SOCIAL AND ADMINISTRATIVE PHARMACY
PHARMACEUTICAL ECONOMICS AND POLICY (SAPh 8235)

Fall Semester 2019

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Office hours: Arranged.

Class Hours: Tuesday, 1:00 – 3:00 p.m.

Classroom: 7-173 WDH

Credit Hours: 3.0

Catalog Description: Economic and policy analysis of the pharmaceutical sector of the health care system. Problems of pricing, production, and distribution of pharmaceuticals. Domestic and international policy issues relevant to price and access of pharmaceuticals.

Course Objectives:

1. Describe the structure, conduct, and recent performance of the US pharmaceutical industry.
2. Describe the drug approval process and its impact on pharmaceutical R&D.
3. Describe the intent and function of regulations bearing on the pharmaceutical industry in the US and abroad.
4. Discuss managed care and its relation to the development and pricing of pharmaceuticals.
5. Discuss current trends and public policy relevant to the promotion of pharmaceuticals in the US.
6. Explain the process of public policy formation, implementation, and evaluation.
7. Apply the public policy process to issues in the pharmaceutical market.
8. Understand the historical events that influenced and shaped current pharmaceutical policies.
**Required Readings:** Class readings will and links will be posted to Canvas prior to class. Completing the readings will likely require 3 - 5 hours of your time (sometimes more) each week. Much of the learning in this course will be done independently through assigned readings. Class or discussion time will complement, but not replace, the material presented in these readings. The readings should be viewed as an opportunity to explore complicated topics, critically appraise the evidence regarding different pharmaceutical policies, and explore more deeply than what is covered in lecture format the areas related to each topic. You are required to complete the readings each week and must come prepared to discuss these readings in class.

**Course Philosophy:** Pharmaceutical policy is a major factor in developing and evolving the delivery of health care. This course will help student develop an understanding of pharmaceutical policy and its relationship to the health of patients, delivery of health care, and influence on the health care system. A broad understanding of these relationships is critical for student seeking careers in health related fields including academia, the pharmaceutical industry, managed care, health consulting, and/or governmental health organizations. Given the influence of pharmaceutical policy on the health of patients, it is also critical for students pursuing research foci in both quantitative and qualitative fields of health care. By necessity, the course will focus on breadth, not depth, in each area. A complete course could easily be taught on many of the individual topics discussed in the course.

Each week we will read from a variety of sources; some didactic, others empirical. These sources will often present differing viewpoints, conceptualizations, opinions, etc. regarding the week’s topic. The overarching goal of this course is to help you to develop critical thinking skills in the area of pharmaceutical economics and policy.

**Course Functioning:** Each week we will meet for approximately two hours and discuss the required readings. These readings usually will consist of journal articles, government reports and/or book chapters relating to a specific topic. We have attempted to limit the readings each week so that you will be more likely to complete the readings and take more time in doing so. This approach, however, sacrifices a more complete understanding of the topics. Although we have attempted to choose readings that are representative, often, there is more that could be done.

Attendance, adequate preparation, and participation in class discussions are required if you want to receive full credit in the course. Some of the material we cover in class is not in the assigned readings, while some material is sufficiently covered. Therefore, class time will be used to expand and discuss materials in the readings, not simply to restate it. If you are unable to attend a class meeting, please discuss this with the course director and make arrangements to assure adequate coverage of the learning objectives.

We will not lecture in this course. Instead, one of us, students, faculty, and/or guests, will lead the discussion each week. The Instructors will act as facilitators and attempt to answer questions and clarify points in the readings. During weeks in which no one is assigned to lead the discussion, we will discuss the readings as a group.
Grading: Your grade will be based on the following criteria:

1. Class attendance and participation: 10 points

You are expected to read assigned materials prior to class; assessment of attendance and participation will be based on whether you have prepared sufficiently to participate in class discussions. Although you may be excused from class if a valid reason is presented to the course director prior to the start of class, excessive absences may affect the final grade assigned.

2. Leading the class discussion once: 15 points

Each student will be expected to present assigned readings related to a topic area presented during the semester. Presentation schedules will be assigned during the first week of class. Presentations should be based on the assigned reading(s). Students will be asked to summarize the readings assigned to them and lead in class discussion to facilitate an exchange of ideas surrounding the article topic presented. The method of presentation (e.g., Powerpoint, handout, example, etc) is to be selected by the individual presenter. The delivery of content is important. It is expected that each student engage the class in active discussion and not simply lecture on content. A grading rubric for this assignment is included in Moodle and you are encourage to review the rubric to see exactly what criteria you will be graded on so that you include these criteria in your discussion.

