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## SYLLABUS

### Professionalism and Ethics in Medical and Pharmacy Practice

#### Instructors

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#### Learning Objectives

After the course is completed, the student should be able to:

- Review generally the ethical issues, laws, public policy, and professionalism considerations relevant to medical and pharmacy practice in the United States.
- Define and explain the implications of beneficence, nonmaleficence, autonomy, and justice as it relates to medical and pharmacy practice, give specific examples.
- Detail the role of local, state, and federal authorities that enforce ethical, legal, public policy, and professional standards related to medical and pharmacy practice, including particularly the Drug Enforcement Administration (DEA), the Food and Drug Administration (FDA), and state administrative agencies.
- Provide an administrative law and regulatory overview for drug approval and drug use.
- Define the basic terms used in the Food, Drug, and Cosmetic Act (FDCA), the Controlled Substances Act (CSA), and state medical and pharmacy practice acts.
- Explain the landmark trial and appellate cases important in historical ethical, legal, public policy, and professionalism developments related to medical and pharmacy practice in the United States.
- Clarify the enforcement authority and describe the enforcement strategies of the DEA, the FDA, and state administrative agencies.
- Explain the pre-marketing and post-marketing drug approval process and surveillance processes relative to safe and effective use of drugs in the United States.
- Compare and contrast medical device regulation with drug regulation in the United States.
- Explain and assess post-marketing strategies for reporting of adverse drug events (ADEs).
- Articulate the ethical and professional responsibilities (including malpractice liabilities) of those involved in drug approval and use in the United States, emphasizing the roles of researchers, prescribers, and dispensers.

### Description

It is difficult to pick up a daily paper anywhere today and not see a headline that mentions drug use or abuse of some sort:

- Harmon A. After long fight, drug gives sudden reprieve [to melanoma patients]. New York Times. 2010;Feb 24. Available at: <http://www.nytimes.com/2010/02/23/health/research/23trial.html> (accessed December 12, 2024).
- Wilson D. Doctor training aided by drug industry cash. New York Times. 2010;Feb 22. Available at: <http://www.nytimes.com/2010/02/23/business/23docs.html> (accessed December 12, 2024).
- Gardiner H. Research ties diabetes drug to heart woes. New York Times. 2010; Feb 19. Available at: <http://www.nytimes.com/2010/02/20/health/policy/20avandia.html> (accessed December 12, 2024).
- Archibold RC. Doctor is charged in death of [Michael] Jackson. New York Times. 2010;Feb 8. Available at: <http://www.nytimes.com/2010/02/09/us/09jackson.html> (accessed December 12, 2024); and
- Lacey M. Mexican drug trafficking. New York Times. 2009;Oct 16. Available at: [http://topics.nytimes.com/top/news/international/countriesandterritories/mexico/drug\\_trafficking/index.html](http://topics.nytimes.com/top/news/international/countriesandterritories/mexico/drug_trafficking/index.html) (accessed December 12, 2024).

These and other news stories show, perhaps better than any other way, how drugs and drug use directly and indirectly impact the quality of life of innumerable people. More distressing is the fact that decisions to use a drug often fails to include a thorough analysis of the ethics involved—a complete understanding of the benefits and burdens entailed. The course will allow opportunity to explore core ethical, legal, and public policy concepts related to drug availability and drug use in the United States.

### Requirements

Assigned readings are from the text, White BD. *Drugs, Ethics, and Quality of Life: Cases and Materials on Ethical, Legal, and Public Policy Dilemmas in Medicine and Pharmacy Practice*. New York: Informa Healthcare (Taylor & Francis), 2007.

The book may be purchased online at: <http://www.amazon.com/Drugs-Ethics-Quality-Life-Materials/dp/0789028565/> (accessed December 8, 2024).

### Course Topics and Evaluation

It is anticipated that each participant will devote 32 contact hours to course-related activities. There will be a continuing education exercise consisting of 20 multiple choice questions which each participant must complete before receiving a certificate of attendance and course completion.

Eight three-hour topical sessions are scheduled over 4 consecutive days.

The critical core of this course is the discussions that take place in the small group discussions and in the last hour of each session. Your participation and contributions to these discussions are essential. There will generally be two one-hour conversation opportunities allocated for each session. It is expected that all participants will take part in all discussions.

