

USC Mann

Alfred E. Mann School of Pharmacy
and Pharmaceutical Sciences

SP 2023: BPSI-414: Pharmacoethics

Instructor:	Terry David Church, DRSc, MA, MS Assistant Professor, Department of Regulatory and Quality Sciences USC School of Pharmacy tdchurch@usc.edu (323) 442-0241 Office: HSC campus CHP-140
Office Hours:	Virtual Office Hours, Thursdays 11am-1pm (link in Blackboard) University Park Campus, UPC – appointment, tdchurch@usc.edu Health Sciences Campus, HSC – appointment, tdchurch@usc.edu
Course Weight:	2 units (course meets 2 hours per week)
Days/Time/Location:	Mon; Wed 3:00pm-3:50pm in KAP 140

Catalogue description: *Ethics as a challenge in the pharmaceuticals industry. Organizational ethics and bioethics related to research, development, and marketing across the public and healthcare professional groups.*

Introduction

The business of pharmaceutical research and development requires ethical and professional conduct to be successful. Due to the changing nature of the practice of pharmacy, today's pharmacists, pharmaceutical scientists, and researchers are faced with an increasing number of ethical dilemmas. Through the introduction of current ethical problems, this course will prepare students through application of ethical decision making for current and future issues.

This course will focus on seven clinical and research ethical competencies that pharmaceutical scientists will face in real world settings: professional responsibility, patient's rights, privacy and confidentiality, truth telling, reproductive ethics, distributive justice, and research ethics. Students will learn to work through difficult ethical situations and attain a positive clinical, behavioral, or social outcome. This course will help establish a framework for developing the critical set of patient-related skills necessary for the practice of pharmaceutical science.

Objectives

This course will develop core competencies in dealing with ethical issues in healthcare and research settings amidst a biologically, socially, and culturally diverse patient population. This will include a

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discussion of the ethical responsibilities and professional conduct of the pharmaceutical industry, including clinical drug trials and studies, research, and marketing and promotion. This course will also provide a discussion of basic principles of business ethics and proper ethical conduct in other healthcare industries.

Students will be presented with case studies to help explore and understand the principles guiding the conduct of healthcare professionals. In addition, issues presented will involve the welfare and consideration of others in deciding how to act ethically. Topics including criminal and civil acts, contracts, negligence, and ethical concepts as they relate to the medical profession. Managed care, HIPAA, and other health care legislative rulings are discussed.

Upon successful completion of this course, the student should be able to –

- Identify sources of moral judgements
- Describe the ethical cornerstones of beneficence, justice, and autonomy
- Critique ethical questions in terms of veracity and fidelity
- Evaluate key issues in healthcare ethics and formulate arguments in defense and interrogation of those issues
- Appraise the consequences of improper drug use and abuse and its relationship to health, economy, wellbeing and society as presented in the literature

During the semester each student will be encouraged to participate in presenting his or her opinions on a given ethical topic. The subject matter presented allows for critical thinking and analysis. When a student states an opinion or takes a stand on a given subject, the major question posed is to understand why the student takes the position that he or she takes and to determine if his or her position is grounded in reasonableness and logic. Has the student carefully thought out the “why I believe what I believe” and perhaps the factors of influence (e.g. societal, religious, political, ethnic, economic, family, friends, education, etc.) that establish the belief?

The involvement in this course allows for students to, even though they may have a strong belief regarding one side of an argument, open-up their thought process to recognize that there is another or other sides of an argument, and be able to identify what the other sides of the argument might be.

Communication Method

If you have questions or concerns, please contact Dr. Church via email (tdchurch@usc.edu). Your email will be attended as quickly as possible within a 48-hour window. For more urgent or pressing issues, please contact Dr. Church via telephone at 323.442.0241.

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Evaluation and Grading:

Evaluation will be based on case study debates and a final.

<i>Description</i>	Points	Weight
<i>Case Study Reports 12 (@ 10 pts each)</i>	120 pts	55%
<i>Final exam</i>	100 pts	45%
Total	200 pts	100%

Attendance at all classes is expected. Participation will include asking and answering questions and being actively involved in the discussion. It is expected that the students read the assigned materials prior to the lecture and be prepared to discuss background, current understanding, treatments, and gaps in knowledge for the topic in each lecture. Due to the nature of ethics, it is expected that we will not always agree, and a richness of perspectives often helps illuminate the issues at hand.

