
Syllabus – PHA 6269 Pharmaceutical Products and Public Policy

[3] Semester Credit Hours Spring B 2020

Course Purpose:

This course challenges students to think about the development of public policy positions and the articulation of organizational policy positions. Students will have the opportunity to develop and debate public policy positions related to the supplying of pharmaceutical products and services and to decide whether specific policies stimulate or stifle the 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 levers that the government has to address pricing issues.

Course Faculty and Office Hours

Course Instructor:

Melissa Andel, MPP, Adjunct Lecturer, Department of Pharmaceutical Outcomes and Policy
Email: melissa.andel@ufl.edu

Teaching Assistant:

Yun Shen, MPH, PhD Student, Department of Pharmaceutical Outcomes and Policy
Email: yunshen@ufl.edu

Office Hours:

You can contact the Teaching Assistant Yun Shen at yunshen@ufl.edu or the Course Instructor Melissa Andel at melissa.andel@ufl.edu. Please allow 24-hours for an email response.

Place and Time of Class Sessions

Class sessions occur weekly (see schedule of weekly class sessions) using the Zoom web conferencing software. To access the Class Zoom meeting link, click on the “Zoom Conferences” tool in the course navigation, left-hand side, once logged in.

Pre-recorded lectures as well as Zoom recordings will be available in the course Modules tool and on the course web page.

Course Objectives

Upon successful completion of this course, the student will be able to:

- Discuss how various types of organizations develop public policy positions;
- Understand how public policy positions lead to enacted legislation;
- Articulate various perspectives on a public policy issue;
- Develop an advocacy document supporting a position on a public policy issue; and
- Discuss current public policy issues related to prescription drug products and their use, including, but not limited to:

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- Describe Risk Evaluation and Minimization Strategies (REMS) programs and related FDA policies;
 - Discuss the current public policy issues related to biosimilars;
 - Identify and discuss various proposed solutions to combat the opioid/prescription drug abuse crisis; and
 - Discuss the 340B drug pricing program and current issues affecting participating entities.

Pre-Requisite Knowledge and Skills

Microsoft Word, Microsoft PowerPoint

Course Structure

Course will be comprised of class discussions, a weekly graded quiz (based on the previous week's lecture and the current week's reading assignment), a presentation, and a project. Pre-recorded lectures may be used in order to allow additional time during class sessions for discussion; if a pre-recorded lecture is assigned, a notice will be sent to students.

During the course, you will communicate with a Congressional office or federal agency with regards to a public policy issue. You will also independently research and prepare to lead a class discussion on one of the current public policy issues challenging the health care system: antibiotic resistance. This discussion will take place during the last class session. More information on both of these assignments will be discussed during the first class session.

Textbooks

None; resource materials for each week are listed in Appendix B.

For each discrete topic, I have included examples of statements from organizations that advocate on opposite sides of the issue discussed; commentary/opinion articles are also referenced some weeks. Neither the instructor nor the University of Florida endorses the organizations' positions. Instead, they are included to show students examples or real-world advocacy pertinent to the discussion topic. The instructor selected organizations based on their visibility and familiarity and are not intended to be exhaustive examples of all opinions on a topic. During the semester, students are encouraged to seek out advocacy statements from various groups – particularly those on opposing sides of one another.

Many news organizations cover health policy issues. Students are expected to stay informed on health policy generally throughout the semester. The following sites are provided as examples and suggestions (several also offer regular newsletters). If sites have a paywall, I have made a note for convenience; subscriptions are not required for this course. I have also not listed well-known national news sources such as the New York Times, Wall Street Journal, Washington Post, National Public Radio, Vox, etc., all of which also cover health policy issues:

- Health Affairs Blog: <https://www.healthaffairs.org/blog>
- Kaiser Health News: <https://khn.org/>

- Politico PULSE Newsletter (publishes M-F at 10:00 am ET):
<https://www.politico.com/politicopulse/>
- STAT News (many stories available free, STAT+ requires paid subscription):
<https://www.statnews.com/>

Other Health Policy Resources:

- Medicare Payment Advisory Commission (MedPAC) Payment Basics: <http://medpac.gov/-documents/-payment-basics>. MedPAC, a non-partisan Congressional advisory commission, maintains brief, accessible overviews of all the different payment systems used by Medicare. If you are interested in how Medicare pays for any service (from ambulance services to skilled nursing facilities), this is a great place to start.
- Medicaid Payment Advisory Commission (MACPAC) Medicaid 101: <https://www.macpac.gov/medicaid-101/>. MedPAC's companion, MACPAC, does not maintain a payment basics series, but if you have questions about Medicaid, they are an excellent resource.
- ACASignups.net: <http://acasignups.net/>. Charles fastidiously tracks and analyzes data on ACA trends and enrollment. While he is a supporter of the ACA, his analysis is fair and balanced.
- Healthcare Triage video series: <https://www.youtube.com/user/thehealthcatriage>. Dr. Aaron Carroll is a health services researcher at Indiana University and also contributes to the New York Times (<https://www.nytimes.com/by/aaron-e-carroll>). These videos cover explanations of various topics in health care and health care policy.

