ETHICAL ISSUES FOR PHARMACISTS: CONSIDERATIONS IN THE MANAGEMENT OF OPIOIDS

William J. Stilling, BS Pharm, MS, JD
Utah Pharmacy Association
Mid-Year Meeting
November 5, 2016

Disclaimer

This presentation and handout materials are not intended to establish an attorney-client relationship between the speakers or their respective firms and any member of the audience. Rather, this presentation and handout materials are intended to provide education about the topics covered and should not be relied on as legal advice. If anyone needs legal advice about the topics covered, separate legal advice should be sought.

Objectives

- After attending this presentation, attendees should be able to:
  1. Apply two methods of resolving ethical issues.
  2. Identify and describe the principles of pharmacy ethics that apply to scenarios involving the use of opioids.
  3. Apply the principle of “Double Effect” to evaluate ethical issues involving opioids.
  4. Describe the effect of implicit bias may have on ethical decisions involving opioids.
  5. Identify and apply sections of laws and regulations that reference ethical standards.
What are ethics as distinguished from the law?
- Law
  - Binding
  - Implemented by government (external)
    - “This is a court of law, not a court of justice.”
      - Oliver Wendell Holmes, Jr.
  - Violations carry penalties
- Ethics
  - Often aspirational
  - Generated by the profession (internal)
  - Often “should” not “shall”
  - Can conflict with laws or produce different outcomes

Law and Ethics Conflicts
- Quill Letter
- Antitrust and restraint on trade
  - 1852 APhA Code of Ethics guided pharmacists to
    “protect themselves and the public from the ill effects of
    undue competition, and the temptation to gain at the
    expense of quality.”
Ethics

- Definitions
- Black’s Law Dictionary (8th ed.): “Ethics. See LEGAL ETHICS.”
- Oxford English Dictionary: “Ethics . . . moral principles that govern a person’s or group’s behavior.”
- The New Oxford American Dictionary (2nd ed.): “Ethic . . . a set of moral principles, esp. one relating to or affirming a specified group.”

Ethics Origins

- Aristotle’s Nicomachean Ethics
  - One of the earliest and most well known philosophical treatises about ethics
  - A good life is a life of happiness, but happiness is not a goal as much as an experience from taking the morally correct action
  - Golden mean is to act moderately between extremes
- The Bible
  - “The love of money is the root of all evil.” I Timothy 6:10.

Handling patients

- Pharmacist and patient requesting syringes
  - Ethical issues
  - Is it better to provide syringes or to let users share syringes?
  - Profiling
- Drug seeker
  - https://www.youtube.com/watch?v=GuA2QULcmsg
Consequentialism
- Ethical decisions are based on determining the action that minimizes harms and maximizing good
  • What is “good?”
  • What is “harm?”
  • Identify values
    - Resolution of health
    - Relief of symptoms
    - Saving or prolonging life
    - Educating or counseling patients
    - Avoiding harm to patients

Duty-Based Ethics
- Focuses on duties and rights of the parties to a relationship
- Duties are absolute
  • Do not kill an innocent person
  • Do not tell a lie
  • Do not do physical harm to an innocent person
- Ethical principles derived from duties
  • Autonomy
  • Nonmaleficence
  • Beneficence
  • Justice

Duty-Based Ethics
- Autonomy: Respecting people as free agents who are responsible for their own decisions (basis for informed consent)
- Nonmaleficence: One must not hurt others—“Do no harm”
- Beneficence: Do good
- Justice: People should receive that to which they are entitled; resources must be allocated fairly
Covenantal Relationship

- **Covenant**
  - “A mutually beneficial exchange in which a patient promises to grant authority to the provider, and the provider promises competence and commitment (responsibility) to the patient”
- **Covenant** is opposite of a business relationship based on *caveat emptor*
- Examples of covenantal relationships: marriage, religions, professional

Double Effect

- An ethical principle that applies when a person’s actions are legitimate, but also has an effect that one would morally avoid.
- From a consequentialist perspective, there are clearly harms based on an action to achieve good.
- Often applies in cases when the goal of treatment is legitimate and good, but serious harmful effects are likely to occur.

