The Linkages Between Professional Ethics and Pharmacy Law

John L. Colaizzi, Ph.D., R. Ph.
University Professor
Professor of Pharmacy Practice
Professor of Pharmaceutics
Rutgers, The State University of New Jersey
Ernest Mario School of Pharmacy
February 28, 2009
Objectives

At the completion of this program:

the participant will be able to explain the fundamental relationship between professional ethics and pharmacy laws and regulations;

identify some of the major ethical dilemmas in pharmacy practice and their implications related to legal and regulatory requirements;

and utilize knowledge of pharmacy laws and ethical responsibilities in solving common problems that arise in every day pharmacy practice situations.
Definitions: **Ethics, Bioethics**

- **Ethics** is a branch of Philosophy.

- **Ethics** focuses on *values, rules of conduct, moral principles*.

- **Bioethics** is the systematic study of the moral dimensions (decisions, behavior, policies) of the *life sciences and healthcare*.

Ernest Mario School of Pharmacy
Why be Concerned About Ethics & Morality in Professional Practice?

- 2008 report: Theft and cheating among American teens is widespread.

- Why be moral???
  - Reputation
  - Avoid “getting into trouble”
  - “Feeling good about myself”
  - Global benefit
  - Religious beliefs

Ernest Mario School of Pharmacy
The Focus of *Bioethics*

- The relationship between the healthcare provider and the patient
- Public Health policy and population ethics
- Healthcare systems and economic viability ("No margin, no mission!"
- Fertility and human reproduction
- Psychological and behavioral health
- Death and end-of-life experiences
- Investigational drugs/clinical research
- Organ transplantation
- Animal experimentation

Ernest Mario School of Pharmacy
Ethics and “The Law”

- “Our law is by definition a codification of morality, much of it grounded in the Judeo-Christian tradition.” – Barack Obama, 2006
- Ethics is the basis of (just) laws.
- It is precisely a breach of ethics that has prompted the enactment of many laws.
- Ethics is sometimes more effective than formal regulation. (e.g., Robert Courtney case* – 2001)

* Robert Courtney was a Kansas City pharmacist who was convicted of intentionally substituting isotonic saline solutions in place of cancer chemotherapy solutions for IV administration to patients. He did this in spite of the pharmacy regulations prohibiting such administration. He is now serving a long prison term.
Ethics as a Component of Continuing Professional Education Programs and Courses in Law

- Ethics is the philosophical basis for laws and regulations.
- “In what ways has the course encouraged your intellectual growth?” - “None in law, some thought (required) in professional ethics.”*
- Ethics asks the hard questions.
- Ethical decision-making is not “black and white.”

* A comment by a pharmacy student in 2008 when providing a final course evaluation of the Pharmacy Law and Bioethics Course.

Ernest Mario School of Pharmacy
Ethics Instruction in Continuing Professional Education and Pharmacy Law Courses

- Laws/Regulations tell us what we have the right to do.
- Ethics tells us what is the right thing to do.
- *New England Journal of Medicine, 2008:* Formal ethics instruction is best reserved for the professional years because it needs to be understood in the context of patient care.
- Ethics instruction, where applicable, should be presented along with case studies involving interactions with patients.

Ernest Mario School of Pharmacy
Value of an Ethical Focus in Pharmacy Practice

- Good Ethical Decision Making skills and ethical instincts in dealing with conflicts in practice will prevent many legal misjudgments and violations.

- Good Ethical Decision Making skills and ethical instincts will usually avoid inadvertent violations of regulations.

- The value and wisdom of “acting in good faith.”
“Can Ethics be Taught?”

- Implication of the question is that it can’t.
- Ethics instruction is not “preaching morality.”
- Basic moral instincts are “hardwired” by the time pharmacy students reach the professional program.
- Both practitioners and students are amenable to being sensitized to the importance of ethics, and can learn the techniques of EDM and apply them in professional practice.
The Pervasiveness of Ethics Instruction in the Business World

- ENRON
- Sarbanes-Oxley legislation*
- Top Business Schools now require palm scan ID checks to eliminate proxy test-takers.
- Questionable ethical practices in corporations and Wall Street as cause of current economic adversity.

