PHA [6935] Foundations of Pharmaceutical Outcomes and Policy II: Drug Marketing, Regulation, Distribution, and Use

3 Semester Credit Hours

Course Purpose:

This is the second course in a two-course series designed to provide students in the Master of Science in Pharmaceutical Sciences with Focus on Pharmaceutical Outcomes & Policy an overview of drug discovery, development, approval, marketing, regulation, and use in the United States. This course is designed to show how the pieces of the "U.S. medication system" fit together.

These courses will provide participants with a basic understanding of topics ranging from drug discovery to disposal. This high-level overview will introduce issues that will be developed in detail in the Master of Science tracks (i.e., Applied Pharmacoeconomics, Managed Care Pharmacy Systems, Patient Safety in Medication Use, and Pharmaceutical Regulation). "Foundations II" will focus on the drug use system after a drug is marketed.

In addition to recorded video lectures and online weekly class meetings, this course will include mandatory readings from a variety of sources and perspectives. It provides a balanced view of controversial topics and invites discussion using the presented content, supplemental information posted to the Discussion Boards, and students' and faculty experiences. The concepts and principles in this course will provide perspectives for students' various chosen specialty areas, which will be addressed in courses that follow this foundational course.

Course Faculty and Office Hours

Course Coordinator:	Randy C. Hatton, BPharm, PharmD, FCCP
	Email: hatton@.ufl.edu
Teaching Partners:	Vakaramoko [Karam] Diaby, PhD, MSc*
	Email: v.diaby@cop.ufl.edu
	Laura Happe, PharmD, MPH
	Email: LHappe@cop.ufl.edu
	W. Thomas Smith, PharmD, JD*
	Email: tsmith@cop.ufl.edu
	Almut G. Winterstein, Ph.D., R.Ph., FISPE*
	Email: Almut@cop.ufl.edu

*Drs. Diaby, Smith, and Winterstein will pre-record lectures, but will not be active participants in the weekly class sessions.

Office Hours

By appointment only. Please refer to **Appendix A** for Who to Contact

Place and Time of Class Sessions

Classes are on Sunday from 6:00 PM to 8:00 PM Eastern Time. **All times are given as Eastern Time unless specifically stated otherwise.** Should any class be scheduled on a University of Florida holiday, it will be recorded before the scheduled day and will be available before the next scheduled class. All classes are via the Internet through the University of Florida's Canvas system.

Course Objectives

Upon completion of this course, the student will:

1. Describe the components and discuss the effectiveness of post-marketing surveillance in the US.
2. Describe the current framework used to mitigate drug risk post-approval.
3. Explain the purpose and related regulations of a drug label and its various components; and, the importance of off-label drug use.
4. Identify the basic limits placed on drug promotion.
5. Recognize factors that affect the cost of various pharmaceuticals.
6. List the most important USP standards and their effects on the production and use of drugs.
7. List reasons for drug shortages and their potential consequences.
8. Describe the drug use process in various health care settings.
9. Recognize the influence of governmental programs, health insurance, and managed care on the use of drugs.
10. Identify high-alert medications, hazardous drug substances, and proper methods of disposal of drugs.
11. Explain the current infrastructure to improve the safe and effective use of drugs.
12. Recognize the role of personalized medicine and individualized drug dosing in health care.

Course Structure & Outline

Course Structure.

Learning activities

a) Video Lectures
b) Mandatory readings
c) Web-based learning
d) Preparation for weekly readiness quiz assessments

e) Participation in live weekly discussions during class
f) Participation in discussion board activities
g) An individually written paper on a topic approved by the course coordinator

Course Outline/Activities.

See the course outline in **Appendix B**. All assignments and topics are subject to change as posted on Canvas to include current issues regarding the topics of discussion.