Goals for the Small Group Discussions (Session Second Hour):

- Encourage Interdisciplinary Dialogue: Promote open communication and understanding between pharmacists and physicians by exploring diverse perspectives on shared ethical and professional challenges.
- Foster Critical Thinking: Allow participants to delve deeply into complex issues, weigh potential solutions, and consider the implications of their professional roles.
- Create a Safe Space for Reflection: Provide an opportunity for participants to share experiences, raise concerns, and explore ethical dilemmas in a confidential and supportive environment.
- Generate Practical Insights: Encourage groups to develop actionable ideas or recommendations that address the topic under discussion.

Goals for the Follow-Up Reporting to the Reassembled Group and Continued Discussion (Session Third Hour):

- Synthesize Key Learnings: Share insights, questions, and proposed solutions generated by the small groups to foster broader understanding and learning.
- Identify Common Themes and Divergences: Highlight recurring ideas or significant differences in perspective to deepen collective engagement with the topic.
- Promote Collaborative Problem-Solving: Use the large group discussion to refine or expand upon small group recommendations, leveraging the diversity of experience and expertise.
- Encourage Broad Engagement: Allow participants who may not have shared in smaller groups to contribute, ensuring everyone has an opportunity to participate.
- Build Consensus and Understanding: Work toward aligning ethical and professional perspectives across disciplines, creating a shared foundation for future collaboration.

## Schedule

### **Pre-Seminar Readings – Foundational Basics: Ethics, Law, Policy, and Professional Decisions**

- Text, pp. 1-6 (Pellegrino), 7-12 (Fink), 227-248 (Law and Decisions).
- House Republicans urge action on ethics trials. New York Times. 2010; Sep 28. Available at: <http://thecaucus.blogs.nytimes.com/2010/09/28/house-republicans-urge-action-on-ethics-trials/> (accessed December 12, 2004).
- Harzenhorn D, Hulse C. In House ethics battles, a partywide threat. New York Times. 2010; Aug 1. Available at: <http://www.nytimes.com/2010/08/02/us/politics/02ethics.html> (accessed December 12, 2001).

### **Session One – Definitions: Ethics, Law, Public Policy, and Professionalism**

#### First Hour

- Text, pp. 15-36.
- Liptak A. Supreme Court hears case on flavored vapes popular with teenagers. New York Times. 2024; Dec 2. Available at: <https://www.nytimes.com/2024/12/02/us/supreme-court-vapes-e-cigarettes.html> (accessed December 9, 2024).
- Kolata G. He's the F.D.A.'s cancer chief, not a fortune teller. New York Times. 2024; Nov 8. Available at: <https://www.nytimes.com/2024/11/08/health/cancer-fda-richard-pazdur.html> (accessed December 9, 2024).
- Wilson D. Congress passes measure on tobacco regulation. New York Times. 2009; Jun 12. Available at: <https://www.nytimes.com/2009/06/13/business/13tobacco.html> (accessed December 9, 2024).
- Wilson D. Senate approves tight regulation over cigarettes. New York Times. 2009; Jun 12. Available at: <http://www.nytimes.com/2009/06/12/business/12tobacco.html> (accessed December 9, 2024).

#### Suggested Second Hour Discussion Questions

- What is most appealing about Justice O'Connor's arguments in the majority opinion? What is least appealing? Describe her balancing the law with lived experience and theory and practice.
- Why did the Congress ultimately decide to allow the F.D.A. to regulate tobacco products?
- What are key challenges to legislators and regulators who draft the statutes and regulations which regulate an array of activities and behaviors in society?
- How best to describe the difference between law and ethics and the importance of professionalism concepts in medical and pharmacy practice?
- What might be some future challenges in medical and pharmacy practice after thinking about the session's topics?

