**The University of Florida**

**College of Pharmacy**

**Department of Pharmaceutical Outcomes & Policy**

**PHA 5263 Pharmaceutical Industry and Public Policy**

**Spring 2014 2 Semester Credit Hours**

**Course Purpose:**In this course students are challenged to think about the supply of pharmaceutical products and services in a broad context. Discussion begins with research and development, the importance of intellectual property protection, and legislation that stimulates or stifles the R&D process. Channels of distribution for pharmaceutical products are examined, contrasting the flow of goods and the flow of payments. Product pricing is deliberated along with the role of comparative effectiveness research. Impact and oversight of promotional practices are considered. The global implications of domestic pharmaceutical policies are introduced.

Course Faculty and Office Hours

Course Coordinator:
Earlene Lipowski, R.Ph., Ph.D.

Email: lipowski@cop.ufl.edu Office: 3319 HPNP Building in Gainesville, Florida

Phone (direct line): 352-273-6256

Office Hours

The instructor is available by appointment for individual consultation. General questions posted to the course discussion board typically receive a response in 24 hours, and email and telephone calls are additional options.

***Graduate Teaching Assistant***:

Rishi Ramkissoon, PharmD, MBA

rangerram@ufl.edu

**Place and Time of Class Sessions**Classes are held Tuesday and Fridays from 10:45-12:30 using the Adobe Connect system. **Classes begin on Tues., March 11, 2014 and end Tues., April 22, 2014.**

* The link to the classroom is **https://connect.cop.ufl.edu/pha5263\_s2014**
* Tutorials and other information for Adobe Connect are posted in the Resources section of the course web site.
* Recordings of classes are available through links in this folder.

Course Objectives

Cognitive Objectives. Upon successful completion of this course, the student will be able to

1. Give an overview of the pharmaceutical industry, both within the U.S. and at a global level.
2. Discuss issues related to prescription drug products, R&D, pricing, promotion, and distribution.
3. Describe matters of public policy currently under debate and stakeholder positions.

Skill Objectives. Upon successful completion of this course the student will be able to

1. Locate and summarize the position statements of stakeholders on matters of public policy related to the pharmaceutical industry.
2. Submit a policy statement for consideration by a professional organization or advocacy group.
3. Compose effective letters to editors, legislators and others advocating a position on a matter of public policy.

**Pre-Requisite Knowledge and Skills**

This elective class is open to 4PD students in the PharmD program; others upon consent of the instructor.

## Course Structure & Outline

**Course Structure.** Multiple self-directed learning activities are required, i.e., videos, readings, and web-based learning. Students participate in discussion twice weekly in a live online forum and are expected to contribute to ongoing discussions using the discussion board which is part of the course web site.

**Course Outline/Activities.** Refer to the Course Calendar posted as a separate document in the Resources Section of the course web site. A copy of the Course Calendar current as of 3/4/14 is attached to this document as Appendix A.

Textbooks

There is no textbook for this course. Reading assignments, or links to background materials, will be found in the Resources Section of the course web site.

Active Learning Requirements

There will be a folder on the course web site for each unit in the course, roughly one unit per week of the course. In the respective folders you will find:

* Learning objectives for the unit.
* Reading assignments with links to reading materials. These may include, but are not limited to, articles from the peer reviewed medical literature, newspapers, reports issued by government agencies, white papers from advocacy groups, web sites and blogs. Occasionally, students will be asked to view a video-taped program or participate in a webcast to prepare for class discussion.
* Discussion questions
* Information about any short written assignments, one assigned approximately every 2 weeks
* Tasks to be completed in preparation for class meetings

Feedback to Students

Each written assignment will be evaluated and scored using the rubric found in Appendix B; comments will be found in the assignment section of the course site. Students receive feedback on an outline of their paper prior to submission of the final work product. Due to the short duration of the course, there will be no mid-term feedback but students are welcome to speak with the instructor at any time about the expectations and their performance.

Student Evaluation & Grading

**Evaluation Methods**

This syllabus includes grading rubrics (Appendix B and Appendix C) that will be used for the evaluation of written assignments and class participation. Use them as guidelines when preparing the work products that you are submitting. An overall course grade is determined from the three components, equally weighted.