Textbooks

There is no required textbook for this course; however, students are required to subscribe to *STAT+*, which is a pharma/health care news and analysis Website. To subscribe, go to www.statnews.com/subscribe. At the payment page, use code ACADEMIC75 to receive a 75% student discount on the subscription rate. Reading assignments from online textbooks, journal articles, lay media articles (*New York Times* and *Wall Street Journal*), and websites will be assigned for each module (see **Appendix B**). UF students have access to the *New York Times* and *Wall Street Journal* at no cost (https://news.hr.ufl.edu/technology/did-you-know-uf-offers-free-online-subscriptions-to-the- new-york-times-wall-street-journal/). In this manner, students will have access to the latest in the ever-changing landscape of information.

Active Learning Requirements

Participation in the live online classroom sessions is **mandatory**. These sessions are an important part of this course. Students may be permitted to submit a make-up assignment for up to two excused absences. (See Class Attendance Policy)

Student Evaluation & Grading

Evaluation Methods

Online quizzes: This course will be a mixture of mandatory readings and pre-recorded lectures that must be reviewed before each weekly quiz. The weekly quiz will be available for at least three days before each Sunday class session. Quizzes will include ten multiple-choice or short-answer questions. There will be seven quizzes, and the lowest quiz grade will be dropped. The purpose of the quizzes will be to assess your readiness for the weekly discussions and your understanding of the course materials. The quiz average will contribute 48% towards the final grade in this course (i.e., each quiz will contribute 8% towards your final grade).

Class participation: Class participation is mandatory. Bulletin board participation, class attendance, and participation in discussion will be used to award 32% of your final grade. There are eight participation grades (seven weeks plus the introductory class); thus, each week will contribute 4% towards your final

grade. Each student is expected to post one substantial comment to the discussion board each week. **These posts MUST be made by 4:00 PM Eastern Time on the Sunday of the weekly class session.** Students with excused absences are **not** exempt from these posts. A post can be an opinion regarding one of the topics being covered, a thoughtful reaction to another student's post, an extension of the concepts covered in readings or lectures, or an addition to the general theme of the week (e.g., Post-Marketing Surveillance and Regulation of Drugs). A quality post must cite new material not covered in class.

Final Paper: Students will identify a topic and submit it to the course coordinator for approval. Approval must occur before Week 3 class session. Students must pick a subject for in-depth evaluation related to the topics listed in Appendix B. The content must be more extensive than the materials covered in class. The paper should be a Word document with a maximum of 10 pages using a 10-pt font, 1.5-line spacing, and 1-inch margins for the top, bottom, and sides. Proper attribution is mandatory; similarity [a surrogate for plagiarism] will be assessed using Turnitin. References should be sequentially numbered and listed as a superscript at the end of a sentence and sequentially at the end of the paper. All students must watch and follow the instructions contained in the pre-recorded lecture, **"Writing a Final Paper"**. **All papers are due on March 1, 2020, by 4:00 PM Eastern Time.** The final paper will count for 20% of your final grade. Refer to **Appendix C** for a grading rubric.

Grading	% of grade
Final Paper [topic approved by the course coordinator] *Grades will be based on a rubric following the assignment directions*	20%
Class Participation* *Discussion Board participation, class attendance, and class participation will be used to award a weekly participation score*	32%
Online quizzes (6 of 7; the lowest quiz grade is dropped) *Dropped for technical problems or excused absences*	48%

*There will be eight sessions from January 12, 2020, to March 1, 2020.

Grading Scale

>92.500%	A	79.500–82.499%	B-	66.500–69.499%	D+
89.500–92.499%	A-	76.500–79.499%	C+	62.500–66.499%	D
86.500–89.499%	B+	72.500–76.499%	C	59.500–62.499%	D-
82.500–86.499%	B	69.500–72.499%	C-	<59.499%	E

Note: this scale already reflects a rounding of grades! A grade of 92.4 is not 0.1 from an A; it is 0.6 points from an A. There will be no additional rounding or awarding of "extra" points because a grade is close to the cut-off. This course's rounding policy already considers these issues.