## Session Two — COX-2 Inhibitors and Beneficence and Nonmaleficence

### First Hour

- Text, pp. 37-59.
- Kolata G. Obesity is just the start for the new weight-loss drugs, says Eli Lilly's chief. New York Times. 2024; Dec 4. Available at: <https://www.nytimes.com/live/2024/12/04/business/dealbook-summit-news.html> (accessed December 10, 2024).
- Blum D. Should you take Paxlovid? New York Times. 2024; Aug 16. Available at: <https://www.nytimes.com/2024/08/16/well/covid-paxlovid-treatment-risks.html> (accessed December 10, 2024).
- Mandavilli A. Thousands believe Covid vaccines harmed them, is anyone listening? New York Times. 2024; May 4. Available at: <https://www.nytimes.com/2024/05/03/health/covid-vaccines-side-effects.html> (accessed December 10, 2024).
- Zimmer C. Ivermectin does not reduce the risk of Covid hospitalization, large study finds. New York Times. 2022; Apr 1. Available at: <https://www.nytimes.com/2022/03/30/health/covid-ivermectin-hospitalization.html> (accessed December 10, 2024).
- Liptak A. The Supreme Court won't block Indiana University's vaccine mandate. New York Times. 2021; Aug 12. Available at: <https://www.nytimes.com/2021/08/12/us/supreme-court-indiana-university-covid-vaccine-mandate.html> (accessed December 10, 2024).
- Wilson D. Doctor training aided by drug industry cash. New York Times. 2010; Feb 22. Available at: <http://www.nytimes.com/2010/02/23/business/23docs.html> (accessed December 10, 2024).
- Saul S. Merck wrote drug studies for doctors. New York Times. 2008; Apr 16. Available at: <http://www.nytimes.com/2008/04/16/business/16vioxx.html> (accessed December 10, 2024).

### Second Hour Discussion Questions

- What criteria should be used to determine when it is ethical for new drugs to move from human trials to the marketplace?
- How can healthcare professionals ensure informed consent in recently approved drugs while avoiding coercion or undue influence, especially with vulnerable populations?
- What mechanisms should be in place to protect patients from unforeseen adverse effects, and how should accountability be managed when harm occurs?
- What role do pharmacists and physicians play in identifying and mitigating conflicts of interest in drug experimentation, such as financial incentives or institutional pressures?
- How can clinical trial designs be made more inclusive to ensure diverse representation without compromising participant safety or data integrity?

- What are the potential long-term ethical and legal consequences of fast-tracking drug approvals in emergencies (e.g., pandemics), and how can these risks be managed in future situations?
- How should healthcare professionals handle ethical dilemmas that arise when experimental drugs show promise but carry significant risks or lack robust evidence?

### **Session Three — Medical Marijuana and Autonomy**

- Text, pp. 61-84.
- Londona E. Voters reject efforts to loosen drug laws in several states. New York Times. 2024; Nov 6. Available at: <https://www.nytimes.com/2024/11/06/us/florida-marijuana-massachusetts-psychedelics.html> (accessed December 10, 2024).
- Twohey M, Ivory D, Kessler C. As America's Marijuana Grows, so do the harms. New York Times. 2024; Oct 4. Available at: <https://www.nytimes.com/2024/10/04/us/cannabis-marijuana-risks-addiction.html> (accessed December 10, 2024).
- Jewett C, Weiland N. Federal scientists recommend easing restrictions on marijuana. New York Times. 2024; Jan 12. Available at: <https://www.nytimes.com/2024/01/12/health/marijuana-fda-dea.html> (accessed December 10, 2024).
- McGinley T. What's going on with legal marijuana in New York? New York Times. 2024; Mar 26. Available at: <https://www.nytimes.com/2024/03/26/insider/marijuana-in-new-york.html> (accessed December 10, 2024).

### Suggested Second Hour Discussion Questions

- How has the historical use of marijuana in medicine influenced current perceptions and practices regarding its clinical applications?
- What are the key therapeutic areas where marijuana has demonstrated potential benefits, and how should healthcare providers evaluate the evidence supporting its use?
- How can pharmacists and physicians navigate the conflict between state and federal laws regarding marijuana to ensure ethical and professional patient care?
- What role should healthcare providers play in educating patients about the risks, benefits, and limitations of medical marijuana compared to other treatment options?
- How should healthcare professionals address the stigma surrounding marijuana use while maintaining a focus on patient-centered care and evidence-based practice?
- What safeguards and guidelines should be in place to minimize misuse and ensure appropriate use of marijuana for medical purposes? How can interdisciplinary teams work together to integrate medical marijuana into treatment plans where appropriate, while considering potential drug interactions and patient safety?