Active Learning Requirements

- Reading assignments
- Online lectures
- Presentation

Student Evaluation & Grading

Evaluation Methods:

Student evaluation is by grades received on weekly questions and the grades on the presentation and project. The assignment breakdown will be as follows:

ASSIGNMENT	WEIGHT
WEEKLY QUIZ	15%
CLASS/DISCUSSION BOARD PARTICIPATION	30%
PRESENTATION CLASS-LED DISCUSSION	40%
PROJECT/ADVOCACY COMMUNICATION	15%
TOTAL	100%

Grading Scale

95-100 = A
 90-94 = A-
 86-89 = B+
 83-85 = B

80-82 = B-
76-79 = C+
73-75 = C
70-72 = C-
66-69 = D+
63-65 = D
60-62 = D-
<60 = E

Class Attendance Policy

Every student works independently to access and maintain pace with the lectures, readings, discussions, and completes the weekly quiz. If an issue arises, please contact Yun Shen concerning your inability to maintain pace. Failure to notify will be marked as non-participation.

Requirements for class attendance and make-up exams, assignments, and other work in this course are consistent with university policies found in the online catalog at:

<https://catalog.ufl.edu/UGRD/academic-regulations/attendance-policies/>.

Quiz/Exam Policy

Questions about quiz grades go to Yun Shen. For questions about the project, presentation, or final grades go to Melissa Andel.

Make-up Quiz/Exam Policy

There will be no make-up quizzes.

Assignment Deadlines

A deduction of two points occurs for late projects and quizzes.

While we understand that our students have other work and personal commitments, we expect every effort to meet these deadlines. If for some reason, because of circumstances beyond your control, you are unable to meet an assignment deadline, students should e-mail the professor and explain the situation in advance. A consistent lateness in submitting assignments disrupts the discussion of topics on the bulletin board and results in loss of marks for that assignment up to a full letter grade.

If you email us, we will work with you around the deadline. If you have outstanding assignments at the end of the semester, we will send you a follow-up email as a reminder and as a means to determine your plans for completion. If you do not respond to us before the final day of class, you will be assigned a grade based on the completed assignments.

Incomplete Grades

Under special circumstances, if a student is unable to finish a course before the end of the semester we may be able to assign an incomplete grade. An incomplete grade is a non-punitive grade assigned at the discretion of the course instructor. In this course, an incomplete grade may be assigned if 1/3rd or more

of the course assignments have been completed and if the student has remained in communications with the TA and instructor throughout the course or has made an effort to request an incomplete grade. For an incomplete grade, outstanding assignments and quizzes are completed the next semester. If the assignments are not completed in this time, you will be assigned a grade based on the completed assignments.

Students must inform the University of an intent to withdraw from a course to ensure appropriate tuition reimbursement. Deleting yourself from the course roster does not officially withdraw you from a course.

General College of Pharmacy Course Policies

The College of Pharmacy has a website that lists course policies that are common to all courses. This 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

Please see the following URL for this information:

<http://www.cop.ufl.edu/wp-content/uploads/dept/studaff/policies/General%20COP%20Course%20Policies.pdf>

Complaints

Should you have any complaints with your experience in this course please visit:

<http://www.distancelearning.ufl.edu/student-complaints> to submit a complaint.

Appendix A

Directions for Contacting Faculty & Course Faculty List

The Canvas Inbox tool is for most communications between the faculty and students. Check for new announcements at least once a day for any course updates. UF email will occasionally go out for mass communication to the class, so please check your email at least once a day as week. All emails sent out to the entire class are also communicated via Canvas announcements.

General questions about course content (e.g. assignments or lectures) or policies go to the discussion board. We expect students to help each other track down answers as best as possible. Read all the other posts on the discussion board first before posting to make sure your question has not been addressed/answered already. Please include clear subjects for your post topics to make your intent clear.

Emotions can easily be misinterpreted on discussion boards/emails, so make sure your message is clear before sending it since there are no physical gestures or voice inflections that accompany posts/emails. Posts/emails deemed inappropriate are handled on a case-by-case basis with the instructor directly or students will be sent to the Associate Dean for Professional Affairs.

For personal issues/questions, please email your instructor or TA.

If you have issues with the course site, please email the PoP Support Team at popsupport@ahc.ufl.edu.