55% Case Study Reports (each worth ~4.6% of the class grade): The reports will be related to the weekly topic. Students will select ethical or legal cases related to the weekly lecture topic to be discussed. These reports will be used to guide the topical discussions. Students will need to research their topics and build their discussions based on a journal article, legal case, ethical issue, or policy review they researched. The discussion will be driven by the weekly lecture topics.

45% Final: The Final Exam will be in the form of a take home test during exam week. The final exam will allow students to express their ideas based on facts derived from the course.

Please note, below is the “Approximate” grading scale breakdown. However, this scale is not set in stone and may slightly shift up or down based on overall scores. There are no pluses (+) or minuses (-) assigned to grades in this course.

Percent	Letter Grade
90-100%	A
80-89%	B
70-79%	C
60-69%	D
Below 60%	F

There are no make-up exams. If exceptional circumstances prevent you from attending an exam, your reason for missing it must be accompanied by a written statement from a third party (e.g. a note from a medical doctor). After receipt of the written statement, a make-up exam will be provided.

Notes, books, calculators, electronic dictionaries, regular dictionaries, cell phones or any other aids are not allowed during exams.

Students will be asked to complete an anonymous critical evaluation of the course at its completion.

Use of Artificial Intelligence

There is an expectation about AI (e.g., ChatGPT and image generation tools) use for this class. Learning to use AI is an emerging skill, and discussions about appropriate use are welcome. It is recommended that you take the opportunity to meet with your professor to get guidance with the use of these tools during office hours or after class. Keep in mind the following:

- AI tools are allowed to help you brainstorm topics or revise work you have already written.
- If you supply minimum-effort prompts, you will get low-quality results. You will need to refine your prompts to get good outcomes. This will take work.
- Proceed with caution when using AI tools and do not assume the information provided is accurate or trustworthy. If it gives you a number or fact, assume it is incorrect unless you either know the correct answer or can verify its accuracy with another source. You will be responsible for any errors or omissions provided by the tool. It works best for topics you understand.
- AI is a tool, but one that you need to acknowledge using. Please include a paragraph at the end of any assignment that uses AI explaining how (and why) you used AI and indicate / specify the prompts you used to obtain the results what prompts you used to get the results. Failure to do so is a violation of academic integrity policies.
- Be thoughtful about when AI is useful. Consider its appropriateness for each assignment or circumstance. The use of AI tools requires attribution. You are expected to clearly attribute any material generated by the tool used.

Course Readings

This course is designed to be current and as such will rely on journal articles, book chapters, and other materials relevant to the weekly topics.

Other topical materials including but not limited to the syllabus, supplemental reading assignments and additional handouts will be posted on <http://blackboard.usc.edu/>. Students will also be encouraged to use the online discussions sessions (via Blackboard) as an additional learning tool.

Course Outline

This course will be in the format of a directed seminar/lecture under the guidance of the instructor for the specific session. During each weekly session the instructor will engage the students with questions and draw comments or interpretations primarily based on the assigned reading. Students are expected to ask questions and participate in an interactive fashion. Because this is an area of rapid change in policies, the readings may vary from one term to the next. Additional readings for each section that may be of added use are listed in the table below.

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Content Warning

Our course readings and classroom discussions will often focus on mature, difficult, and potentially challenging topics. As with any course dealing with drug use, abuse and addiction, course topics can at times be political and personal. Readings and discussions might trigger strong feelings—anger, discomfort, anxiety, confusion, excitement, humor, and even boredom.

Some of us will have emotional responses to the readings; some of us will have emotional responses to our peers' understanding of the readings; all of us should feel responsible for creating a space that is both intellectually rigorous and respectful. Above all, be respectful (even when you strongly disagree) and be mindful of the ways that our identities position us in the classroom.

