



2022 KNOWLEDGE-BASED HOME-STUDY CE FOR PHARMACISTS AND PHARMACY TECHNICIANS

Pharmacy Law and Ethics

Speaker: Keith Yoshizuka, PharmD, MBA, JD, FCSHP, Assistant Dean for Administration Chair, Social Behavioral & Administrative Sciences, Touro University California – College of Pharmacy Vallejo, CA

Learning Objectives

Upon completion of this CE activity, the participant will be able to do the following:

- Identify the four elements of the foundation of biomedical ethics, also known as the Georgetown Mantra
- Cite an example of how the ethical principle of justice had to be applied during the SARS COVID-19 pandemic
- Give an example of an ethical dilemma
- Cite a reason that pharmacists should periodically review elements of ethics and cognitive moral development as it relates to clinical performance

Accreditation Information:

ACPE UAN: 0122-0000-22-035-H03 P/T (Pharmacy Law CE)

CPE Credit Hours: 1.0 hour (0.1 CEU) of home-study CE credit

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1. Log on to <https://ce.pharmacy.premierinc.com> to register for the activity under “Home Study CE”
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Note: A passing grade of 75% or better is required to receive CE credit. Three opportunities will be provided to successfully complete the post-test.

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2022 HOMESTUDY CE FOR PHARMACISTS AND PHARMACY TECHNICIANS

PHARMACY LAW AND ETHICS

Live CE Webinar: Wednesday, March 23, 2022 from 12:00-1:00 p.m. (EST)

Keith Yoshizuka, PharmD, MBA, JD, FCSHP
Assistant Dean for Administration
Chair, Social Behavioral & Administrative Sciences
Touro University California – College of Pharmacy
Vallejo, CA

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Speaker Bio:

Dr. Keith Yoshizuka is Assistant Dean for Administration at the Touro University California College of Pharmacy in Vallejo, CA where he teaches law and management and is also Chair of Social, Behavioral, & Administrative Sciences Department. He received his PharmD from the University of the Pacific, MBA from California State University, Sacramento, and his JD from the University of San Francisco. He completed ASHP's Pharmacy Leadership Institute at Boston University's School of Management. He was named as a fellow by the California Society of Health System Pharmacists (FCSHP). He has spent almost 40 years in pharmacy management and administration, spending the majority of his career with Kaiser Permanente and Sutter Health. He is active with the California Society of Health System Pharmacists' Government Affairs Advisory Committee (GAAC) and has served as chair of that committee and is also active in the American Society for Pharmacy Law (ASPL).

Ethics and Pharmacy Law

Keith Yoshizuka, PharmD, MBA, JD, FCSHP
Asst. Dean for Administration
Touro University California College of Pharmacy
Chairman of the Board of Directors,
California Society of Health System Pharmacists

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Conflict of Interest Disclosure

I declare that neither I nor any immediate family members have a current affiliation or financial arrangement with any potential sponsor and/or organization(s) that may have a direct interest in the subject matter of this presentation.

This program is for educational purposes only and should not be construed as legal advice

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What is the Big Deal about Ethics in Pharmacy?

- Is there really a problem?
- Isn't Ethics just being able to tell right from wrong and moral duties and obligations? ¹

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Several States are requiring that a portion of the CE hours required for licensure renewal be based in Ethics or Law

- Arizona, California, Connecticut, Idaho, Iowa, Massachusetts, Michigan, New Jersey, New Mexico, Ohio, Oregon, & Utah all require that a portion of the CE hours be based in pharmacy law.
- Several require medication safety or error reduction
- An increasing number are requiring ethics

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APhA Code of Ethics³ Code of Ethics for Pharmacists

PREAMBLE

Pharmacists are health professionals who assist individuals in making the best use of medications. This Code, prepared and supported by pharmacists, is intended to state publicly the principles that form the fundamental basis of the roles and responsibilities of pharmacists. These principles, based on moral obligations and virtues, are established to guide pharmacists in relationships with patients, health professionals, and society.

