

Normative Ethics for Pharmacists: Defending the Sanctity of Life in a Secular Work Place

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Through Pharmacy



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I have no financial relationships to disclose.

AND

I will not discuss off label use and/or investigational use in my
presentation.



Thanks to my very good friend and bioethics
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Objectives

By completion of this activity participants should be able to:

1. Define the philosophical basis for human value.
2. Discuss the organismal nature of humans from conception onward.
3. Analyze a clinical scenario utilizing these principles.



Definitions

- Ethics: The processes of how we work through moral issues
- Morality: good vs. evil, right vs. wrong
- Moral Responsibility and Freedom of Action
- Two basic branches
 - Deontological: Duty, moral obligation, right action
 - Consequentialism: It is only a right action if it produces a right outcome
 - Means justifies the ends
- Normative ethics: Right and wrong are generally agreed upon




Levels of Duty

- Morally permissible
- Morally obligatory
- Morally heroic




Human Value and Systems of Ethics




Ethical Systems

System	Proponents	Example	Branch	Human Value	Christian Compatibility
Natural Law	Thomas Aquinas, John Locke	Declaration of Independence	Deontological	Fully	Yes
Categorical Imperatives	Immanuel Kant	"Doctors must always lie to their patients."	Deontological	Mostly	Mostly
Divine Command	Bible and other religious texts	The Ten Commandments	Deontological	Mostly	When Bible based
Utilitarianism	Marx	Socialism, government social programs	Consequentialist	Means to an end	Sometimes
Hippocratic Tradition	Hippocrates	Hippocratic Oath	Deontological	Fully	Mostly




Hippocrates and Medical Principlism




Who Was Hippocrates?

- New Oxford Illustrated Dictionary: "the most famous of all physicians, of whom almost nothing is known."
- Hippocrates of Cos (c. 400 BC)
 - May have lived to over 100
 - Countercultural ideas
 - Along with his followers, founded a school based on the Oath




The Oath

- I swear by Apollo the physician, and Aesculapius, and Hygeia, and Panacea and all the gods and goddesses, making them my witnesses, that I will fulfill, according to my ability and judgment, this Oath and covenant . . .
- The Oath of the Pharmacist tips its hat to Hippocrates



Oath and Covenant

- Covenant:
 - More than a contract
 - Judeo-Christian implications
- Fiduciary Relationship:
 - Covenantal, based on trust
 - High level of responsibility
- Note: The Hippocratic Oath is highly deontological.
- Based on tradition, but easily compatible with Christianity



Duties to Patients: Medical Principlism

- Principle #1:
- I will apply treatment for the benefit of the sick according to my ability and judgment . . .
- The principle?
- Physicians (healthcare providers) should always have a patient's best interests in mind

BENEFACTENCE



Duties to Patients: Medical Principlism

- Principle #2:
- I will keep [my patients] from harm and injustice . . .
- Principle?
- "Primum non nocere:" First, do no harm (Latin version may have been first said by Galen)
- Implied in the oath, embodied in the Hippocratic corpus
- Actual quote: "As to diseases, make a habit of two things -- to help, or at least to do no harm."
- Written by Hippocrates in his Epidemics

NON-MALIFECENCE



Duties to Patients: Medical Principlism

- Principle #2a: Closely related to Non-Maleficence
- What I may see or hear in the course of treatment or even outside of the treatment in regard to the life of men, which on no account ought to be spread abroad, I will keep to myself, holding such things shameful to be spoken about.
- Patients must be able to trust providers with intimate details that they do not want known by others.