1. Written assignments 1/3 of grade

Four (4) short assignments at approximately two week intervals. Each written assignment will be assigned a letter grade. Written comments on assignments are posted to the course web site and grades are be posted to the grade book on the course web site. See Grading Rubric Appendix B.

1. Class Participation 1/3 of grade

Includes live class meetings and discussion board on the course web site. A satisfactory goal for each student should be to initiate one discussion thread per unit and participate in at least two other threads in each instructional unit. See Grading Rubric Appendix C.

1. Issue Brief, oral and written 1/3 of grade

Components include your oral presentation to the class and the instructors’ evaluation of your final written paper. Instructions for the course paper will be specified at the start of the course. Detailed instructions are posted in a separate document.

**UF Recommended Grading** **Scale**

A 93.0 - 100

A- 90.0 – 92.9

B+ 86.6 – 89.9

B 83.3 – 86.5

B- 80.0 – 83.2

C+ 76.6 – 79.9

C 73.3 – 76.5

C- 70.0 – 73.2

D+ 66.6 – 69.9

D 63.3 – 66.5

D- 60.0 – 63.2

E <60

## Class Attendance Policy

Each student receives a grade for their participation in this class according to the rubric described in Appendix C. Absences or chronic tardiness without a satisfactory explanation will be noted and result in lowering of the participation grade. Students who miss a session conducted in Adobe Connect are expected to access the audio archive and listen to the session. You are responsible for content delivered in the scheduled Adobe Connect sessions.

Requests to be excused from class should be sent to the instructor by email, in advance of the class meeting. In an emergency, a telephone message may be used in place of email.

Quiz/Exam Policy

There are no quizzes or exams in this course.

 Policy on Old Assignments

An example of a policy brief paper is provided in the Resources section of the course web site as a model for the final paper requirement. Questions about assignments may be posted to the discussion board in the designated folder where responses from the instructors are viewable by all students enrolled in the course

**Assignment Deadlines**

Because assignments will be discussed in class, all submissions must be submitted electronically on the due date prior to the start of class. No late assignments will be accepted without the instructor’s specific permission.

**General College of Pharmacy Course Policies**

The College of Pharmacy has a website that lists course policies that are common to all courses. This information is posted at: <http://www.cop.ufl.edu/wp-content/uploads/dept/studaff/policies/General%20COP%20Course%20Policies.pdf>

The website covers the following:

1. University Grading Policies
2. Academic Integrity Policy
3. How to request learning accommodations
4. Faculty and course evaluations
5. Student expectations in class
6. Discussion board policy
7. Email communications
8. Religious holidays
9. Counseling & student health
10. How to access services for student success
11. Intellectual property and use of course materials

### Complaints

Should you have any complaints with your experience in this course please contact your course coordinator. If unresolved, contact the COP Senior Associate Dean-Professional Affairs. For unresolved issues, see: <http://www.distancelearning.ufl.edu/student-complaints> to submit a complaint.

Appendix A: Schedule of Course Activities/Topics as of 3/4/14

**PHA 5263 Pharmaceutical Industry and Public Policy**

**Spring 2014**

**Instructor** Earlene Lipowski, PhD lipowski@cop.ufl.edu

 Office Telephone (direct line): 352-273-6256

**TA** Rishi Ramkissoon, PharmD, MBA rangerram@ufl.edu

**Class Meetings Tuesday and Friday 10:45 AM -12:30 PM**

**Location of Class Meetings https://connect.cop.ufl.edu/pha5263\_s2014**

**(this direct link is posted on SAKAI site in RESOURCES Folder along with links to the recordings of each class session)**