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APhA Code of Ethics Code of Ethics for Pharmacists

- I. A pharmacist respects the covenantal relationship between the patient and pharmacist.
- II. A pharmacist promotes the good of every patient in a caring, compassionate, and confidential manner.
- III. A pharmacist respects the autonomy and dignity of each patient.
- IV. A pharmacist acts with honesty and integrity in professional relationships.

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APhA Code of Ethics Code of Ethics for Pharmacists

- V. A pharmacist maintains professional competence.
- VI. A pharmacist respects the values and abilities of colleagues and other health professionals.
- VII. A pharmacist serves individual, community, and societal needs.
- VIII. A pharmacist seeks justice in the distribution of health resources.

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The Four Basic Principles of the “Georgetown Mantra”⁴

- Beneficence
- Non-maleficance
- Respect for Autonomy
- Justice

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Beneficence

- The act of doing good, as in an act of kindness or charity
- Derived from the root word benefit, it means to bring or create benefit for others.
- It is altruism in its purist sense.
- The corollary to bringing or creating benefit is to protect from harm or evil.
- The ethical pharmacist has a duty to do good for the patient.

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Non-maleficance

- Non-maleficance is the act of refraining from doing harm.
- Non-maleficance is the foundation for the maxim found in the Hippocratic Oath, “first, do no harm”, or *primum non nocere*.⁵
- The underlying principle is to refrain from causing pain, suffering, or loss of life.

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Respect for autonomy

- Respect for autonomy is to honor that the patient has the right to choose for him or herself according to the individual’s beliefs and values.
- This principle not only requires the professional to respect the individual’s right to determine their own course of therapy, but to do so in an informed fashion.
- It infers that the patient has full disclosure of the potential benefits and risks of the therapy (informed consent)

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Respect for autonomy (continued)

- It is the foundation for the concept of informed consent (besides avoidance of the risk of being accused of the tort of battery).
- The inference is that in providing this disclosure, that the pharmacist will also respect the privacy and maintain the confidentiality of the information on behalf of the patient.
- Establishment of privilege

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Justice

- Justice refers to the doctrine of fairness and equitable treatment.
- It deals with the equitable distribution of social benefits and burdens.
- Theories of justice in bioethics are divided into the theories of utilitarian, egalitarian, and libertarian.⁶
- All of the theories propose a system of just distribution of benefits and burdens equally without bias or preference.
- The ethical pharmacist is duty bound to allocate the benefits of drug therapy in a just manner based on objective criteria and not influenced by personal preference or bias.

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Three Theories of Justice⁷

- Utilitarianism is a normative ethical theory that places the locus of right and wrong solely on the outcomes (consequences) of choosing one action/policy over other actions/policies. As such, it moves beyond the scope of one's own interests and takes into account the interests of others.
- Egalitarianism (from French égal, meaning 'equal') – or equalitarianism – is a school of thought that prioritizes equality for all people. Egalitarian doctrines maintain that all humans are equal in fundamental worth or social status.
- Libertarianism is a political philosophy that affirms the rights of individuals to liberty, to acquire, keep, and exchange their holdings, and considers the protection of individual rights the primary role for the state.

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Self Assessment Poll

Which of the following is NOT one the four elements of biomedical ethics as defined by the "Georgetown Mantra".

- Beneficence
- Non-maleficance
- Honesty
- Justice

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Ethical Principles of Duty⁸

Others have divided ethical principles according to whom duty relates to:

The patient The consumer The Community
The profession The Business The employer
Others on the healthcare team (prescribers, c-workers, nurses, etc.)