Appendix B: Spring B 2020 Course Schedule
Classes meet Sunday from 7:00 pm – 9:00 pm ET
except for Week 5, which meets Monday, April 13 from 7:00 – 9:00 pm

Week	Class Date	Reading Assignments	Due Dates
<p><u>Week 1</u> Class Overview</p> <p>Drug Pricing 101</p> <p>Topics: Follow the dollar through the prescription drug supply chain</p> <p>What tools do the government and private sector have to regulate drug pricing?</p>	March 15	<p>Association for Accessible Medicines: Introduction to the Generic Drug Supply Chain and Key Considerations for Policymakers: https://accessiblemeds.org/sites/default/files/2017-10/AAM-Generic-Brand-Drug-Supply-Chain-Brief.pdf</p> <p>Medicare Payment Advisory Commission (MedPAC): Payment Policy for Prescription Drugs Under Medicare Part B and Part D: http://www.medpac.gov/docs/default-source/congressional-testimony/04_30_2019_medpac_drug_testimony_for_eandc.pdf?sfvrsn=0</p> <p>Pew Charitable Trusts: The Prescription Drug Landscape Explored: https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored</p>	Discussion Board: March 14 @ 11:59 pm
<p><u>Week 2</u> Developing a Public Policy Position</p> <p>Topics: Opportunities to shape public policy</p> <p>Update on recent drug pricing reform efforts</p> <p>How do organizations develop policy positions?</p> <p>Communicating with policymakers</p>	March 22	<p>AARP: AARP Urges Congress to Address Drug Pricing: https://www.aarp.org/politics-society/advocacy/info-2019/jenkins-drug-prices-medicare-invest.html</p> <p>Health Affairs: Prescription Drug Policy: The Year in Review and the Year Ahead: https://www.healthaffairs.org/doi/10.1377/hblog20200103.861605/full/</p> <p>Health Affairs: Understanding the Senate Finance Committee’s Drug Pricing Package: https://www.healthaffairs.org/doi/10.1377/hblog20190726.817822/full/</p> <p>Health Affairs: Understanding the House Democrats’ Drug Pricing Package: https://www.healthaffairs.org/doi/10.1377/hblog20190919.459441/full/</p> <p>Pharmaceutical Research and Manufacturers Association (PhRMA): https://www.phrma.org/en/Press-</p>	<p>Discussion Board: March 21 @ 11:59 pm</p> <p>Weekly Quiz: March 21 @ 6:00 pm</p>

Week	Class Date	Reading Assignments	Due Dates
		<p>Release/PhRMA-Statement-Opposing-Senate-Finance-Committee-Drug-Pricing-Legislation</p> <p>U.S. Office of the Federal Register: A Guide to the Rulemaking Process: https://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf</p>	
<p><u>Week 3</u> 340B Drug Pricing Program</p> <p>Topics: Overview of 340B Drug Pricing Program</p> <p>Recent Policy Changes Related to Drug Pricing Program</p>	March 29	<p>MedPAC: Overview of the 340B Drug Pricing Program: http://medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0 (pgs. 1-17 only)</p> <p>Mintz: CMS Finalizes Medicare Part B Reimbursement Cut for 340B – What Does It Mean? https://www.mintz.com/insights-center/viewpoints/2146/2017-11-cms-finalizes-medicare-part-b-reimbursement-cut-340b-what</p> <p>STAT News: 340B is a Well-Intentioned Drug Discount Program Gone Awry: https://www.statnews.com/2018/03/22/340b-drug-discount-program-gone-awry/</p> <p>American Hospital Association: Fact Sheet: the 340B Drug Pricing Program: https://www.aha.org/system/files/media/file/2019/04/fact-sheet-340b-0419.pdf</p> <p>Pharmaceutical Research and Manufacturers Association (PhRMA): Advocacy: the 340B Program: https://www.phrma.org/en/Advocacy/340B</p>	<p>Discussion Board: March 28 @ 11:59 pm</p> <p>Weekly Quiz: March 28 @ 6:00 pm</p>
<p><u>Week 4</u> FDA Issues</p> <p>Topics: Pharmaceutical Supply Chain Safety</p> <p>Drug Shortages</p>	April 5	<p>U.S. House of Representatives Committee on Energy & Commerce Hearing on Safeguarding Pharmaceutical Supply Chains in a Global Economy (October 30, 2019): https://energycommerce.house.gov/committee-activity/hearings/hearing-on-safeguarding-pharmaceutical-supply-chains-in-a-global-economy</p> <p>Option 1: Read opening statements from committee website and watch recording of hearing, starting at 39:00 (approx. 3 hrs. 10 mins.)</p>	<p>Discussion Board: April 4 @ 11:59 pm</p> <p>Weekly Quiz: April 4 @ 6:00 pm</p>

