Pharmaceutical Industry and Public Policy
SPEA-H 455
Spring 2016
Monday – Wednesday 1:00 – 2:15, AC C112

Professor Victoria Perez
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To make sure your email does not get lost, make the subject line “SPEA H 455”
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Office Hours:
Prof Perez: Monday, 2:30 – 4:00

Course Description
This course provides an overview of the pharmaceutical industry, its stakeholders and the key policy issues facing this industry. The course will focus on firms that operate in the traditional chemical pharmaceutical industry, biotechnology and medical devices. The course perspective is global, with an emphasis on the U.S. as the largest and most profitable market.
We will focus on issues that differentiate the biopharmaceutical industry from most others, including:

- Substantial investments in research and development (R&D) and rapid technological change; the role of biotechnology and genomics in transforming the industry
- A complex global market place where customers include governments and private health insurers, as well as physicians, pharmacists, and individual patients
- Government regulation of every dimension of the business, including the safety and efficacy of drugs, pricing, manufacturing, and marketing
- Continually evolving mergers, joint ventures, and alliances
- Global products and multinational firms, with growing tension between the needs and ability to pay for different market segments

Learning Outcomes
1. Describe the objectives and behavior of major stakeholders in the pharmaceutical industry
2. Assess the benefits and drawbacks of various policies to improve the efficiency and effectiveness of the pharmaceutical industry.
3. Analyze policy and innovations using data from traditional and digital sources.

Course Format
Lecture/presentation by instructor, with student participation
Guest lecture/discussion from industry experts
Team-based learning

Grades
Participation/Attendance 20%
Policy Analysis Project (see due date below) 30%
Midterm Exam (March 7 in class) 25%
Final Exam (12:30-2:30, May 4) 25%

Participation and Attendance
Students are expected to contribute to a collaborative learning environment by:

- Attending class on time and prepared to discuss the readings.
- In each class, you will submit answers to discussion questions or questions on the reading. You are responsible for submitting your answers at the end of class with your name on it to receive credit for attending class that day.
- On days we host a guest lecturer, you are expected to arrive on time. You are also expected to dress appropriately, along the lines of business casual. You will be meeting people in the industry who could be future networking opportunities. Not only do you want to look presentable, but you want to also act professional.
- Respect others’ opportunities to speak, and promoting open discussion.
- Do not use electronic devices, writing or reading outside materials, chatting, or other classroom behaviors during lecture. that inhibit your or others’ ability to learn.

If you require assistance or academic accommodations for a disability, please make an appointment with me. I am open to valid exceptions to this rule.

This ban on technology is not intended to make your life more difficult. I appreciate that laptops can be useful for taking notes and looking up additional resources. There will be sessions when we need to make use of those features, but generally, research has shown that people retain information more effectively the first time they hear it when not distracted.¹

Excused absences include documented illness, deaths in the immediate family and other documented crises, call to active military duty or jury duty, religious holy days, and official University activities. Accommodations for these excused absences will be made and will do so in a way that does not penalize students who have a valid excuse. Consideration will also be given to students whose dependent children experience serious illness.

Policy Analysis Project
The purpose of this project is to evaluate a pharmaceutical policy of your choosing and present your findings to the class. This is a team-based assignment (groups of 5). More details are posted on Canvas, under the “Policy Analysis Project” folder. For this assignment, you will:

- Work in teams. Team sign-ups are due: **February 3**.
- Describe a policy of pharmaceutical innovation to study and a chosen effect of that policy/innovation. **Due date: February 15**.
- Determine a list of search queries and data sources relevant to answer your proposed question. **Due date: February 24**.
- Professor Perez will meet with each team during class. Submit preliminary findings and conclusion before the start of class. **Due date: March 21**.
- Secondary results due via Canvas. **Due date: April 5**.
- Professor Perez will meet with each team during class to discuss findings. **Due date: April 6**.
- Submit final slides for your presentations: **Due date: April 17**.
- Present your findings to the class. **Dates: April 18 & 20**.

Readings
There are two **recommended** textbooks for the class. They are available at the SPEA library on hold and I have posted some of the readings in the “Readings” folder on Canvas:


The Oxford Handbook on the Economics of the Biopharmaceutical Industry

The **required** texts for this class are

(1) a course pack from from the Harvard Business School. To access the course pack, use the following link:
https://cb.hbsp.harvard.edu/cbmp/access/42907662


Any additional readings will be posted under “Readings” on Canvas. Come to class prepared to discuss the assigned readings.

Academic Integrity Statement
Absolute integrity is expected of every student in all academic undertakings. Integrity entails a firm adherence to a set of values, and the values most essential to an academic community are grounded on the concept of honesty with respect to the intellectual efforts of oneself and
others. Academic integrity is expected not only in formal coursework situations, but in all University relationships and interactions connected to the educational process, including the use of University resources. A student's submission of work for academic credit indicates that the work is the student's own. All outside assistance should be acknowledged, and the student's academic position truthfully reported at all times. In addition, students have a right to expect academic integrity from each of their peers. For further information regarding the Code of Academic Integrity see:
http://www.iu.edu/~code/code/responsibilities/academic/index.shtml

Lecture Slides
The slides will be posted under “Slides” on Canvas on the morning of class. Some guest lecture slides may also be posted, but some speakers may prefer not to post them.