Implicit Bias

- **National Center for State Courts**
  - “Unlike explicit bias (which reflects the attitudes or beliefs that one endorses at a conscious level), implicit bias is the bias in judgment and/or behavior that results from subtle cognitive processes (e.g., implicit attitudes and implicit stereotypes) that often operate at a level below conscious awareness and without intentional control.”

  See Project Implicit at:  
  [https://implicit.harvard.edu/implicit/takeatest.html](https://implicit.harvard.edu/implicit/takeatest.html)
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.

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.

**Utah Pharmacy Practice Act Rules**
- Unprofessional conduct includes: (1) violating any provision of the American Pharmaceutical Association (APhA) Code of Ethics for Pharmacists, October 27, 1994, which is hereby incorporated by reference. R156-17b-502.
- Penalty for "violating any ethical code provision of the American Pharmaceutical Association Code of Ethics for Pharmacists, October 27, 1994" is $250 - $500 for initial offense and $2,000 - $10,000 for subsequent offense(s). R156-17b-402 (27).
Interface of Ethics and Law

- Utah Pharmacy Practice Act Rules
  - R156-17b-614a. Operating Standards - General
    Operating Standards, Class A and B Pharmacy.
    - ... the following operating standards apply to all Class A and
      Class B pharmacies. ... The general operating standards
      include:
      - be equipped to permit practice within the standards and ethics
        of the profession as dictated by the usual and ordinary scope
        of practice to be conducted within that facility.
      Utah Admin. R156-17b-614a(d).

Interface of Ethics and Law

- Division of Occupational and Professional Licensing
  Act
  - "Unprofessional conduct" includes: (b) violating, or aiding or
    abetting any other person to violate, any generally accepted
    professional or ethical standard applicable to an occupation or profession

Pharmacists’ Responsibility for
Controlled Substances

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.

21 C.F.R. 1306.04
### DEA Red Flags
- “Pattern prescribing” – prescriptions for the same drugs and the same quantities coming from the same doctor;
- Prescribing combinations or “cocktails” of frequently abused controlled substances;
- Geographic anomalies;
- Shared addresses by customers presenting on the same day;

### DEA Red Flags
- The prescribing of controlled substances in general;
- Quantity and strength;
- Paying cash;
- Customers with the same diagnosis code from the same doctor;
- Prescriptions written by doctors for infirmaries not consistent with their area of specialty;
- Fraudulent prescriptions.

### Scenario 1
You are manager of an inner city pharmacy in a major U.S. city. You have discretion as to which drugs to carry in the pharmacy’s inventory.

- Will you carry opioids?
- Will you impose any restrictions that are not required by laws and regulations?

---

Information comes to you that Dr. Candy is being investigated by the DEA. Other pharmacists hear that Dr. Candy generates prescriptions without examining patients.

- What actions do you take, if any, based on this information?

**Scenario 2**

- **Information comes to you that Dr. Candy is being investigated by the DEA. Other pharmacists hear that Dr. Candy generates prescriptions without examining patients.**

- **What actions do you take, if any, based on this information?**

---

**Defamation**


  - **RELIEF SOUGHT:** CVS sought dismissal of claims of physician’s defamation claims alleging CVS employees made statements about the legality of physician was engaging in illegal activities.

  - **FACTS AND PROCEDURAL HISTORY:** Physician, who specialized in physical and rehabilitation medicine, sued CVS claiming that CVS employees committed per se defamation based on alleged statements including: (i) he “he operates a pill mill”; (ii) is a “murderer”; (iii) is “under DEA investigation”; and (iv) “had been or would soon be arrested” and the patients “should find another doctor.” CVS moved to dismiss the defamation claim.

  - **HOLDING:** The court denied the motion to dismiss because:
    - The defamation claim was “plausible on its face.”
    - The plaintiff sufficiently pled actual malice.
    - CVS was not entitled to dismissal based on qualified privilege because the privilege is a fact-based defense for the jury to decide.
Defamation

  - **RELIEF SOUGHT:** Walgreen moved for summary judgment to dismiss orthopedic surgeon’s defamation claims.
  - **ISSUES:**
    - Did notices in Walgreens’ computer system meet the elements of a defamation claim?
    - Did alleged defamatory statements by pharmacists (i.e., about plaintiff being investigated by DEA and his overprescribing, etc.) survive motion for summary judgment?