3. Reflection papers 25 points

Students will be given a series of 6 short written assignments to complete during the course of the semester related to topics being discussed. Each assignment will have 5 points and the lowest grade received on a written assignment will be thrown out for a final cumulative total of 25 points.

4. Pharmaceutical Policy Commentary Paper 50 points

A grading rubric is posted on Moodle. Students are expected to select a relevant policy issue of interest to them. This could be a topic discussed in class or another topic of interest which was not covered, but related to pharmaceutical policy. Prepare a commentary of this topic for submission to a journal of your choice. A number of points should be included in the commentary as outlined in the grading rubric posted on Moodle. Each commentary should include a presentation of the effectiveness of the policy and potential limitations of the policy. The commentary should include an extensive review of the literature on the selected topic and the strength of evidence about the policy and its effect on at least one stakeholder of interest. Attention should also be paid to the gaps in the literature. References should be included in each paper. The papers should be written independently and must be between 8 and 10 pages in length (double-spaced, 12 point font) excluding references. Papers should be formatted for journal submission as a commentary and must include the following information:
1) A cover page with title and student name and affiliation
2) A structured abstract no longer than 300 words in length
3) The primary text of the paper (8-10 pages in length)
4) A structured reference section.

The cover page, abstract, and references will not be counted toward the 8-10 page length requirement. Papers will be evaluated on content, clarity, and originality. A description of the topic and a brief 1-2 page outline of the paper will be due in class on October 9th. The final paper is due in class on December 4th. Examples of prior commentaries derived from this a similar course which have been published in relevant medical journals are available on Moodle as reference.

**Grading Scale:** This course will use the standard University approved grading scale, A-F.

<table>
<thead>
<tr>
<th>Grade</th>
<th>Range</th>
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<tbody>
<tr>
<td>A</td>
<td>100 – 92</td>
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<tr>
<td>A-</td>
<td>91 – 90</td>
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<tr>
<td>B+</td>
<td>89 – 88</td>
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<td>B</td>
<td>87 – 82</td>
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<tr>
<td>B-</td>
<td>81 – 80</td>
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<tr>
<td>C+</td>
<td>79 – 78</td>
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<tr>
<td>C</td>
<td>77 – 72</td>
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<tr>
<td>C-</td>
<td>71 – 70</td>
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<tr>
<td>D</td>
<td>69 – 60</td>
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<tr>
<td>F</td>
<td>59 and below</td>
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A -- achievement that is outstanding relative to the level necessary to meet course requirements.

B -- achievement that is significantly above the level necessary to meet course requirements.

C -- achievement that meets the course requirements in every respect.

D -- achievement that is worthy of credit even though it fails to meet fully the course requirements.

S -- achievement that is satisfactory, which is equivalent to a C- or better (achievement required for an S is at the discretion of the instructor but may be no lower than a C-).

F (or N) -- Represents failure (or no credit) and signifies that the work was either (1) completed but at a level of achievement that is not worthy of credit or (2) was not completed and there was no agreement between the instructor and the student that the student would be awarded an I (Incomplete).

**Policy on Incomplete Coursework**
Incomplete coursework is a major inconvenience for students and instructors. We expect you to do everything in your power to avoid this situation. Legitimate excuses include verified illnesses and family emergencies (serious illnesses and funerals). No incompletes will be given unless you have a prior written agreement with one of the instructors.

If an illness, family emergency or other extreme situation arises, we will discuss the circumstances and agree on an appropriate timeline for completion of any work. We will both sign an agreement that specifies what work needs to be completed and by what date. **If the work is not completed by that point, your incomplete will be changed to and ‘F’ for the course.**

**Plagiarism Policy**

Academic integrity is essential to a positive teaching and learning environment. All students enrolled in University courses are expected to complete coursework responsibilities with fairness and honesty. Failure to do so by seeking unfair advantage over others or misrepresenting someone else’s work as your own can result in disciplinary action. The University Student Conduct Code defines scholastic dishonesty as follows:

**Scholastic Dishonesty:** Scholastic dishonesty means plagiarizing; cheating on assignments or examinations; engaging in unauthorized collaboration on academic work; taking, acquiring, or using test materials without faculty permission; submitting false or incomplete records of academic achievement; acting alone or in cooperation with another to falsify records or to obtain dishonestly grades, honors, awards, or professional endorsement; altering, forging, or misusing a University academic record; or fabricating or falsifying data, research procedures, or data analysis.

