**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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**Office Hours**:
Prof Perez: Monday, 2:30 – 4:00

**Course Description**
This course provides an overview of the pharmaceutical industry, it's 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.

[1] http://www.consumeraffairs.com/news/banning-cell-phones-in-schools-raises-test-scores-study-finds-051815.html
http://money.cnn.com/2015/05/18/technology/smartphones-schools-ban/
http://www.newyorker.com/tech/elements/the-case-for-banning-laptops-in-the-classroom

**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:

Understanding Pharma: The Professional's Guide to How Pharmaceutical and Biotech Companies Really Work, by John J. Campbell, 2nd edition. Pharmaceutical Institute (publisher).

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

(2) Health Policy Issues: An Economic Perspective, by Paul Feldstein, 6th Edition. Health Administration Press (publisher)

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**

- Campbell, John J. (2008). Chapter 4: "Discovery," in Understanding Pharma: the Professional's Guide to How Pharmaceutical and Biotech Companies Really Work.
- Feldstein, Paul J. (2011). Health Policy Issues: and Economic Perspective, Chapter 28: pages 458-462 only.

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

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

- Feldstein, Paul J. (2011). Health Policy Issues: and Economic Perspective, Chapter 26: pages 421-432 only.
- Campbell, John J. (2008). Chapter 5: "Drug Development," in Understanding Pharma: the Professional's Guide to How Pharmaceutical and Biotech Companies Really Work, pages 78-99 only.

January 25: **The Value of Pharmaceuticals: Health Improvement and Cost Offsets**

- Garthwaite and Duggan (2012). "Empirical Evidence on the Value of Pharmaceuticals," in The Oxford Handbook of the Economics of the Biopharmaceutical Industry, edited by Patricia M. Danzon and Sean Nicholson, Oxford University Press, pages 463-479.
- Parker, Ian (2013). "The Big Sleep," *The New Yorker,* December 9, 2013.

January 27: **Patents, the Generic Drug Industry, and the Hatch-Waxman Act**

- Grabowski, H.G., M. Kyle, R. Mortimer, G. Long, and N Kirson (2011). "Evolving Brand-name and Generic Competition May Warrant a Revision of the Hatch-Waxman Act." *Health Affairs*, November: 2157-2166.

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

- Feldstein, Paul J. (2011). Health Policy Issues: an Economic Perspective, Chapter 25.
- Kaiser Family Foundation (2005). "Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain." Pages 17-23 only.

February 3: **Pricing and Reimbursement: Basic Principles**

- Sign up for team assignment for Policy Analysis Project on Canvas due by 11 pm
- Gladwell, Malcolm (2004). "High Prices," *The New Yorker*.
- Whoriskey, Peter, and Dan Keating (2013). "An Effective Eye Drug is Available for $50. But Many Doctors Choose a $2,000 Alternative," *The New York Times*, December 9, 2013.

Recommended:

- Reinhardt, Uwe E. (2007). "The Pharmaceutical Sector in Health Care," in Pharmaceutical Innovation: Incentives, Competition, and Cost-Benefit Analysis in International Perspective, edited by Sloan and Hsieh. Pages 35-44 only.

February 8: **Commercialization and Marketing Strategies**

- Kenkel and Mathios (2012). "Promotion to Physicians and Consumers," in The Oxford Handbook of the Economics of the Biopharmaceutical Industry, Danzon and Nicholson editors, Oxford University Press, pages 493-508.

Recommended:

- Campbell, John J. (2008). Chapter 8: "Marketing and Brand Management," in Understanding Pharma: the Professional's Guide to How Pharmaceutical and Biotech Companies Really Work, pages 156-166 only.

February 10: **Regulation of Pharmaceutical Marketing**

- Campbell, John J. (2008). Chapter 9: "Sales," in Understanding Pharma: the Professional's Guide to How Pharmaceutical and Biotech Companies Really Work, pages 180-192 only.
- Agrawal et al. (2013). "The Sunshine Act – Effects on Physicians," *New England Journal of Medicine*, May 30, 2013.

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.
- Feldstein, Paul J. (2011). Health Policy Issues: an Economic Perspective, Chapter 27.

- Feldstein, Paul J. (2011). Health Policy Issues: an Economic Perspective, Chapter 28: pages 382-391 only.

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.
- DiMasi, Joseph A, and Henry G. Grabowski. (2012). "R&D Costs and Returns to New Drug Development: a Review of the Evidence," in Handbook on the Economics of the Biopharmaceutical Industry, edited by Patricia M. Danzon and Sean Nicholson. Pages 34-44 only.

Recommended:

- Reinhardt, Uwe E. (2007). "The Pharmaceutical Sector in Health Care," in Pharmaceutical Innovation: Incentives, Competition, and Cost-Benefit Analysis in International Perspective, edited by Sloan and Hsieh. Pages 31-35 only.

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.
- Zaric, G. (2010). "Difficult Choices – An Introduction to Cost-Effectiveness Analysis." Ivey School of Business Note 910E07.
- O'Dell, James R. et al. (2013). "Therapies for Active Rheumatoid Arthritis after Methotrexate Failure." *New England Journal of Medicine,* accessed June 12, 2013.

March 7: **Midterm Exam**

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

- Grabowski, Henry G., and Margaret Kyle (2012). "Mergers, Acquisitions, and Alliances," in Handbook on the Economics of the Biopharmaceutical Industry, edited by Patricia M. Danzon and Sean Nicholson. Pages 552-563 only.

Recommended:

- Campbell, John J. (2008). Chapter 7: "Business Development," in Understanding Pharma: the Professional's Guide to How Pharmaceutical and Biotech Companies Really Work.

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*

- Novak, S. P., Calvin, S. L., Glasheen, C., & Edlund, M. J. (2011). The epidemiology and treatment of prescription drug disorders in the United States. Psychiatric disorders–Trends and developments, 367.
- Fischer, B., Bibby, M., & Bouchard, M. (2010). Non-medical use and diversion of psychotropic prescription drugs in North America: a review of sourcing routes and control measures. *Addiction*, *105*(12), 2062-70.

March 28: **Pharmaceuticals in Emerging Markets: BRIC**

- Kapczynski, Amy (2013). "Engineered in India – Patent Law 2.0," *New England Journal of Medicine*," July 18, 2013.
- Chen, Jing et al. (2013). "TRIPS-plus and Access to Medicines in China," *Journal of Public Health Policy* 34(2): pages 226-233 only.

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.
- Hamburg, Margaret A., and Francis S. Collins (2010). "The Path to Personalized Medicine," *New England Journal of Medicine* 363(4): 301-304.
- Winslow, Ron (2014). "Custom-Fit Treatments for Prostate Cancer," *New York Times*, January 13, 2014.

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**

- Woodcock, Janet (2012). "The Future of Orphan Drug Development," *Clinical Pharmacology & Therapeutics* 92(2): 146-148.
- Pollack, Andrew (2012). "Questcor Finds Profits, at $28,000 a Vial," *The New York Times*, December 29, 2012.

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

- "Biosimilars," *Health Affairs*, October 10, 2013.
- Outterson, K. and A. Kesselheim (2009). "How Medicare could get Better Prices on Prescription Drugs." *Health Affairs* 28(5): w832-41.

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