HPM 890
Pharmaceutical Industry

(Credit Hours: 2)

Department of Health Policy and Management

Gillings School of Global Public Health

Spring 2019 – Preliminary Syllabus (some minor changes possible)
Class Location (McGavran Greenberg 2308)
Meeting Times: Generally every Tuesday 5:15p to 6:55p (final schedule TBD)

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Course Overview

This course will give an overview of the pharmaceutical industry including organization, financing, major regulations, drug development, and ethical considerations. Topics will give a real-world perspective from professionals in the pharmaceutical industry. Students will debate and discuss some of the controversial topics related to medicines and public health including patient safety, data integrity, financial conflicts of interest, and pricing. These topics will introduce students to careers in the pharmaceutical industry.

Learning Objectives and HPM Competencies`

	Course Learning Objective	*HPM Competencies*
1.	Give an overview of the history and organization of the pharmaceutical industry highlighting the complex interplay of science, politics, and economics.	Systems Thinking
2.	Understand the financial considerations in pharmaceutical development including pricing, value, and costs of development.	Analytical Thinking
3.	Be familiar with the major regulations that both stimulate and stifle drug development.	Change Management
4.	Be able to distinguish between the major stages of drug development, understand the drug approval process, and the balance of safety and efficacy that determines if a drug has a favorable benefit-risk ratio.	Innovative Thinking Organizational Management
5.	Be familiar with how pharmaceuticals are marketed and the laws and guidelines that govern these activities.	Professionalism
6.	Be able to discuss the resulting controversial issues with the promotion of pharmaceuticals and ethical considerations currently under debate with an understanding of several perspectives including: patients, regulatory authorities, industry, and health care providers.	Community and Public Health Orientation
7.	Be familiar with the range of professional careers available within the pharmaceutical and related industries.	Human Resources Management

Resources:

Website:

HPM 890 has its own website using Sakai software (See http://sakai.unc.edu.) All registered students are automatically enrolled in the site. This website will be used extensively during the course, and students should check the site for the syllabus, readings, and changes to the schedule, etc.

Textbooks:

No textbooks are required for this course

Articles:

Articles for class reading will be available on Sakai or through the Health Sciences Library. Reading assignments will also be listed below in the Course Schedule or students will be notified in advance by a Sakai announcement.

Requirements and Expectations:

Course Structure

The course will generally meet every Tuesday from 5:15 PM to 6:55 PM. (a few exceptions on final schedule)

Classes will usually alternate between lecture format with extensive interactive discussion with the guest lecturer and sessions that focus on a group case study discussion that applies the principals learned in the related lecture. (cases will usually be posted on Sakai site in advance).

Class Attendance and Participation:

Attendance, on time arrival, and active participation is expected. You are responsible for coming to class prepared, having read all assigned readings and cases. Please let the TA know in advance via email if you have an unavoidable conflict and are unable to attend class.

Course attendance and participation will account for 45% of your final grade (group peer evaluations will account for 10% and the remaining 35% will be determined by the professor and TA). Credit for participation is earned by participating fully in discussions with faculty, fellow students, and guest discussants. Peer assessment will be based on your perception of their level of participation and contribution to the group (using one of the HPM measurement tools assessed at the end of classes).

Group Presentation:

In place of a final exam, groups will analyze and present a final case to the class worth 40% of the grade (group peer evaluations will account for 10% and the remaining 30% will be determined by the professor and TA). The specific assignment for the case presentation will be posted on the Sakai site 3-4 weeks prior to due date.

Presentations will be held on the last session of class and attendance is required. Please let the TA know if you have a schedule conflict with this session.

Discussion Questions and Hot Topics for Guest Speaker Lectures/Case Discussions:

Each individual will submit and be prepared to ask one question for each session with a guest speaker (lecture or case discussion) to facilitate discussion with the lecturer and fellow students. The questions should attempt to integrate material from the readings, lecture, and real world experience. Additionally, each individual will submit a "hot topic" 3 bullet point summary with a reference of an important issue related to the topic of the guest speaker. These are required and the quality of these questions and hot topics will count as 15% of the course grade.