CONFIDENTIALITY



Duties to Patients: Medical Principlism

- Principle #3:
- Whatever houses I may visit, I will come for the benefit of the sick, remaining free of all intentional injustice, of all mischief, and in particular of sexual relations with both male and female persons, be they free or slaves.
- Principle?
- Treat all patients equally

DISTRIBUTIVE JUSTICE



Duties to Patients: Medical Principlism

- Principle #4
- Not contained in the Hippocratic Oath → 18th Century addition (Immanuel Kant)
- Two roots (L.):
 - auto (self)
 - nomos (rule)
- Autonomy = "self-rule"
- Definition:
 - The right of competent patients to make informed decisions about their own medical care.
 - Basis of informed consent
 - Implies decision-making capacity

PATIENT AUTONOMY



Duties to Patients: Medical Principlism

1. **Beneficence:** benevolent intent
2. **Non-maleficence:** no injurious intent
- 2a. **Confidentiality:** holding sacred the trust of intimate details about the patient
3. **Distributive Justice:** equal treatment of all patients, regardless of irrelevant factors
4. **Patient Autonomy:** patients make informed decisions about their own care



Beginning and End of Life

When do we become and stop being human?



What of the life that we live?

Psalms 139:13-14 For you created my inmost being; **you knit me together in my mother's womb**. I praise you because I am fearfully and wonderfully made; your works are wonderful, I know that full well.

1 Corinthians 6:19-20 Do you not know that your bodies are temples of the Holy Spirit, who is in you, whom you have received from God? **You are not your own; you were bought at a price.** Therefore honor God with your bodies.

Galatians 2:20 I **have been crucified with Christ and I no longer live, but Christ lives in me.** The life I now live in the body, I live by faith in the Son of God, who loved me and gave himself for me.

John 15:15 I no longer call you servants, because a servant does not know his master's business. **Instead, I have called you friends**, for everything that I learned from my Father I have made known to you.

Creator, Owner, Savior, Friend



Conception

- Prior to conception
- At the moment of fertilization: No longer an ovum or a sperm, a unique one-celled organism
- Unique set of DNA
 - *Derived* from mother and father
 - *Distinct* from both mother and father
- The entirety of the coding for full formation is now present



Implantation

- Implantation is required for full formation
- Implantation is actually more rare than conception
 - Estimated 78% of conceptions fail to implant
 - 15% of women have at least one known miscarriage in their lifetime, most are unknown
- Commensal relation to mother, not parasitic

Lancet 1975, March 1:498-9.
AJOG 1999;181(2):396-401.



Other Points

- Fetal physiological measures (e.g. heart beat, brain waves)
- Number of weeks of gestation (viability)
- Birth
 - Double-homicide
- Post-birth¹

1. *J Med Ethics* 2013;39(5):261-3



End of Life

- Body *and* Soul
- Disability
- Self-awareness/expression
- Death



Sanctity of Life in a Secular Work Place

Rights of Conscience



Pharmacy, Law, and Bioethics

- Focus of pharmacy has been on law
- Ethics has only recently been added to pharmacy curricula
- Pharmacists acting in unprofessional and perhaps unethical ways



Healthcare Right of Conscience

"The right of institutions and healthcare professionals to exercise their conscience and refusal to participate in or cooperate with certain medical practices or procedures they deem morally, ethically or religiously objectionable."

Christian Medical and Dental Association

- Rooted in the Hippocratic tradition
 - First do not harm
- Rooted in the First Amendment
 - "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof..."
- Rooted in Scripture
 1. We must avoid every kind of evil (1 Thessalonians 5:22)
 2. We must hate and oppose evil (Romans 12:9)
 3. We should separate ourselves from evil (II Corinthians 6:17)
 4. We should overcome evil with good (Romans 12:21)
 5. We should seek wisdom (James 1:2-5)



The Noesen Case

- Neil Noesen, a relief pharmacist at the Kmart in Menomonie, Wis.
- Only person on duty one day in 2002
- Refill for Loestrin FE
- Noesen refused because of his religious opposition to birth control
 - Also declined to transfer the prescription to a nearby pharmacy
 - Refused once again when the woman returned to the store with police
 - Rx filled several days later by the managing pharmacist
- Noesen was accused of unprofessional conduct
 - Received a reprimand and restrictions on his license



State Board Action Against Noesen

- Charge of Unprofessionalism
- Reprimanded
- Prior to providing pharmacy services at any pharmacy, Noesen was required to:
 - Prepare a written notification specifying in detail:
 - State the practices he will decline to perform as result of his conscience
 - Steps he will take to ensure that a patient's access to medication is not impeded by his declination(s).
 - Provide this to any potential employer "at least five (5) business days prior to Respondent commencing practice at the pharmacy."
 - Provide at the same time a copy of the State Board action
- Complete a minimum of 6 hours of CE in Ethics for pharmacy practice, approved by the Board
- *Noesen v. Wisconsin Department of Regulation and Licensing Pharmacy Examining Board*
 - Upheld the state's discipline
 - Noesen's refusal to transfer the prescription violated a pharmacist's standard of care.