Week	Class Date	Reading Assignments	Due Dates
		<p>Option 2: Watch entire committee hearing recording (3 hrs. 48 mins), no reading</p> <p>FDA: Drug Shortages: Root Causes and Potential Solutions (October 2019): https://www.fda.gov/media/132058/download <i>(Executive Summary only)</i></p> <p>PhRMA: Drug Shortages: https://www.phrma.org/en/Advocacy/Safety/Drug-Shortages-Supply-Chain</p> <p>FYI: FDA Drug Shortage Database: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm</p>	
<p><u>Week 5</u> Biosimilars</p> <p>Topics: Overview of biosimilars</p> <p>Biosimilar issues at the federal level</p> <p>Biosimilar issues at the state level</p> <p>Biosimilar issues with payers and providers</p>	<p>April 13</p>	<p>FDA: Biosimilar and Interchangeable Products in the U.S.: Scientific Concepts, Clinical Use, and Practical Considerations. Slide deck: https://www.fda.gov/media/122832/download Or Presentation: https://collaboration.fda.gov/p722nxwu6hjq/?poto=true</p> <p>Washington Post: Marketers are Having a Field Day: Patients Stuck in Corporate Fight Against Generic Drugs: https://www.washingtonpost.com/business/economy/drugmakers-alleged-scare-tactics-may-hold-back-competition/2019/01/09/612ac994-046d-11e9-9122-82e98f91ee6f_story.html</p> <p>American Medical Association Journal of Ethics: Why are Biosimilars Not Living Up to Their Promise? https://journalofethics.ama-assn.org/article/why-are-biosimilars-not-living-their-promise-us/2019-08</p> <p>PhRMA: Biologics and Biosimilars: https://www.phrma.org/en/Advocacy/Research-Development/Biologics-Biosimilars</p> <p>Biosimilars Council: Advocacy: https://biosimilarscouncil.org/advocacy/</p>	<p>Discussion Board: April 11 @ 11:59 pm</p> <p>Weekly Quiz: April 11 @ 6:00 pm</p>

Week	Class Date	Reading Assignments	Due Dates
		Biosimilars Council Advocacy Video on Interchangeability: https://biosimilarscouncil.org/resource/interchangeability-vs-biosimilar/	
<p><u>Week 6</u> Opioids</p> <p>Topics: Opioid Crisis: Why are we here?</p> <p>What are states and the federal government currently doing?</p>	April 19	<p>Centers for Disease Control and Prevention: CDC Guidelines for Prescribing Opioids for Chronic Pain: https://www.cdc.gov/drugoverdose/prescribing/guideline.html</p> <p>National Institute on Drug Abuse: Opioid Overdose Crisis: https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis</p> <p>National Public Radio: Despite Warnings, FDA Approves Potent New Painkiller: https://www.npr.org/sections/health-shots/2018/11/02/663395669/despite-warnings-fda-approves-potent-new-opioid-painkiller</p> <p>Washington Post Opioid Epidemic Investigative Package: https://www.washingtonpost.com/national/2019/07/20/opioid-files/?arc404=true</p> <p>American Academy of Pain Management: Use of Opioids for Chronic Pain: https://painmed.org/about/position-statements/use-of-opioids-for-the-treatment-of-chronic-pain</p> <p>Coalition to Stop Opioid Overdose: 2019 Policy Platform: http://www.stopopioidoverdose.org/wp-content/uploads/2019/01/CSOO-2019-Policy-Platform-FINAL.pdf</p>	<p>Discussion Board: April 18 @ 11:59 pm</p> <p>Weekly Quiz: April 18 @ 6:00 pm</p>
<p><u>Week 7</u> Putting it all Together: Antibiotics</p>	April 26	<p>The problem of antibiotic resistance is complex. The Pew Charitable Trusts has identified the following challenges facing antibiotics:</p> <ol style="list-style-type: none"> 1. Inappropriate use of antibiotics in humans 2. Inappropriate use of antibiotics in animals 	<p>Discussion Board: April 25 @ 11:59 pm</p>

Week	Class Date	Reading Assignments	Due Dates
		<p>3. Investment in antibiotic research and development</p> <p>4. Implementing adequate stewardship programs</p> <p>5. Addressing global challenges and threats</p> <p>https://www.pewtrusts.org/en/research-and-analysis/articles/2019/11/13/how-to-combat-antibiotic-resistance-5-priorities-for-2020</p> <p>Students will be assigned a challenge to independently research. During class, students will be expected to:</p> <ul style="list-style-type: none"> • Explain their assigned challenge to the rest of the class • Identify the major stakeholders involved in the challenge • Suggest rational policy recommendations to address the challenge • Discuss potential tradeoffs of policy recommendations <p>We will spend approximately 25 minutes discussing each challenge as a group. Students will be evaluated on their preparation with respect to their assigned challenge, their success in framing their challenge for the class, the thoughtful management of their respective discussions and the appropriateness of their participation in other discussion topics.</p>	