Although there is a certain logic to identifying these duties by stakeholders, the practitioner is left to prioritize these duties on their own

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Cognitive Moral Development

Other academicians propose a psychological theory of cognitive moral development (CMD), which is based upon an individual's progression through various mental stages of moral development over time.⁹ Kohlberg identifies three levels of moral development, with two sub-stages within each level¹⁰:

- (1) pre-conventional morality, where decisions are made based upon what is best for them, with stage 1 consisting of punishment avoidance and obedience and stage 2 being exchange of favors;
- (2) conventional morality, where decisions are made to please others, especially authority figures and persons with higher status, with stage 3 seeking positive feedback or compliments, and stage 4 consisting of law and order
- (3) post-conventional morality, where decisions are made based upon an abstract principle, with stage 5 reflecting a social contract, and stage 6 being universal ethical principle

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Linking Ethics with Clinical Performance

- One study demonstrated that pharmacists are aware of the ethical issues and possess the practical skills required to resolve the issues¹¹
- Another study linked community pharmacists' moral reasoning with clinical performance, showing that pharmacists with a higher capacity for moral reasoning demonstrated a higher level of clinical performance.¹²

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Linking Ethics with Clinical Performance

- However, it appears that the longer a pharmacist is employed in a community setting, application of moral reasoning appears to erode.¹³
- This may be due in part to the "commercialization" of healthcare, and the conflicting obligations of duty to the employer for profitability and managing affordability with beneficence and the other elements of the "Georgetown Mantra."¹⁴

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Self Assessment Poll

Why should pharmacists should periodically review elements of ethics and cognitive moral development?

- Most pharmacists are unaware of the ethical issues and lack the practical skills required to resolve the issues
- The longer a pharmacist is employed in a community setting, the application of moral reasoning appears to erode
- Pharmacists are predisposed to commit moral and ethical breaches
- It is required by law

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Ethical Dilemmas

An ethical dilemma exists when two or more ethical principles are mutually exclusive.

- For example, the California End of Life Options Act passed by the legislature and signed by the governor in 2015 allows a terminally ill patient not expected to live beyond one year to choose to end his/her life with the assistance of health care professionals.¹⁵
- This pits the ethical principle of autonomy (self-determination) against the principle of non-maleficence (do no harm).
- The patient has a right to choose to avoid pain and loss of dignity associated with loss of bodily functions (autonomy), but to do so results in the death of the patient (harm).

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Ethical Dilemmas

A woman seeking to purchase emergency contraception approaches a pharmacist who subscribes to strict religious beliefs regarding abortion and contraception.

The pharmacist is faced with the ethical dilemma pitting the adherence to his religious beliefs versus his duty to the woman as a patient who is seeking him out as a health professional for treatment.¹⁶

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Ethical Challenges We Face Every Day

- The pharmacist notices that a man is non-adherent with his antihypertensive medications.^{17, 18}
- Upon inquiry, the man admits that he stopped taking the medication because of the erectile dysfunction side effect of the drug.
- Although the pharmacist is bound by the duty of beneficence, the pharmacist is also bound by the obligation to respect autonomy and self-determination.
- After a detailed explanation of the consequences, it is ultimately up to the patient to determine whether or not to continue the treatment
- Duty to notify prescriber?

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Examples from the Hospital

- There is a national shortage of sodium bicarbonate for injection.
- How is the determination made as to which acidotic patients receive infusions containing bicarbonate?¹⁹
- Of course, the resolution must be determined by an inter-professional group (P&T Committee) who develop objective guidelines based upon clinical criteria, so that the allocation of the scarce resources may be carried out fairly (justice)
- The issue of ethics in hospital pharmacy practice is not isolated to the United States; in 2014, there was a worldwide pharmacy meeting to discuss the future of hospital pharmacy practices and ethics.²⁰

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Bridges v Houston Methodist Hospital²¹

- Jennifer Bridges and 116 other employees sued Houston Methodist Hospital over their termination for failure to receive the COVID-19 vaccination as a condition of employment.
- Although plaintiffs claim coercion, defendants are just trying to do their business of saving lives without giving them the COVID-19 virus.
- Plaintiff has a constitutional right to either accept or decline the vaccination, however plaintiff has no constitutional right to work wherever she chooses.
- At will employment means that both employer and employee must agree on the terms of employment. If they don't agree, then no employment.

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Self Assessment Poll

What constitutes an Ethical Dilemma?