Fall Out

- **2004 APhA:** "Recognizes the individual pharmacist's right to exercise conscientious refusal and supports the establishment of systems to ensure patient's access to legally prescribed therapy without compromising the pharmacist's right of conscientious refusal."
- **AMA 2005** – Pharmacists should make an immediate referral
- **APhA 2005** – "supports the ability of the pharmacist to step away from participating in an activity to which they have personal objections—but not to step in the way."
- **ASHP 2006** - Recognizing the right of pharmacists and other pharmacy employees not to participate "in therapies they consider to be morally, religiously, or ethically troubling."
- **Royal Pharmaceutical Society of Great Britain 2006**
 - "ensure your professional judgment is not impaired by personal or professional interests, incentives, targets or similar measures; declare any personal or professional interests to those who may be affected;"
 - "ensure that, if you have a conscientious objection to particular services, this is clearly known by your patients and employer, and have in place the means to make a referral to another relevant professional within an appropriate time frame."



The Stormans Case

- Family owned Ralph's and Bayview Thriftways in Olympia, Wash. for over 70 years
- 2006 pro-abortion activists were "test-shopping" and found that Ralph's didn't carry Plan B; boycotts and pickets ensued
- Governor of Washington joined the boycott



Washington Pharmacy Commission

- Pressure by Gov. Christine Gregoire
- 2007 Regulations
 1. Pharmacies must stock all FDA approved drugs
 2. Pharmacists may not refer to another pharmacy for conscience reasons; may only refer to another pharmacist
- Referral to another pharmacy was then legal in all 49 other states
- Multiple exemptions are allowed to the Stocking rule
 - Religious or moral conscience rights are not among the exemptions for either pharmacies or pharmacists.



Fall Out

- Pharmacists Margo Thelan and Rhonda Mesler
 - One was terminated from her job, the other was offered to be transferred to another state.
- Stormans v. Weisman
 - District court in 2012 overturned the regulations finding that the regs were written specifically "solely to target religiously conscience rights."
 - Federal 9th circuit court overturned the decision.
 - Appeal was made to SCOTUS who denied certiorari, June 2016.
 - Free exercise
 - Equal protection and due process
 - Make-up of the court was 8 judges due to the death of Scalia
- Effectively denies right of conscience to pharmacists.
- Puts pharmacies in the position of having to know about possible religious objections of pharmacists



Ethical Analysis

- Competing ethical duties
- Professional duty to protect the patient, do no harm
 - Including harm to unborn
- Honor patient autonomy
 - Right to legal service
 - Freedom from discrimination
- Professionalism is the balancing of these ethical duties
 - At stake is the ability of the pharmacist to balance harm vs autonomy
 - Prevention of harm should generally over-ride autonomy



FOR IMMEDIATE RELEASE
January 18, 2018

Contact: Office for Civil Rights
202-774-2009
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HHS Announces New Conscience and Religious Freedom Division

Today, the U.S. Department of Health and Human Services (HHS) is pleased to announce the formation of a new Conscience and Religious Freedom Division in the HHS Office for Civil Rights (OCR). The announcement will take place at an event at HHS headquarters from 10:30 a.m. to noon. It will be livestreamed [here](#). Speakers will include Acting Secretary Eric D. Hargan, House Majority Leader Kevin McCarthy, Representative Vicky Hartzler, Senator James Lankford, OCR Director Roger Severino, and special guests.