Suggested sources/blogs:

FDA newsroom

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/default.htm?Page=2

Politico Prescription Pulse https://www.politico.com/prescripti onpulse/

Health Affairs blog https://www.healthaffairs.org/

Evaluation / Grading:

Component	% of Grade
Class Attendance and Participation	45%
Discussion Questions and Hot Topics	15%
Group Case Presentation	40%
TOTAL	100%

Grading Scale:
Your scores from each of the assignments will be combined to calculate your total score. Final grades will be assigned according to the following scheme:

Graduate Students:

90 and above	H
75 to 90	P
65 to 75	L
Below 65	F

Undergraduate Students:
94 or above: A
90 to 93: A-
87 to 89: B+
83 to 86: B
80 to 82: B-
77 to 79: C+
73 to 76: C
70 to 72: C-
67 to 69: D+
63 to 67: D
60 to 62: D-
Below 60: F

Guidelines on Use of Laptops and Other Electronics in Classroom:

Please turn off all cell phones in class. Laptops and other electronic devices may be used in class only for taking notes.

Recognizing, Valuing, and Encouraging Diversity:

The importance of diversity is recognized in the mission statement of HPM. In the classroom, diversity *strengthens* the products, *enriches* the learning, and *broadens* the perspectives of all in the class. Diversity requires an atmosphere of inclusion and tolerance, which oftentimes challenges our own closely-held ideas, as well as our personal comfort zones. The results, however, create a sense of community and promote excellence in the learning environment. This class will follow principles of inclusion, respect, tolerance, and acceptance that support the values of diversity.

Diversity includes consideration of: (1) life experiences, including type, variety, uniqueness, duration, personal values, political viewpoints, and intensity; and (2) factors related to "diversity of presence," including, among others, age, economic circumstances, ethnic identification, family educational attainment, disability, gender, geographic origin, maturity, race, religion, sexual orientation, social position, and veteran status.

Disability Accommodation

UNC-CH supports all reasonable accommodations, including resources and services, for students with disabilities, chronic medical conditions, a temporary disability, or a pregnancy complication resulting in difficulties with accessing learning opportunities.

All accommodations are coordinated through the UNC Office of Accessibility Resources & Services (ARS), http://accessibility.unc.edu; phone 919-962-8300 or email accessibility@unc.edu. Students must document/register their need for accommodations with ARS before any accommodations can be implemented.

UNC Honor Code:

The principles of academic honesty, integrity, and responsible citizenship govern the performance of all academic work and student conduct at the University as they have during the long life of this institution. Your acceptance of enrollment in the University presupposes a commitment to the principles embodied in the Code of Student Conduct and a respect for this most significant Carolina tradition. Your reward is in the practice of these principles.

Your participation in this course comes with the expectation that your work will be completed in full observance of the Honor Code. Academic dishonesty in any form is unacceptable, because any breach in academic integrity, however small, strikes destructively at the University's life and work.

If you have any questions about your responsibility or the responsibility of faculty members under the Honor Code, please consult with someone in either the Office of the Student Attorney General (966-4084) or the Office of the Dean of Students (966-4042).

Read "The Instrument of Student Judicial Governance" (http://instrument.unc.edu).

Course Evaluation:

HPM participates in the UNC-CH's online course evaluation system, enabled at the end of the semester by Scantron Class Climate. Your responses will be anonymous, with feedback provided in the aggregate. Open-ended comments will be shared with instructors, but not identified with individual students. Your participation in course evaluation is an expectation, since providing constructive feedback is a professional obligation. Feedback is critical, moreover, to improving the quality of our courses, as well as for instructor assessment. Students are notified when the evaluation is available online, towards the end of each semester.