**Course Calendar**

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| --- | --- |
| **Week 1** March 10-14 | **Unit I: Policy and Policy Formation****Tues 3/11**: Orientation to course and course requirements; student topics assigned The intersection of economics, polity and politics; What is public policy? **Unit II: The Pharmaceutical Industry** **Fri 3/14**: Channels of Distribution for Pharmaceuticals in the U.S. |
| **Week 2**March 17-21 | **Tues 3/18**: Pharmaceutical Industry: Sectors and Future Trends**Assignment 1 (**Company Profile) **DUE 3/18 PRIOR TO START OF CLASS** **Unit III: Research & Development of Pharmaceutical Products** **Fri 3/21**: Pharmaceutical R&D |
| **Week 3**March 24-28 | **Tues 3/25**: Legislation Affecting R&D**Fri 3/28:** Intellectual Property Protection |
| **Week 4**Mar 31-Apr 4 | **Unit IV**: **Price and Value** **Tues 4/1:** Setting a Price and Pricing Differentials**Assignment 2** (Engaging in Public Debate) **DUE 4/1 PRIOR TO CLASS**  **Fri 4/4**: Reimbursement |
| **Week 5**April 7-11 | **Unit V: Safety and Efficacy****Tues 4/8:** Medication Safety ~ Patient Safety **Fri 4/11:** FDA: Calls for Reform and the Response |
| **Week 6**April 14-18  | **Unit VI: Marketing Pharmaceutical Products** **Tues 4/15:** Controversies and control of promotional practices **Assignment 3** (Professional Policy Position) **DUE 4/15 PRIOR TO CLASS****VII: The Global Market for Pharmaceuticals**  **Fri 4/18:**  Policies and Practices inHigh-Income Countries  |
| Week 7April 21-23 | **Tues 4/22:** Policy Dilemmas in Low-to-Middle Income Countries **Assignment 4** (Enduring Controversies) **DUE 4/22 PRIOR TO CLASS** |
|  | **Final Written Paper DUE Sunday, 4/27/14 by 11:59 PM**  |

###### **Appendix B. Rubric for Grading Written Assignments and Oral Presentations**

Written assignments and scheduled presentations are evaluated on three criteria described below.

1. The work product is responsive to the assignment, i.e., the document or presentation
2. answers the questions that were posed.
3. states assumptions and goals when applicable.
4. presents feasible recommendations that take time, personnel and finances into account.
5. demonstrates professional knowledge, skill and judgment.
6. The work product includes the rationale and evidence for the conclusions or recommendations, that is,
7. relevant points are raised and support the conclusions or recommendations.
8. information from multiple sources is integrated and alternatives are compared.
9. statements are accurate and limitations are noted.
10. references are provided where appropriate using standard bibliographic style..
11. Any document or presentation is professional, i.e., it
12. is well organized with a beginning, middle and end.
13. uses proper sentence and paragraph structure.
14. is free of errors in grammar, or in punctuation and spelling.
15. is an appropriate length.

The letter grade assigned is based upon how well the work product meets the three criteria.

**A** work is excellent across all evaluation criteria

**B+** work satisfactorily meets all evaluation criteria and is excellent in some aspects

 **B** work satisfactorily meets all evaluation criteria

 **C+** work is satisfactory or excellent on two criteria but deficient on one

 **C** work is satisfactory on two criteria but deficient on one criterion

 **D** work is unsatisfactory on two of the three criteria

 **E** work is unsatisfactory in all aspects

**APPENDIX C. Rubric for Scoring Class Participation**

The grade for class participation will be determined by consensus of the faculty and teaching assistant(s) assigned to the course. Ratings are based upon performance in live discussion sessions and written postings to the course discussion board.

**During live discussion sessions and in posting to the discussion board:**

**A** Students enhance the class. They

* are prepared to make relevant comments;
* contribute readily to the conversation but do not dominate it;
* make thoughtful contributions that advance the conversation;
* display interest and respect the views of others.

**B** Students contribute to the class. They

* come prepared;
* make thoughtful comments when called upon, and from time to time contribute without being prompted;
* show interest in and respect for views of others;
* may be active participants whose contributions are less cogent than those of other students, but still advance the conversation.

**C** Students neither add nor detract to the class. They

* bluff their way when not prepared;
* do not voluntarily contribute to discussions;
* participate in discussion, but not in a way that advances the conversation;
* exhibit no interest in increasing their participation in class activities.

**D** Students have a negative effect on the class. They

* participate only when called upon and then give minimal responses, or they interrupt the discussion and otherwise impede discussions;
* are not prepared to participate;
* are late with assignments, and absent and tardy without excuse.

**E** Students disturb the class. They

* are rude;
* are not responsive to expressions of annoyance from the instructor or fellow students;
* radiate negative energy through hostile or bored attitudes and comments;
* have a negative effect on the participation of others;
* disrupt class proceedings.