Within this course, a student responsible for scholastic dishonesty can be assigned a penalty up to and including an "F" or "N" for the course. **If you have any questions regarding the expectations for a specific assignment or exam, ASK!!**
<table>
<thead>
<tr>
<th>Date</th>
<th>Week Title</th>
<th>Learning Objectives</th>
<th>Required Readings</th>
<th>Suggested Readings</th>
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| 9/3/2019   | Week 1: An Overview of the U.S. Health Care System and Pharmaceutical Spending | 1. Introduction to the class  
2. Discuss the role of government regulation in the health care sector  
3. Compare and contrast the pharmaceutical market to other health care sectors  
2. Describe the importance and process of agenda setting in policy making  
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| 10/1/2019  | Week 5: Prescription Drug Development and the Pharmaceutical Industry | - Provide an overview of the pharmaceutical and biotechnology industries  
- Review estimates of the cost of developing new medications  
- Describe dilemmas between innovation and access for medications  
- Review research and development trends in the pharmaceutical industry  
3. Light DW, Lexchin JR (2012) Pharmaceutical research and development: what do we get for all that money? *BMJ*. 344 [https://www.bmj.com/content/345/bmj.e4348](https://www.bmj.com/content/345/bmj.e4348) |
| 10/8/2019  | Week 6: Generic Medication Approval, Pharmaceutical Patents, and Market Exclusivity | - Discuss the Abbreviated New Drug Process  
- Describe the Drug Price Competition and Patent Term Restoration (Hatch-Waxman Act) of 1984 and other market exclusivity provisions  
- Discuss the balance between incentives for innovation and the need for affordability  


### Suggested Readings


### 10/15/2019

**Week 7: Limitations in the Generic Pharmaceutical Market**

**Learning Objectives**

1. Describe industry strategies to limit or delay competition to generic medications
2. Describe the follow-on biologic process and limitations
3. Describe the impact and potential solutions to drug shortages in the marketplace
4. Review proposals to improve generic pharmaceutical approval and marketing

**Required Readings**


**Suggested Readings**
<table>
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2. Understand common price references (AWP, WAC) for pharmaceuticals in the U.S.  
3. Examine the role of rebates on pharmaceutical prices  
2. Understand the arguments for and against federal management of pharmaceutical pricing  

**Suggested Readings**


**Learning Objectives**
1. Describe the different federal programs covering prescription benefits for patients
2. Describe the Medicaid insurance benefit, eligibility and enrollment
3. Describe the Medicare insurance benefit, eligibility and enrollment
4. Discuss limitations and policy proposals to improve federal prescription coverage

**Required Readings**


**Suggested Readings**


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**Week 11: Pharmaceutical Managed Care Strategies**

**Learning Objectives**

1. Describe the use of demand side controls to curb pharmaceutical spending (e.g. copayments and deductible)
2. Describe the use of supply side controls available to curb pharmaceutical utilization and spending (e.g. prior authorizations, quantity limits, & formularies)
3. Understand the effectiveness and unintended consequences from applying managed care policies to pharmaceuticals

**Required Readings**


**Suggested Readings**


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**Week 12: Pharmaceutical Policies: International Variations**

**Learning Objectives**

1. Compare and contrast pharmaceutical policies from other countries to the U.S.
2. Explore the evidence of effectiveness of international pharmaceutical policies
3. Understand how cost-effectiveness analysis is applied to pharmaceutical coverage decisions in other countries

**Required Readings**


**Suggested Readings**


11/26/2019

**Week 13: Pharmaceutical Promotion**

**Learning Objectives**

1. Understand the pro and con arguments for promoting pharmaceuticals
2. Describe the spending and types of promotion for pharmaceuticals employed by manufacturers
3. Provide an overview of the regulation for promotion of pharmaceuticals
4. Describe the different types of promotion directed to providers and patients

**Required Readings**


**Suggested Readings**

<table>
<thead>
<tr>
<th>12/3/2019</th>
<th>Week 14: The Shift from Volume to Value in Health Care</th>
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<tbody>
<tr>
<td><strong>Learning Objectives</strong></td>
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<tr>
<td>1. Describe the process of outcomes-based contracting for pharmaceuticals</td>
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<td>2. Describe the process of pay-for-performance for health care services</td>
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<tr>
<td>3. Understand the types of performance measurements available to measure value</td>
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<td>4. Understand the evidence of effectiveness for using value to pay for health care</td>
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12/10/2019 | **Week 15: Stump the Professor** |