Class Attendance Policy

Unexcused absences from the online group discussions carry a 4-point (~1/2 letter grade) reduction i n the final grade. Absences due to illness and other emergencies must be conveyed by e-mail to your facilitator AND Dr. Hatton (hatton@ufl.edu) **before** the group discussion begins. Email via Canvas is preferred, but a telephone text will be accepted if you cannot email. Messages from friends or classmates will not be accepted. When a student has an excused absence, they will receive no deduction for participation. Excused absences will require a 2-page make-up paper within 2 weeks of the missed class to obtain your participation points. This paper requires you to listen to the recorded class session and write a reflection paper on the content covered during the missed classed.

The course coordinator will address more than two excused absences; an incomplete grade (i.e., I Grade) is a strong possibility.

Quiz/Exam Policy

There will be no appeals for quizzes. Analytics will be used to make adjustments to these assessments as needed.

Make-up Quiz/Exam Policy

The course coordinator will handle make-up quizzes on a case-by-case basis. Usually, a missed quiz will be graded as zero and will be your dropped quiz. If more than one quiz is missed for a valid reason (i.e., medical excuse), the course coordinator will make accommodations on a case-by-case basis.

Policy on Old Quizzes and Assignments

No old quizzes, exams, or assignment examples will be provided.

Assignment Deadlines

Assignments will be posted with explicit due dates and time [note: these times are Eastern Time]. Students are responsible for complying with these deadlines. **Late assignments will not be graded (0 points).** Delays due to unforeseen and/or distressing events will be treated on a case-by-case basis by the course coordinator.

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 about your experience in this course or suggestions for improvement, please visit:

http://www.distancelearning.ufl.edu/student-complaints

Appendix A: Directions for Contacting Faculty & Course Faculty List

Directions for Contacting Course Faculty

Canvas will be used for most communications between the faculty and students. Check for new announcements **at least once a day** for any course updates. Email will also be used occasionally for mass communication to the class, so please check your email at least once a day, as well. All emails sent out to the entire class will also be posted as an announcement on Canvas.

General questions about course content (e.g., assignments or lectures) or policies should be posted to the discussion board. We expect students to help each other track down answers as best as possible. Read through 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.

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

For personal issues/questions, please email Dr. Hatton (hatton@ufl.edu). Be sure to include in your subject line the course listing and then a quick subject (i.e., PHA6355 Foundations II – Your Name -). This will allow coordinators to easily identify emails related to the course amongst the plethora of junk and other emails that are received each day. Emails not properly addressed may get lost in the shuffle and unintentionally deleted or ignored, so be sure to follow the guidelines exactly. If you have any issues with the course site, please email the POP Support Team at popsupport@ahc.ufl.edu.

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Appendix B. Schedule of Course Activities/Topics

Dates & Week	Instructor(s)	Learning Activities/Topics	Graded Assignments
1/12/2020	Hatton*	Introduction and Course Overview Writing a Final Paper	Participation graded 1/13†
Module 1: Post-Marketing Surveillance and Regulation of Drugs			
1/19/2020 Week 1	Hatton* Winterstein Smith	Phase IV Formal Commitments Passive and active surveillance systems Risk Evaluation and Mitigation Strategies (REMS) USP Standards Compounding: Nonsterile compounding (USP 795) and Sterile compounding (USP 797)	Quiz open from Thursday at 0800 to Sunday 1200. **Week 1 Quiz** due 1/19 by noon. Participation graded 1/20††
Module 2: Indications, Uses, and Promotion of Drugs			
1/27/2020 Week 2	Hatton*	Drug labeling & consumer medication information Off-Label Drug Use Promotion of Pharmaceuticals • "False Claims" and Free Speech in Drug Promotion • Samples, Vouchers, Coupons, and Patient Assistance Programs • Direct to Consumer Advertising	Quiz open from Thursday at 0800 to Sunday 1200. **Week 2 Quiz** due 1/27 by noon. Participation graded 1/27††
Module 3: Drug Distribution Systems			
2/2/2020 Week 3‡	Hatton*	Purchase & Distribution of Drugs (wholesalers, pedigrees, GPOs) Shortages The Medication Use System	Quiz open from Thursday at 0800 to Sunday 1200. **Week 3 Quiz** due 2/2 by noon. Participation graded 2/3††
Module 4: Drug Costs, Pricing, and Value			
		Introduction to Pharmacoeconomics Drug Costs and Finances in the Inpatient Setting	Quiz open from Thursday at 0800