Schedule of Topics

Week	Date	Topic	Notes
1	8 Jan; 10 Jan	Introduction to Course	
2	15 Jan; 17 Jan	Moral Standing	15 Jan – No class
3	22 Jan; 24 Jan	Duty*	*Report Week
4	29 Jan; 31 Jan	Research Involving Human Subjects, Part 1*	*Report Week
5	5 Feb; 7 Feb	Research Involving Human Subjects, Part 2*	*Report Week
6	12 Feb; 14 Feb	Conflict of Interest*	*Report Week
7	19 Feb; 21 Feb	Emerging Technologies	19 Feb – No Class
8	26 Feb; 28 Feb	Breaking Promises*	*Report Week
9	4 Mar; 6 Mar	End of Life Decisions*	*Report Week
	11 Mar; 13 Mar	Spring Break	
10	18 Mar; 20 Mar	Death and Dying – When You Are Not Your Own Decision Maker	*Report Week
11	25 Mar; 27 Mar	Patents and Discovery*	*Report Week

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Week	Date	Topic	Notes
12	1 Apr; 3 Apr	Reproductive Choice*	*Report Week
13	8 Apr; 10 Apr	Economics of Pharmaceuticals*	*Report Week
14	15 Apr; 17 Apr	Allocating Resources and Health Insurance*	*Report Week
16	22 Apr; 24 Apr	International Business*	*Report Week
Final Exam: Friday, May 3, 2024 by 4pm			

Academic Integrity

The University of Southern California is a learning community committed to developing successful scholars and researchers dedicated to the pursuit of knowledge and the dissemination of ideas. Academic misconduct, which includes any act of dishonesty in the production or submission of academic work, comprises the integrity of the person who commits the act and can impugn the perceived integrity of the entire university community. It stands in opposition to the university's mission to research, educate, and contribute productively to our community and the world.

All students are expected to submit assignments that represent their own original work, and that have been prepared specifically for the course or section for which they have been submitted. You may not submit work written by others or "recycle" work prepared for other courses without obtaining written permission from the instructor(s).

Other violations of academic integrity include, but are not limited to, cheating, plagiarism, fabrication (e.g., falsifying data), collusion, knowingly assisting others in acts of academic dishonesty, and any act that gains or is intended to gain an unfair academic advantage.

The impact of academic dishonesty is far-reaching and is considered a serious offense against the university. All incidences of academic misconduct will be reported to the Office of Academic Integrity and could result in outcomes such as failure on the assignment, failure in the course, suspension, or even expulsion from the university.

For more information about academic integrity see [the student handbook](#) or the [Office of Academic Integrity's website](#), and university policies on [Research and Scholarship Misconduct](#).

Please ask your instructor if you are unsure what constitutes unauthorized assistance on an exam or assignment, or what information requires citation and/or attribution.

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Students and Disability Accommodations:

USC welcomes students with disabilities into all of the University's educational programs. The Office of Student Accessibility Services (OSAS) is responsible for the determination of appropriate accommodations for students who encounter disability-related barriers. Once a student has completed the OSAS process (registration, initial appointment, and submitted documentation) and accommodations are determined to be reasonable and appropriate, a Letter of Accommodation (LOA) will be available to generate for each course. The LOA must be given to each course instructor by the student and followed up with a discussion. This should be done as early in the semester as possible as accommodations are not retroactive. More information can be found at osas.usc.edu. You may contact OSAS at (213) 740-0776 or via email at osasfrontdesk@usc.edu.

Support Systems:

[Counseling and Mental Health](#) - (213) 740-9355 – 24/7 on call

Free and confidential mental health treatment for students, including short-term psychotherapy, group counseling, stress fitness workshops, and crisis intervention.

[988 Suicide and Crisis Lifeline](#) - 988 for both calls and text messages – 24/7 on call

The 988 Suicide and Crisis Lifeline (formerly known as the National Suicide Prevention Lifeline) provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week, across the United States. The Lifeline is comprised of a national network of over 200 local crisis centers, combining custom local care and resources with national standards and best practices. The new, shorter phone number makes it easier for people to remember and access mental health crisis services (though the previous 1 (800) 273-8255 number will continue to function indefinitely) and represents a continued commitment to those in crisis.

[Relationship and Sexual Violence Prevention Services \(RSVP\)](#) - (213) 740-9355(WELL) – 24/7 on call

Free and confidential therapy services, workshops, and training for situations related to gender- and power-based harm (including sexual assault, intimate partner violence, and stalking).

[Office for Equity, Equal Opportunity, and Title IX \(EEO-TIX\)](#) - (213) 740-5086

Information about how to get help or help someone affected by harassment or discrimination, rights of protected classes, reporting options, and additional resources for students, faculty, staff, visitors, and applicants.