- When a person chooses the lesser of two evils
- When two or more ethical principles are mutually exclusive.
- When someone is forced to do something they don't want to do
- When a person is forced to choose between which one they like better

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Professional Ethics and Social Media²²

- Freedom of speech and expression are guaranteed by the first amendment to the Constitution
- The first amendment only prevents the government from infringing speech
- Even the government as an employer can place restrictions as a condition of employment

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The Temptation to Share Frustrations on Social Media

- In doing this, extreme care must be taken so as not to violate HIPAA.
- Even if the identity of the patient could not be discerned, the employer would not be pleased upon seeing one of their pharmacists complaining about patients or making fun of customers in a public forum.
- This reflects poorly on the company, and the employer could very convincingly argue that such actions would dissuade customers from using not only that pharmacy, but the entire pharmacy chain.
- Some of the postings on social media may run afoul of the ethical principle of non-maleficence by doing harm to either the subject being complained about or ridiculed, or injury to the reputation and standing in the community of the employer.²⁹

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False Claims Act ²³

- The False Claims Act (FCA) was passed by congress in 1863 as a result of suppliers of goods to the Union Army during the Civil War defrauding the government.
- The FCA provided that any person knowingly defrauding the government would be liable for double the government's damages plus a \$2000 fine
- Since then, the act has been amended several times, increasing the liability to treble (triple) damages and fines to a range of \$5000 - \$10,000 per incident.

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Qui Tam Provisions of the False Claims Act ²⁴

- Qui Tam is an abbreviation of the Latin term "*qui tam pro domino rege quam pro se ipso in hac parte sequitur*"
- This translates to "who sues in this matter for the king as well as for himself"
- The act provides for whistleblowers to file an action on behalf of the government for false claims against the government
- The whistleblower, referred to as the relator, is eligible for 15-30% of the judgement

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United States v. Andrew Assad et al. ²⁵

- This was a 32 count indictment against four individuals and seven companies including pharmacists and their compounding pharmacies
- This was a large case involving \$1 billion health fraud scheme
- Charges included
 - Conspiracy to commit healthcare fraud
 - Mail fraud
 - Introducing misbranded drugs into interstate commerce
- Verdict: Several defendants plead guilty; the remaining were found guilty by a federal jury in December. Sentencing to occur in 2022.

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United States v. Peter Khaim et al ²⁶

- Two New York area pharmacy owners were charged with exploiting emergency codes implemented during the COVID-19 pandemic while perpetrating a fraud scheme involving \$30 million in false claims for Targretin gel in December 2020
- Defendants Khaim and Khaimov owned 13 pharmacies and used COVID-19 emergency override billing codes to submit fraudulent claims for Targretin Gel 1%, which sells for more than \$34,000 per 60 gram tube.
- Claims were submitted for drugs, even though not ordered by either physicians or the pharmacies, and not actually dispensed or even warranted
- The case expanded in January 2022 to Two Indictments Charging the Defendants, Including an NYPD Police Officer, Doctors, an Attorney, and Others, With Healthcare Fraud, Money Laundering, Bribery, and Other Offenses in One of the Largest No-Fault Automobile Insurance Fraud Takedowns in History ²⁷

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Ohio Department of Medicaid et al. v. Buckeye Health Plan Community Solutions et al ²⁸

- Centene Corp. agreed to pay \$88.3 million to Ohio and \$55 million to Mississippi to end claims that Evolve Pharmacy Solutions, Inc. overbilled state agencies for drugs in 2017 and 2018
- Centene Corp. also agreed to set aside another \$1.1 billion related to this issue
- Ohio Attorney General Dave Yost sued Centene and its subsidiary Buckeye Health Plan, accusing its pharmacy benefit manager (Evolve Pharmacy Solutions, Inc.) of overbilling the Ohio Department of Medicaid for drugs.
- PBM was alleged to have been charging the plan sponsor more than what it paid the pharmacy for the drug. The PBM would keep the "spread" as the profit.