Exams

Midterm: The midterm exam will cover the material through the February 29th session. Re-grade requests must include a written explanation of the reason for the request. These requests must be submitted within one week of the day the exams are returned in class. Re-grades may increase or decrease the score.

Date: March 7, 2016: 1-2:15 pm. AC C112 (In-class)

Final exam: The final exam is not cumulative, but may build on concepts introduced in the first half of the course. The focus of the exam will be the material covered from March 2 and on. Information presented during team presentation is considered fair game for final exam questions.

Date: May 4, 2016: 12:30-2:30 pm. AC C112

Both Exams: Two weeks before each exam, a folder with practice exams, solutions and a study guide will be available on Canvas, under the "Exams" folder.

An unexcused absence from an exam recorded as a grade of zero (0). The following are the only acceptable excuses:

- If submitted prior to the day of the scheduled exam:
  - A written and signed explanation as to why the exam will missed. Illness is an acceptable reason; discretionary or personal travel are not. In any case the explanation should be accompanied by corroborating documentation, including names and contact information, and the explanation must be accepted by the instructor prior to missing the exam.
  - Evidence from a university official that you will miss the exam due to university sanctioned travel or extracurricular activity.
- If submitted on or after the day of the scheduled exam:
  - A note from a physician or university dean indicating an illness or other extraordinary circumstance that prevented you from taking the exam and could
not be planned for in advance. Again, corroborating information must be supplied.

All excuses must be submitted in writing, must be signed by the excusing authority, and must include complete contact information for the authority, including telephone numbers and address.

Missed midterm exams with acceptable excuse will be made up. Missed, and acceptably excused, final exams will result in the course grade of 'I' and must be made up in the first two weeks of the following semester.

**SYLLABUS CHANGE POLICY:**

Except for changes that substantially affect implementation of the evaluation (grading) statement, this syllabus is a guide for the course and is subject to change with advance notice. Such notice will be in the form of a posting to the course web site on Canvas.

**Class Schedule and Readings**

January 11:  **Introduction and Course Overview**

January 13:  **Discovery, Drug Development, and Clinical Trials**

January 18:  **Martin Luther King Day (No class)**

January 20:  **Government’s Role in Regulating Pharmaceutical R&D and Recent Drug Development Trends**

January 25:  **The Value of Pharmaceuticals: Health Improvement and Cost Offsets**
January 27:  **Patents, the Generic Drug Industry, and the Hatch-Waxman Act**

February 1:  **How U.S. Health Insurers Manage Pharmaceutical Use and Spending**

February 3:  **Pricing and Reimbursement: Basic Principles**
- Sign up for team assignment for Policy Analysis Project on Canvas due by 11 pm

Recommended:

February 8:  **Commercialization and Marketing Strategies**

Recommended:

February 10:  **Regulation of Pharmaceutical Marketing**

February 15:  **Should the U.S. Manage Pharmaceutical Spending Like Europe and Japan?**
- Topic choice for Policy Analysis Project due on Canvas by 11 pm.

February 17: **Should the U.S. Manage Pharmaceutical Spending Like Europe and Japan? (Part II)**

February 22: **International markets, pricing and firm strategy, Guest Lecture, Patricia Trowers-Johnson, Global Pricing, Reimbursement & Access Director of Eli Lilly and Company**

- Readings-TBA

February 24: **A Physician’s Perspective, Guest Lecture**

- Readings-TBA

February 29: **The Cost of R&D, the Returns to R&D Investment, and How Changes in Expected Pharmaceutical Profits Would Affect R&D Investment**

- Submit search queries and data sources for Policy Analysis Project due on Canvas by 11 pm.

Recommended:

March 2: **Comparative Effectiveness Analysis in the United States**

- Submit search queries and data sources for Policy Analysis Project due on Canvas by 11 pm.

March 7: **Midterm Exam**

March 9: **Financing Innovation and the impact of Mergers, Acquisitions, and Alliances**


Recommended:

March 14 – March 16: SPRING BREAK, no classes

March 21: Policy Analysis Working Session/Individual Group Meetings

March 23: Prescription Drug Misuse in the United States, Guest Lecture, Hsien-Chang Lin, Professor of Applied Health Sciences

March 28: Pharmaceuticals in Emerging Markets: BRIC

March 30: GSK in Brazil Case Study

April 4: Drug Testing in Nigeria Case Study

April 6: Policy Analysis Working Session/Individual Group Meetings

April 11: Genomics and Personalized Medicine
- Submit preliminary findings and conclusions for Policy Analysis Project due on Canvas by 5pm.

April 13: 23 and Me Case Study

April 17: Submit final slides via Canvas by 11 pm.

April 18: Presentations

April 20: Presentations
April 25:  **The Orphan Drug Act**

April 27:  **Impact of the Affordable Care Act (ACA) on the Pharmaceutical Industry**

May 4:  **Final Exam, 12:30-2:30**