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

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Disclosure Information
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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.

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

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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?

  **BENEFICENCE**
  • Physicians (healthcare providers) should always have a patient’s best interests in mind

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Duties to Patients: Medical Principlism

• Principle #2:
  • I will keep [my patients] from harm and injustice . . .
  • Principle?

  **NON-MALIFECENCE**
  • “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 Epemics

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Duties to Patients: Medical Principlism

• Principle #2a: Closely related to Non-Maleficence

  **CONFIDENTIALITY**
  • 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.

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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?

  **DISTRIBUTIVE JUSTICE**
  • Treat all patients equally

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Duties to Patients: Medical Principlism

• Principle #4

  **PATIENT AUTONOMY**
  • Not contained in the Hippocratic Oath → 18th Century addition (Immanuel Kant)
  • Two roots (L.):
    • aut (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

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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?

Psalm 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

Other Points

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

End of Life

- Body and Soul
- Disability
- Self-awareness/expression
- Death
Normative Ethics for Pharmacists:
Defending the Sanctity of Life in the Secular Work Place

Sanctity of Life in a Secular Work Place
Rights of Conscience

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
• 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 (1 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:
    • The position 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.”

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
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

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
  - 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
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 performing or participating in abortion under programs funded by the Department's yearly appropriations acts
- Conscience protections related to the provision of abortion in a hospital or clinical office, the ACA individual mandate, and other matters of conscience
- 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 for objections to counseling and referral for certain services in Medicaid or Medicare Advantage
- Conscience protections related to the performance of assisted suicide
- 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, vaccinations, and mental health treatment; and

Protections for religious nonmedical health care

Both 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. 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 have access to contraceptives. The Wisconsin courts upheld the Pharmacy Board's ruling.

In 2004 a pharmacist in Denton, Tx refused to fill a prescription for Plan B for a rape victim. 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.

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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?
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

3. Treat others as you would want to be treated. Luke 6:31, Matt 7:12

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.