Pharmaceutical Economics and Policy
Course#: 25-PADM-571
Credits: 3 Quarter Hours
Spring 2006

Course Information:

Title: Pharmaceutical Economics and Policy
Students: MS/PhD graduate and professional PharmD students
Lecture Time/Date: 8:30am – 9:50am Monday
8:30am – 9:50am Wednesday
Location: HPB Room 231
Office hours: 8:00am-12:00pm Monday, Tuesday, Wednesday

Course Coordinator:

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Required Text Books:

Stuart O. Schweitzer. Pharmaceutical Economics and Policy. Oxford University Press, New York, NY. 1997.

Reference Text Books:

Mickey C. Smith. Studies in Pharmaceutical Economics. Pharmaceutical Products Press. New York, NY. 1996.

James Henderson. Health Economics & Policy. Wouth-Western College Publishing. Cincinnati, Ohio. 1999.

Jonathon Erlen, Joseph F. Spillance. Federal Drug Control: The Evoluation of Policy and Practice. Pharmaceutical Products Press. Binghamton, NY. 2004.

Course Mission:

The goal of the course is to introduce economic and policy analysis of the pharmaceutical industry, discuss demand and supply issues related to research and development of therapeutic agents, setting drug prices, and motivation of pharmaceutical industry. So that, students can have a better understanding of how economic theories are associated with pharmaceutical industry regulations, health policy process, patent protection, market and competitions, as well as pharmacy performance. Concepts introduced in the course will be expanded and refined throughout the professional curriculum.

Educational Outcomes:

This course contributes to the achievement of the following outcomes of the Center for the Advancement of Pharmaceutical Education (CAPE): provide pharmaceutical care, manage medication use systems, promote public health, provide drug information and education, thinking, and communication.

Course Objectives

The objectives of this course consist of three components: Knowledge, Skill, and Values/Attitude.

Knowledge

Upon completion of this course, students will be able to:

1. Understand pharmaceutical industry:
(Cognitive: comprehension)
   - Supply of pharmaceuticals,
   - Demand of pharmaceuticals,
   - Research and development, and
   - Industry organization.

2. Understand pharmaceutical prices:
(Cognitive: calculation and evaluation)
   - Costs of pharmaceutical products,
   - Measurement of drug prices,
   - Determination of drug prices,
   - Price elasticity of demand, and
   - Price discrimination.

3. Understand pharmaceutical market:
(Cognitive: comprehension)
   - Drug utilization and price trends in US,
   - Pharmaceutical market,
   - Profit maximization for pharmaceutical company,
   - Monopoly power and brand name drug firm,
   - Antitrust policy and price-fixing issue, and
   - Pharmaceutical industry mergers.

4. Discuss pharmaceutical regulatory and policy:
(Cognitive: comprehension)
   - Industry regulatory systems,
   - Drug approval process,
   - Patent protection and Drug Price Competition and Patent Term Restoration Act,
   - OBRA'90 and drug utilization review,

- Prescription Drug Use Fee Act (PDUFA),
- FDA Modernization Act,
- Drug re-importation in US, etc.

5. Evaluate pharmaceutical regulatory events and policy implications based on the medical and pharmacy literature.

(Cognitive: evaluation)

Skills

At the end of this course, the student will be able to:

- Apply the foregoing economics theories and concepts in analyzing and determining industry performance and health policy process.
- Apply the knowledge in pharmacy management and practice in term of drug pricing, marketing and economic efficiency.
- Interpret and understand the economic literature and analyses on pharmaceutical industry and policy.

Values and Attitudes

At the end of this course, the student will tend to:

- Accept the value of economics theory, critical thinking applied to pharmaceutical industry.
- Regard economic analyses and regulatory implications as fundamentals to understand and improve pharmacy management and practice.

Educational Methods

Course material is presented in interactive lectures with various demonstrations, examples, and discussions.

Each topic will have assigned reading from the reference articles or textbook chapters. Students are expected to prepare by reading the chapters prior to the class. Faculty may assign additional readings such as journal articles.

Educational Assessments

The professional and general educational outcomes that will be evaluated in this course include:

1) Evaluate and interpret pharmaceutical economic analyses to improve pharmacy management and practices;

2) Develop critical thinking skills to understand and solve basic economics or policy related problems.

3) Two individual projects will be provided for students. Students will complete projects individually on topic of pharmaceutical economics and/or regulatory issues based on published literature. At least one brief presentation is required before the end of the quarter. Faculty will evaluate their project papers and presentations.

Examinations and Grades:

- Ethical standards: The University Student Code of Conduct and the code of Ethics of the American Pharmaceutical Association will be in effect for this course. A candidate found in violation of this section will receive a score of zero (0%) for the work in question and will be reported to the Dean's office.

- Disability: Any candidate with a disability that may potentially interfere with his/her performance in this course should contact the instructor during the first week of class.

- Course Withdrawal: The University policy on withdrawal from this course will be followed.

- Missed projects or assignments: Any examination or assignment can only be made up with the prior approval of the instructor.

- Incomplete grades: Incomplete grades will only be given with the prior approval of the instructor.

- Criteria for letter grades: Final grades will be assigned in compliance with the grading policies published by the Office of the Registrar, Student Records. No incomplete grade will be given without the course coordinator's approval.

Percentage	Letter Grade
90 – 100	A
86 – 89	B+
80 – 85	B
76 – 79	C+
70 – 75	C
≤ 69	F

Project#1: drug price and utilization study 35%
Project#2: US pharmaceutical regulation review 35%
Presentation (15%) and class involvement (15%)

Course Schedule:

Week	Date	Reading	Topics
1	3/28 & 3/30	Ch 1	Supply-side pharmaceuticals: Pharmaceutical Industry Overview, Industry Concentration, New Drug Research & Development.
2	4/4 & 4/6	Ch 2-3 Handout	Pharmaceutical marketing. Pharmacy Benefit Managers
3	4/11 & 4/13	Ch 3-4 Handout	Demand-side pharmaceuticals Demand utility Demand elasticity
4	4/18 & 4/20	Ch 4-5 Handout	Pharmaceutical market. Market structures Profit maximization. World pharmaceutical industry. Project#1 (drug price/market) out.
5	4/25 & 4/27	Ch 6-7 Handout	Drug prices definition and analysis Medical component consumer price index US Drug expenditure trends (price and utilization trends).
6	5/2 & 5/4	Ch 8-9 Handout	Patent protection, Brand-name vs. generic drug competition Drug cost containment strategies. Project#2 (Regulation/Policy) out. Project#1 due.
7	5/9 & 5/11	Ch 10 Handout	FDA Drug Regulation Timeline, Drug Price Competition and Patent Term Restoration Act. Evaluating new drug approvals. Review research articles.
8	5/16 (no class) & 5/18	Handout	OBRA'90 and drug utilization review. Prescription Drug Use Fee Act Post-marketing surveillance Review for project#2.
9	5/23 & 5/25	Handout	FDA Modernization Act, Orphan Drug Act, Price discrimination law suits Antitrust regulation and firm merger.
10	5/30 & 6/1	Handout	Research application review, Course review and summary, Project#2 due.
11	6/6 & 6/8		Review and Summary Last week