## Session Four — Emergency Contraceptives and Justice

- Text, pp. 85-109.
- Zernike K. For an emergency abortion, Idaho doctors flew her away. New York Times. 2024; Jun 28. Available at: <https://www.nytimes.com/2024/06/28/us/emergency-abortion-idaho-mother.html> (accessed December 11, 2024).
- Zernike K. Supreme Court allows, for now, emergency abortions in Idaho. New York Times. 2024; Jun 27. Available at: <https://www.nytimes.com/2024/06/27/us/politics/supreme-court-idaho-abortion.html> (accessed December 11, 2024).
- VanSickle A. Supreme Court appears sharply divided in emergency abortion case. New York Times. 2024; Apr 24. Available at: <https://www.nytimes.com/2024/04/24/us/politics/supreme-court-idaho-abortion-ban.html> (accessed December 11, 2024).
- VanSickle A. Supreme Court maintains broad access to abortion pill. New York Times. 2024; Jun 14. Available at: <https://www.nytimes.com/2024/06/13/us/politics/supreme-court-abortion-pill-mifepristone-ruling.html> (accessed December 11, 2024).
- Bogel-Burroughs N. Here are the key passages from the Supreme Court's decision overturning Roe. New York Times. 2022; Jun 24. Available at: <https://www.nytimes.com/2022/06/24/us/key-passages-roe-decision-supreme-court.html> (accessed December 11, 2024).

### Suggested Second Hour Discussion Questions

- How have recent changes in abortion laws and emergency contraceptive rulings affected the responsibilities and decision-making processes of healthcare providers in your practice?
- What legal risks do pharmacists and physicians face when prescribing or dispensing emergency contraceptives or abortion-related medications in states with restrictive laws, and how can they mitigate these risks?
- How should healthcare providers balance their ethical duties to patients with potential conflicts arising from state laws or institutional policies regarding abortion and emergency contraception?
- In what ways can healthcare professionals advocate for patient access to reproductive healthcare while remaining compliant with varying state laws?
- What strategies can interdisciplinary teams (e.g., pharmacists, physicians, and legal advisors) employ to navigate unclear or conflicting laws on abortion and contraceptives across state lines?
- How should providers handle situations where patients seek abortion-related care or emergency contraceptives in legally ambiguous or high-liability scenarios?
- What steps can healthcare systems take to support pharmacists and physicians facing moral, ethical, or legal challenges related to reproductive health services?



## Session Five — Pain Medicines and Palliative Care Drugs

- Text, pp. 113-131.
- Szalavitz M, Chodosh S, Clarke A. How fentanyl drove a tsunami of death in America. New York Times. 2024; Sep 27. Available at: <https://www.nytimes.com/interactive/2024/09/27/opinion/fentanyl-overdose-deaths.html> (accessed December 11, 2024).
- Chiarello E. What we lose when pharmacists are forced to act like cops. New York Times. 2024; Oct 28. Available at: <https://www.nytimes.com/2024/10/28/opinion/opioid-crisis-pharmacists.html> (accessed December 11, 2024).
- Hoffman J. Purdue opioid settlement on verge of collapse after Supreme Court ruling. New York Times. 2024; Jun 27. Available at: <https://www.nytimes.com/2024/06/27/health/purdue-pharma-sackler-opioid-supreme-court.html> (accessed December 11, 2024).
- Thrush G, Forsythe M, Bogdanich W. McKinsey is under criminal investigation for its opioid work. New York Times. 2024; Apr 24. Available at: <https://www.nytimes.com/2024/04/24/business/mckinsey-criminal-investigation.html> (accessed December 11, 2024).
- Archibold RC. Doctor is charged in death of [Michael] Jackson. New York Times. 2010;Feb 8. Available at: <http://www.nytimes.com/2010/02/09/us/09jackson.html> (accessed December 11, 2024).
- Rosenberg T. When is a pain doctor a drug pusher? New York Times Magazine. 2007;Jun 17. Available at: <http://www.nytimes.com/2007/06/17/magazine/17pain-t.html> (accessed December 11, 2024).