2/9/2020 Week 4	Hatton* Diaby	Institutional Formularies and P&T Committees	to Sunday 1200. **Week 4 Quiz** due 2/9 by noon. Participation graded 2/10††
2/16/2020 Week 5	Happe* Hatton	Health Insurance Drug Coverage Policies Drug Pricing in the U.S.	Quiz open from Thursday at 0800 to Sunday 1200. **Week 5 Quiz** due 2/16 by noon.

Dates & Week	**Instructor(s)**	**Learning Activities/Topics**	**Graded Assignments**
			Participation graded 2/17††
Module 5: Introduction to Safety and Quality of Drug Use			
2/23/2020 Week 6	Winterstein Hatton*	Overview of Patient Safety & Quality National Framework to Monitor & Improve Quality (Accreditation, Federal Rules, Pay for Performance, Star Ratings, ACOs, Public Reporting) Quality and Safety Organizations (ISMP, IHI)	Quiz open from Thursday at 0800 to Sunday 1200. **Week 6 Quiz** due 2/23 by noon. Participation graded 2/24††
3/1/2020 Week 7	Hatton*	High-alert medications (opioids, anticoagulants, insulins, etc.) Therapeutic Drug Monitoring (pharmacokinetics) Personalized medicine (pharmacogenomics) Drug Disposal (e.g., reverse distributors, hazardous materials, environmental impact, controlled substances) Wrap-up	Quiz open from Thursday at 0800 to Sunday 1200. **Week 7 Quiz** due 3/1 by noon. Participation graded 3/2††
3/1/2020	**Final Papers Due 4:00 P.M. Eastern Time!**		

*Leads weekly discussion.

†Full participation (100%) will be awarded for attending the first class, demonstrating the use of the learning technology, and posting required information to the Introductory Discussion Board. If not registered by this date, participation will be excused with a 2-page makeup paper.

††Participation for weeks 2–7 will be graded based on the quality of your Discussion Board posts and responses when called on in class.
‡Class will be held live, but attendance will be optional because of the Super Bowl. Listening to the recorded class session is highly recommended.

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Appendix C. Final Paper Grading Rubric

	Excellent	Acceptable	Poor
The Relevance of Topic (10)	10 The topic is appropriate for the course and the student's track and is interesting	7 The topic is appropriate for the course and student's track	4 The topic is inappropriate for the course
Format (10) □ # of pages, margins, spacing, etc.	10 Follows the syllabus and is easy to read	7 Follows most of the syllabus directions	4 Follows little of the syllabus directions
Level of content (25)	25 Content shows the synthesis of ideas, in-depth analysis, evidence of original thought, and covers the salient points	20 The content shows critical thinking and reasoning applied with original thoughts on a few ideas	15 Shows some critical thinking and reasoning, but most ideas are underdeveloped or unoriginal
Development of Main Points (25)	25 Well developed with quantity and quality support	20 Limited detail and development. Some critical thinking	15 Lacks detail with vague ideas and little evidence of critical thinking
Grammar and Mechanics (10)	10 Free of distracting spelling, punctuation, and grammatical errors	7 Limited spelling, punctuation, and grammatical errors	4 Distracting spelling, punctuation, and grammatical errors
Style (15)	15 Outstanding style beyond the usual level	12 Approaches style expected for a graduate-level paper	8 Mostly in elementary form.

Appropriate References & Format (5)	5 Excellent choice of reference material cited in the correct format with appropriate reference format at the end of the paper	3 Adequate references cited in the appropriate format.	1 Poor choice of reference material cited in an inappropriate format
Total Points:	**100**		