[Reporting Incidents of Bias or Harassment](#) - (213) 740-5086 or (213) 821-8298

Avenue to report incidents of bias, hate crimes, and microaggressions to the Office for Equity, Equal Opportunity, and Title for appropriate investigation, supportive measures, and response.

[The Office of Student Accessibility Services \(OSAS\)](#) - (213) 740-0776

OSAS ensures equal access for students with disabilities through providing academic accommodations and auxiliary aids in accordance with federal laws and university policy.

[USC Campus Support and Intervention](#) - (213) 740-0411

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Assists students and families in resolving complex personal, financial, and academic issues adversely affecting their success as a student.

[Diversity, Equity and Inclusion](#) - (213) 740-2101

Information on events, programs and training, the Provost's Diversity and Inclusion Council, Diversity Liaisons for each academic school, chronology, participation, and various resources for students.

[USC Emergency](#) - UPC: (213) 740-4321, HSC: (323) 442-1000 – 24/7 on call

Emergency assistance and avenue to report a crime. Latest updates regarding safety, including ways in which instruction will be continued if an officially declared emergency makes travel to campus infeasible.

[USC Department of Public Safety](#) - UPC: (213) 740-6000, HSC: (323) 442-1200 – 24/7 on call

Non-emergency assistance or information.

[Office of the Ombuds](#) - (213) 821-9556 (UPC) / (323-442-0382 (HSC)

A safe and confidential place to share your USC-related issues with a University Ombuds who will work with you to explore options or paths to manage your concern.

[Occupational Therapy Faculty Practice](#) - (323) 442-2850 or otfp@med.usc.edu

Confidential Lifestyle Redesign services for USC students to support health promoting habits and routines that enhance quality of life and academic performance.

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Discussion Structure and Presentation Topics

After Week 02, students will participate in a group discussion during class related to the weekly topic and assigned reading. These will be informal discussions and will provide students with an opportunity to apply the ethical theories to our discussions.

Week	Date	Topic
3	24 Jan	Duty
4	31 Jan	Research Involving Human Subjects, Part 1
5	7 Feb	Research Involving Human Subjects, Part 2
6	14 Feb	Conflict of Interest
8	28 Feb	Breaking Promises
9	6 Mar	End of Life Decisions
10	20 Mar	Death & Dying
11	27 Mar	Patents and Discovery
12	3 Apr	Reproductive Choice
13	10 Apr	Economics of Pharmaceuticals
14	17 Apr	Allocating Resources and Health Insurance
15	24 Apr	International Business

Students will select and share articles by 3pm on the Wednesday before their discussion. For example, if you choose Week 8, your article would be due by 3pm on 14 Feb. This will allow the article to be distributed to the class with time to read and prepare the report. The instructor will cover week 3.

Deliverable

After each discussion, students will write maximum 2-pages, 11 pt font, double-spaced reflection about the debate, this will be due prior to the next class. Week 3 will have the discussion on 24 Jan, the report for Week 3 will need to be uploaded before class on 29 Jan.

How to Write a Reflection Paper

Step One: To beginning working on a reflection paper, you need to read the article thoroughly while taking notes. No matter what type of article you are reflecting on, for example, an activity, book/newspaper, or academic essay, you will want to highlight key ideas and concepts.

Step Two: Start writing your reflection paper by summarizing the main concept(s) from your notes. Your essay should include all the information needed for your readers to understand the main points of the article on which you are reflecting. It can be helpful to add charts, diagrams, and lists to deliver your ideas to the reader in a better fashion.

Step Three: Reflection papers require that you write your opinion on the report week topic, supporting it with your observations from the assigned article combined with your individual experiences. As opposed to an academic essay where you present your reader with the views of other academics and writers, in a reflective essay, you get an opportunity to share your point of view—and the best part is that there is ***no wrong answer***. It is ***YOUR*** opinion, and it is incumbent upon you to express your thoughts in a manner that is understandable and clear for your reader. To help get started, answer some of the basic questions below:

- How did the article affect you?
- How does this article catch your attention (or does it all)?
- Has the article changed your mind about something? If so, explain how.
- Has the article left you with any questions? If so, what are those questions?
- Were there any unaddressed critical issues that did not appear in the article?
- Does the article relate to anything from your past experiences?
- Does the article agree or disagree with any of your past reading experiences?