The Conscience and Religious Freedom Division has been established to restore federal enforcement of our nation's laws that protect the fundamental and unalienable rights of conscience and religious freedom. OCR is the law enforcement agency within HHS that enforces federal laws protecting civil rights and conscience in health and human services, and the security and privacy of people's health information. The creation of the new division will provide HHS with the focus it needs to more vigorously and effectively enforce existing laws protecting the rights of conscience and religious freedom, the first freedom protected in the Bill of Rights.

FEDERAL REGISTER
The Daily Journal of the United States Government

Proposed Rule

Protecting Statutory Conscience Rights in Health Care; Delegations of Authority

A Proposed Rule by the Health and Human Services Department on 01/26/2018

PUBLISHED DOCUMENT Start Printed Page 3680

AGENCY:
Office for Civil Rights (OCR), Office of the Secretary, HHS.

ACTION:
Proposed rule.

DOCUMENT DETAILS
Printed version: PDF
Publication Date: 01/26/2018
Agency: Department of Health and Human Services
Date: 01/26/2018

Summary of Proposed Rule

- Provides protections related to abortion, sterilization, and certain other health services to participants in programs and their personnel, funded by HHS
- Conscience protections for health care entities related to abortion provision or training, referral for such abortion or training, or accreditation standards related to abortion
- Protections from discrimination for health care entities and individuals who object to furthering or participating in abortion under programs funded by the Department's yearly appropriations acts
- Conscience protections under the Patient Protection and Affordable Care Act (ACA) related to assisted suicide, the ACA individual mandate, and other matters of conscience
- Conscience protections for objections to counseling and referral for certain services in Medicaid or Medicare Advantage
- Conscience protections related to the performance of advanced directives
- Conscience protections related to Global Health Programs to the extent administered by the Secretary; Consolidated Appropriations Act, 2017
- Exemptions from compulsory health care or services generally, and under specific programs for hearing screening, occupational illness testing, vaccination, and mental health treatment; and
- Protections for religious nonmedical health care

[B]oth morals and sound policy require that the State should not violate the conscience of the individual.



Case Studies



In 2002 a Wisconsin pharmacist was presented with a prescription for an oral contraceptive.¹ The pharmacist was the only person on duty that day, and not only refused to refer the patient to another pharmacy, but also refused to return the prescription after refusing to fill it. The Wisconsin Board of Pharmacy ordered the pharmacist to attend ethics classes, required him to inform all future employers of his objection to dispensing birth control, and outline the steps to ensure future patients has access to contraceptives. The Wisconsin courts upheld the Pharmacy Board's ruling.²

1. Dale SS. Can a Pharmacist Refuse To Dispense Birth Control? *Time* 2004;2011.
2. Punishment for druggist who opposes birth control upheld. *Associated Press* 2008;2011.



What ethical principles were violated?

- A. Beneficence
- B. Non-maleficence
- C. Distributive Justice
- D. Confidentiality
- E. Patient autonomy



What could the pharmacist have done to both stand on faith and fulfill his ethical duty to the patient?

In 2004 a pharmacist in Denton, Tx refused to fill a prescription for Plan B for a rape victim.¹ In this case the pharmacist returned the prescription to the patient. The patient was able to get the prescription filled at a pharmacy across the street. The pharmacist and two co-workers were subsequently terminated by the pharmacy chain for violating company policy which required them to dispense the medication.²

1. Denial of rape victim's pills raises debate. *Associated Press* 2004;2011.
2. Pharmacists in rape victim case are fired. *The Dallas Morning News* 2004.



What ethical principles were violated?

- A. Beneficence
- B. Non-maleficence
- C. Distributive Justice
- D. Confidentiality
- E. Patient autonomy



Was there anything that the pharmacists in this case could have done from an ethical standpoint for the patient?



The Commandments of Jesus

1. Love God with all your heart, mind, strength, and soul. Luke 10:27, Matt 22:37
2. Love your neighbor as yourself. Luke 10:27, Matt 22:38
3. Treat others as you would want to be treated. Luke 6:31, Matt 7:12
4. Spread the Gospel to the entire world. Mark 16:15, Luke 14:23, Matt 28:19-20

There is truth we must stand for, there is sin we must stand against, and there are people we must win for Christ. We must do each of these in ways that do not hamper the other two.



Questions?