### Suggested Second Hour Discussion Questions

- What strategies can healthcare providers use to ensure effective pain management while minimizing the risk of opioid dependence or misuse?
- How can pharmacists and physicians collaborate to identify and address potential red flags for opioid misuse in patients requiring pain management?
- How should healthcare providers address disparities in access to comprehensive pain management, particularly for underserved populations?
- How can healthcare teams stay informed about and comply with evolving laws and guidelines regarding opioid prescribing while still meeting patient needs?
- What role can pharmacists and physicians play in educating patients and the community about the risks and benefits of various pain management strategies during the opioid crisis?
- How have drug manufacturers and marketers influenced prescribing practices for opioids, and what lessons can healthcare professionals take from this influence?
- What ethical responsibilities do pharmacists and physicians have in counteracting the impact of aggressive marketing campaigns by pharmaceutical companies?
- How can healthcare providers critically evaluate the information and promotional materials provided by drug manufacturers to ensure unbiased decision making?



- What role should regulatory agencies play in holding pharmaceutical companies accountable for their contributions to the opioid crisis, and how can healthcare professionals support these efforts?
- In what ways can interdisciplinary teams work together to identify and mitigate the effects of past marketing practices on current prescribing behaviors?
- What safeguards should be implemented to prevent future crises stemming from pharmaceutical marketing, and how can healthcare professionals contribute to these efforts?

### **Session Six – Assisted Suicide**

- Text, pp. 133-158.
- Chutel L. The U.K. voted to legalize assisted suicide. Which other countries allow it? New York Times. 2024; Dec 6. Available at: <https://www.nytimes.com/2024/12/05/world/europe/assisted-dying-uk-global-state.html> (accessed December 11, 2024).
- Watkins A, Petri AE. British lawmakers voted to legalize assisted dying. Here's what to know. New York Times. 2024; Nov 24. Available at: <https://www.nytimes.com/article/uk-assisted-suicide-parliament.html> (accessed December 11, 2024).
- Shanahan E. Ex-doctor pleads guilty to manslaughter in New York woman's suicide. New York Times. 2024; Sep 5. Available at: <https://www.nytimes.com/2024/09/03/nyregion/doctor-assisted-suicide-ny-guilty.html> (accessed December 11, 2024).
- Yardley W. First death for Washington assisted-suicide law. New York Times. 2009; May 22. Available at: <http://www.nytimes.com/2009/05/23/us/23suicide.html> (accessed December 11, 2024).
- Bergner D. Death in the family. New York Times Magazine. 2007; Dec 2. Available at: <http://www.nytimes.com/2007/12/02/magazine/02suicide-t.html> (accessed December 11, 2024).
- Fink S. Strained by Katrina, a hospital faced deadly choices. New York Times Magazine. 2009; Sep 30. Available at: <http://www.nytimes.com/2009/08/30/magazine/30doctors.html> (accessed December 11, 2024).

### Suggested Second Hour Discussion Questions

- What factors should healthcare providers consider when determining whether a patient's request for assisted suicide is based on informed and voluntary consent?
- How can pharmacists and physicians reconcile their personal beliefs with their professional responsibilities in jurisdictions where assisted suicide is legal?
- What are the potential ethical and legal risks of involving pharmacists in the preparation and dispensing of medications for assisted suicide?
- How can healthcare teams ensure transparent communication and collaboration while respecting confidentiality and ethical boundaries in cases involving assisted suicide?

- What safeguards should be in place to prevent abuse or coercion in assisted suicide practices, especially among vulnerable populations?
- How should healthcare providers navigate situations where laws governing assisted suicide conflict with institutional policies or professional guidelines?
- What role should pharmacists and physicians play in broader societal discussions about the ethics and legality of assisted suicide, and how can they advocate for patients while protecting themselves legally and ethically?