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United States v Robinson ²⁹

- Defendants Scott Robinson, Scott Mangini, Carl Garofalo, Sr. and Michael Posner were charged with several counts of Conspiracy to Defraud the United States and charges of illegal adulteration or misbranding of food/drugs
- Mangini (a Florida pharmacist) designed and produced equine drugs without FDA approval
- Over a period of almost 10 years, Magnini developed several compounds such as blood enhancers, steroid analogs, and ulcer medications in unsanitary conditions
- Robinson sold these products through direct-to-consumer websites
- A New York federal judge ordered Mangini to forfeit \$8.1 million, in addition to the 18 month prison sentence

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United States v Barry J Cadden ³⁰


- Cadden was founder of the New England Compounding Center (NECC) who was convicted after contaminated products sickened more than 800 people and killed more than 100 people from fungal meningitis in 2012
- Cadden failed to use approved sterilizing techniques and used expired ingredients
- Cadden was convicted of racketeering and mail fraud in 2017
- Cadden was originally sentenced to 9 years, but was resented to 14½ years in 2021 by the Court of Appeals because to District Court judge could have considered sentence enhancements for reckless conduct and victim vulnerability during the sentencing

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Criminal Liability


Steven Brandenburg (a Wisconsin pharmacist) was sentenced to three years in prison for attempting to spoil hundreds of doses of COVID vaccine³¹



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Criminal Liability


Dr. Jasna Mrdjen (a California physician) was sentenced to four years in prison for involuntary manslaughter for the reckless prescribing of opiates leading to the death of a patient by overdose³²



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Criminal Liability


Lisa Tseng (a California physician) was sentenced to 30 years–life for three counts of second-degree murder for deaths resulting from reckless over-prescribing of opiates.³³



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Criminal Liability


Thomas Keller (a California physician) was charged with four counts of second-degree murder for the overdose deaths of his patients on opiate therapy (acquitted on 2 counts)³⁴



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Criminal Liability


Rochester physician Sudipt Deshmukh was indicted in February 2021 for second degree manslaughter and other felonies in the overdose death of a patient ³⁵



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Criminal Liability

Long Island physician George Blatti was charged with five counts of second-degree murder in May 2021 under the legal theory that "depraved indifference" to human life led to the patients' deaths. ³⁶



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Criminal Liability

Laurence Doud, former CEO of drug wholesaler Rochester Drug Co-Operative, Inc. was convicted by a federal jury for narcotics conspiracy and conspiracy to defraud the United States February 2022.³⁷



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Doctrine of Corresponding Responsibility³⁸

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but **a corresponding responsibility rests with the pharmacist who fills the prescription.** An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and **the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.**

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Corresponding Responsibility

- A federal court in Ohio found major pharmacy chains liable for contributing to the opioid crisis³⁹
- Several state boards of pharmacy have revoked licenses based upon violations of the doctrine of Corresponding Responsibility⁴⁰
- It is just a matter of time before a pharmacist is convicted for second degree murder for over dispensing of opiates⁴¹

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So, what is the right answer?

- There is no single, "right" answer. Between the good and the bad, there lies an infinite number of shades of gray.⁴²
- An ethical dilemma, by definition, is the conflict between two different ethical principles that are mutually exclusive.
- A decision made by an individual practitioner may vary based upon that individual's personal beliefs, moral conviction, and value systems.

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So, what is the right answer?

- To make the issue more complex, the goals and priorities of employers may conflict with the individual practitioner's values.
- Society provides us with some guidance by the way of passing laws and regulations to facilitate our decision-making when faced with these conflicts.⁴³
- One such example is California Business & Professions Code §733(b)(3), which provides the procedures to be followed if a pharmacist refuses to fill an order or prescription based on ethical, moral, or religious grounds.⁴⁴
- However, laws and regulations will not cover all the ethical dilemmas encountered by the pharmacist in his/her daily practice.

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Where do we go from here?

- One strategy is to develop ethics awareness and skills in practitioners and to provide additional training.
- The Michigan Board of Pharmacy now requires that a portion of the mandatory continuing education hours required for licensure renewal involve a course in law and ethics.⁴⁵
- This is not unusual, as a portion of the continuing education hours for attorneys in several states includes mandatory training in ethics, substance abuse, and elimination of bias for licensure renewal.

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