenol Crisis—Film to Be Shown in Class*

October 2—The Ethics of Clinical Research

*Genzyme and the Research Ethics Questions Associated with its Neurocell-PDTM Trials*


*Novartis in Japan—Readings to Be Provided*


PhRMA, “Principles for Responsible Clinical Trial Data Sharing”

October 7- First Paper Due
Unit II. Law and Ethics of Drug Marketing

October 9—Legal Limits of Marketing—Short, Small Group Presentations

GSK, Novartis in China—Reading to be supplied.


Johnson & Johnson Risperdal Investigation, Reading to be supplied.


October 16—Product Stewardship

Developing and Marketing a Blockbuster Drug: Lessons from Eli Lily’s Experience with Prozac

Myriad and OncorMed: Marketing the First Genetic Tests for Breast Cancer Susceptibility

October 23—Distinguished Guest Lecturer, Tom Abrams, FDA

October 28—Second Paper Due
Unit III. Law, Economics and Intellectual Property

October 30—Patents and Innovation: Economic and Business Perspectives

Michael A. Santoro, Economics of Patents Handout (to be distributed)


November 6—Patents and Human Rights

*Pfizer: Protecting Intellectual Property in the Global Economy*

*Cipla 2011*


November 13—Patents and Strategy

*Office of Technology Transfer - Shanghai Institutes for Biological Sciences*

*Alnylam Pharmaceuticals: Building Value from the IP Estate*

November 20—Recent Legal and Regulatory Developments

United States Supreme Court—*Mayo Case* (2011)

United States Supreme Court—*FTC v Actavis* (2013)

United States Supreme Court—*Assoc. for Molecular Path. v. Myriad Genetics* (2013)

United States Third Circuit Court of Appeal—*K-Dur Case* (2012)

European Commission Case—Lundbeck (2013)

December 4—Larger Group Presentations

December 11—Final Paper Due