Course Schedule

Dates	Topics	Objectives	Readings
1/15/19	**Course Introduction/ History of the Pharmaceutical Industry** Mike Markowitz, MD, MSPH, MBA. Head of Physician Faculty, UCB	• Be familiar with the historical transformation of drug development • Understand regulatory milestones that guide the evolution of the pharmaceutical industry	• To be posted
1/22/19	**Organization of the Pharmaceutical Industry/ Case discussion: Placebo controlled trials** Mike Markowitz	• Understand the key components of the pharmaceutical industry and how they inter-relate including: patients, health care providers, manufacturers, contract research organizations, and regulatory authorities	• To be posted
1/29/19	**Patient Safety** Lorrie Schiano, PharmD, Safety Development Lead & Group Leader, GlaxoSmithKline	• Discuss clinical trial and post marketing safety monitoring, risk management/ limitations • Understand benefit-risk determination and incorporation of patient perspectives • Understand the importance of the product label in communicating appropriate use of products • Discuss important safety issues in the news	• To be posted

2/5/19	**Drug Development: Earlier Stages** Jai Patel, MBBS, Chief Medical Officer, Imbria	• Be able to distinguish the phases of development: pre-clinical, IND, I, II, III, NDA • Address candidate selection and go/ no go decision making • Understand clinical trials and the research site • Discuss the drug patent exclusivity system • Understand the costs of drug development	• To be posted
2/12/19	**Patient Perspectives in Drug Development** Bray Patrick-Lake, MFS DCRI Research Together Kim McCleary Founder, CEO The Kith Collective, LLC	• Understand importance of incorporating patient perspectives into clinical research design • Be familiar with the current focus and initiatives to incorporate patient perspectives across the phases of clinical development	• To be posted
2/19/19	**Case Study: Vioxx safety controversy** Chidi Maduka, MD. Head of International Pharmacovigilance, UCB Biosciences		

2/26/19	**Drug Development**: **Later Stages (Clinical Development)** Rose Snipes, MD. Senior Medical Director, UCB Biosciences **Case discussion: Post-marketing trials:** science or marketing? Mike Markowitz	• Understand the FDA approval process • Discuss phase 4 post-marketing studies, real world evidence and lifecycle management • Be familiar with the purpose and components of the product label • Discuss the different types of pharmaceuticals including: brand, generics, OTC, and specialty drugs • Discuss global drug development and contrast to US	• To be posted
3/5/19	**Case discussion: The Opioid Crisis**-Mike Markowitz		
3/12/19	**Spring Break**		
3/19/19	**Financing** Priti Jhingrin, Allergan, Executive Director Health Outcomes	• Understand pricing determination and the value of pharmaceuticals • Be familiar with channels of distribution • Know the basics of reimbursing pharmaceuticals • Discuss the costs of drugs in context with other health care costs and trends	• To be posted

3/26/19	**Case discussion: Access/reimbursement for a new product** Dominic Robinson, GlaxoSmithKline, Global Market Access, Specialty Medicines Franchise Partner		• To be posted
4/2/19	**Regulation** Bruce Burnett, PhD, Director Regulatory Affairs, Duke	• Understand the major regulations shaping the development and marketing of drugs • Share the important components for protecting patients including: GCP, ICH, IRBs, and informed consent	• To be posted
4/9/19	**FDA** Rob Califf, MD, previous FDA Commissioner and Vice Chancellor for Clinical and Translational Research, Duke	• Understand the FDA role and mission	• To be posted

4/16/19	**Ethical Considerations and DTC case**	• Discuss the financial conflicts of interest seen with health care providers and pharmaceutical companies • Discuss the pros/ cons of DTC advertising • Assess whether medical education is "education" or "marketing" • Discuss controversies and solutions with data transparency	• To be posted
4/23/19	**Class presentations**		
5/7/19	**Careers in the pharmaceutical industry**	Class meets at 4p per UNC finals session requirement	