### **Session Seven – “Dwindling” Patients and Medically-Futile Situations**

- Text, pp. 159-195.
- Ableson R. Weighing the costs of end-of-life care. New York Times. 2009;Dec 22. Available at: <http://www.nytimes.com/2009/12/23/health/23ucla.html> (accessed December 11, 2024).
- Sanghavi D. When does death start? New York Times Magazine. 2009;Dec 16. Available at: <http://www.nytimes.com/2009/12/20/magazine/20organ-t.html> (accessed December 11, 2024).
- Goetz T. Practicing patients. New York Times Magazine. 2008;Mar 23. Available at: <http://www.nytimes.com/2008/03/23/magazine/23patients-t.html> (accessed December 11, 2024).

### Second Hour Discussion Questions

- How can healthcare providers ensure that care plans align with the evolving goals and preferences of patients with progressive diseases, particularly as their ability to communicate diminishes?
- What role should pharmacists and physicians play in educating patients and families about the trajectory of diseases like Parkinson’s and Alzheimer’s and the available options for end-of-life care?
- How can interdisciplinary teams collaborate to manage complex symptoms, such as pain, anxiety, or agitation, in the later stages of progressive neurological diseases?
- What strategies can healthcare providers use to address ethical dilemmas, such as withdrawing life-sustaining treatments or honoring advance directives, in end-of-life care?
- How can pharmacists and physicians support caregivers in understanding and navigating the emotional, physical, and logistical challenges of providing care for patients with these diseases?
- What are the best practices for balancing the use of medications to manage symptoms while minimizing side effects and preserving the quality of life for patients nearing the end of life?
- How can healthcare teams advocate for greater access to palliative care and hospice services for patients with chronic progressive diseases, and what barriers currently exist?

## Session Eight – Liabilities and Experimentation

- Text, pp. 199-223.
- Jewett C. He regulated medical devices. His wife represented their makers. New York Times. 2024; Aug 24. Available at: <https://www.nytimes.com/2024/08/20/health/fda-medical-devices-ethics.html> (accessed December 11, 2024).
- Jewett C .D.A. rushed a drug for preterm births. Did it put speed over science? New York Times. 2022; Mar 25. Available at: <https://www.nytimes.com/2022/03/25/health/fda-drug-approvals-makena.html> (accessed December 11, 2024).
- Mitchell DE. Taxpayers fund research and drug companies make a fortune. New York Times. 2021; Mar 21. Available at: <https://www.nytimes.com/2021/03/24/opinion/coronavirus-vaccine-cost-pfizer-moderna.html> (accessed December 11, 2024).
- Eakin E. Bacteria on the brain. New Yorker. 2015; Dec 7. Available at: <https://www.newyorker.com/magazine/2015/12/07/bacteria-on-the-brain> (accessed December 12, 2024).
- Harmon A. A roller coaster chase for a cure. New York Times. 2010;Feb 21. Available at: <http://www.nytimes.com/2010/02/22/health/research/22trial.html> (accessed December 11, 2024).
- Harmon A. A drug trial cycle: recovery, relapse, and reinvention. New York Times. 2010;Feb 23. Available at: <http://www.nytimes.com/2010/02/24/health/research/24trial.html> (accessed December 12, 2024)).
- Kolata G. A place where cancer is the norm. New York Times. 2009;Oct 24. Available at: <http://www.nytimes.com/2009/10/25/health/research/25anderson.html> (accessed December 11, 2024).
- Liptak A. No legal shield in drug labeling, justices' rule. New York Times. 2009;Mar 4. Available at: <http://www.nytimes.com/2009/03/05/washington/05scotus.html> (accessed December 11, 2024).

### Suggested Second Hour Discussion Questions

- What are the key ethical considerations when selecting participants for human drug trials, and how can bias or exploitation be avoided?
- How should healthcare providers balance the need for scientific advancement with the potential risks to participants in clinical trials?
- What role do pharmacists and physicians play in ensuring that informed consent is truly informed and comprehensible to trial participants?
- How can healthcare professionals address potential conflicts of interest, such as financial incentives or relationships with pharmaceutical companies, in the context of drug trials?
- What legal and ethical responsibilities do pharmacists and physicians have when adverse events occur during a drug trial, and how should these events be managed?

- How can interdisciplinary teams ensure that experimental drug trials are designed and conducted in a way that prioritizes participant safety while yielding scientifically valid results?
- What safeguards should be in place to protect vulnerable populations, such as children or individuals with limited healthcare access, from undue risks in drug experimentation?