Defamation

  - **HOLDINGS**
    - The claims based solely on notices in Walgreens’ computer system that plaintiff was under investigation by DEA were dismissed because they were not published.
    - There were questions of material fact regarding the alleged defamatory statements and the court denied the motion for summary judgment as to those claims.

Defamation  
**Yarus v. Walgreen Co.**

<table>
<thead>
<tr>
<th>Allegations</th>
<th>Ruling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaintiff claimed Walgreen had put a warning in his profile on its computer was “red flagged” with a message “BEING INVESTIGATED BY THE DEA!!!”</td>
<td>Dismissed claims based solely on warning in the system for lack of publication</td>
</tr>
<tr>
<td>Pharmacists refused to fill prescriptions of Plaintiff’s patient, Damien Zajac and stated “Dr. Yarus is an irresponsible doctor who just writes scripts and probably does very little treating.”</td>
<td>Material issue of fact—no dismissal</td>
</tr>
<tr>
<td>Pharmacists refused to fill prescription and allegedly said “[w]e don’t fill this doctor’s prescriptions… there was just nobody going to fill it in the area — no chain store like Walgreen, CVS, Rite Aid. Nobody in the area fills his prescription. They feel he passes out too many pain pills… I’m not going to tell you that anybody is looking at him. But the DEA wants us to report all prescriptions with him. We can’t fill anything until we call him or he has to call us.”</td>
<td>Material issue of fact—no dismissal</td>
</tr>
</tbody>
</table>
Defamation

- **Goulmamine v. CVS Pharmacy, Inc., 3:15-cv-370 (E.D. Vir. October 9, 2015)**
  - Dr. Goulmamine's complaint was based on alleged factually incorrect statements (e.g., he was “in jail,” overprescribed to pregnant patient, one patient died of Xanax overdose, government agencies were investigating him or revoked his license); opinions (e.g., “he fills [sic] too many prescriptions,” he won’t be in business much longer); and statements about patients (e.g., “you shouldn’t be taking these pain pills,” “you are probably a drug addict”) that were defamatory.
  - CVS sought to dismiss Dr. Goulmamine’s complaint alleging CVS employees told his patients they would no longer fill prescriptions he wrote.

---

Defamation

- **Goulmamine v. CVS Pharmacy, Inc.,**
  - **HOLDING:** Court denied the motion to dismiss the defamation claim because: (i) Dr. Goulmamine had pled statements that could be defamatory; (ii) statements are not necessarily protected by privilege; and (iii) even if communications were protected by a qualified privilege, there is a question of fact for the jury as to whether the privilege was lost because the statements were made with malice.

---

Defamation

  - **RELIEF SOUGHT:** Physician sued Walgreens for alleged defamatory statements made by Walgreens pharmacists.
  - **FACTS AND PROCEDURAL HISTORY:** Physician brought defamation claim against pharmacy. Physician claimed pharmacists at Walgreens made defamatory statements to patients regarding his medical reputation and ethics when they attempted to fill prescriptions. “[T]he apparent purpose of the statement was to inform customers about the physician who wrote the prescription.”
  - Plaintiff claimed Walgreens’ employees committed slander per se when they “conveyed defamatory statements” regarding his qualifications as a medical doctor. Walgreens moved for summary judgment.
Defamation

  - HOLDINGS:
    - Pharmacists did not commit slander against physician during consultation with patient.
    - Comments made during the consultation were privileged.

Scenario 3

- As a consultant pharmacist in an LTCF, you review an order for a patient with terminal cancer. The orders are:
  - Lorazepam 2 mg: Take one three times a day as needed for anxiety.
  - Morphine oral liquid 100mg/5ml: Take 8 mg (0.4 mL) every four hours as need for pain.
- What is your recommendation about this order?

Double Effect?
Quill Letter

  - Court ruled New York assisted suicide law does not violate the Equal Protection of the Fourteenth Amendment

Scenario 4

- You work for an employer who requires who prohibits pharmacists from filling opioid prescriptions for Medicaid patients.
  - What ethical principles are implicated?
  - Is the phrase “Medicaid patients” a pretext for some other type of screening?

Questions?

William J. Stilling, B.S. Pharm., M.S., J.D.
Chair, Health and Life Sciences Practice Group
Parsons Behle & Latimer
Salt Lake City, UT
801-536-6765
bstilling@parsonsbehle.com