*This federal legislation was enacted in large part as a result of the ENRON scandal. It applies in an obligatory way to for-profit public corporations, requiring full disclosure for accounting practices and independent auditors.

Ernest Mario School of Pharmacy
The Pervasiveness of Ethical Applications in Healthcare

- Institutional Review Boards (IRBs) – required to approve all investigational research involving human subjects to ensure their ethical treatment.
- Ethics Committees in Hospitals can act as consultants for difficult or recurrent ethical cases.
- Compliance officers in corporations and Managed Care agencies – report directly to the CEO.
- Birth of Octuplets in California in 2009 has raised questions about the ethics of in-vitro fertilization and the need for more regulation of fertility clinics.
Professional Ethics – A Requirement for all Pharmacists

- Ethical obligations and guidelines distinguish professions from occupations.
- Ethical commitment is a counterbalance to the commercialism and competition inherent in healthcare.
- Pharmacy licensing has an ethical basis: to serve the public (Altruism).
- Pharmacy licensing has an ethical requirement.
N.J.S.A. 45:14-50. License to Practice Pharmacy

To obtain a license:

a) Submit a written application.
b) At least 18 years of age.
c) *Be of good moral character.*
d) Received professional degree from a School approved by the Board.
e) Internship or approved experience.
f) Passed examinations.
g) Paid required fees.

Ernest Mario School of Pharmacy
N.J.A.C. 13:39-2.5  Proof of Character

• Submit evidence
• An ongoing requirement
  1. Not presently engaged in drug/alcohol use likely to impair practice.
  2. Not convicted re: Controlled Drug Substances/drug laws.
  4. Not convicted of crimes involving moral turpitude (vile or shameful acts).
  5. Not currently suspended or within 5 yrs. In any jurisdiction.

Ernest Mario School of Pharmacy
Proposed change to N.J.A.C. 13:39 – 2.5

- To be recodified as N.J.A.C. 13:39-2.3 (with amendments)
- Will eliminate the 5 year limitation.
- Any license or permit suspension from another jurisdiction, regardless of amount of time that has passed, may be considered by the Board of Pharmacy.

Ernest Mario School of Pharmacy
Ethics and Pharmacists: Some Considerations

- Ethical guidelines for healthcare professionals are not identical as for those engaged in general commerce.
- Profitability does not preclude the ideals of professionalism.
- Instruction in ethics helps practitioners apply vague or theoretical standards to specific patient care concepts.
- Ethical understanding helps pharmacists to feel more comfortable with their decisions in dealing with ethical dilemmas.
USA Today/Gallup Survey of Professional Integrity: 2008

• “Tell me how you would rate the honesty and ethical standards of people in different fields.”

• “High or Very High:”
  
  Nurses -- 84%
  Pharmacists -- 70%
  High School Teachers -- 65%
  Physicians -- 64%
  Police/Clergy -- each 56%
  (Lawyers -- 18%)
Can Pharmacists Rely Solely on Laws/Regulations?

- Laws/Regulations are too complex and numerous for complete assimilation by all practitioners.

- Failure to incorporate ethical values is likely to lead to infractions of laws/regulations.

- Some ethical conflicts do not yield to “black or white” decisions, but require professional judgment and skillful Ethical Decision Making.
Incorporating Ethics with Adherence to Laws/Regulations

- Likely to minimize pharmacists’ inadvertent violation of laws/regulations.
- Sustain and enhance the pharmacist-patient relationship.
- More satisfying and fulfilling to most modern pharmacists than a solely legalistic approach.
- More consistent with the patient-centered pharmaceutical care model of practice.
Ethics Training for Pharmacists Involved with Medicare Part D

- Fraud, waste & abuse training required for all pharmacists involved with PDP or Medicare Advantage plans.
- Annual training requirements became effective January 1, 2009, and must be completed by December 31, 2009.
- Need to participate in a single PDP training program.
Example of Medicare Fraud, Waste or Abuse in Pharmacy

- Inappropriate billing.
- Prescription drug “shorting” (dispensing less than the prescribed amount but charging Medicare for the full amount)
- Improper pricing.
- Prescription altering.
- Dispensing expired or adulterated Rx-drugs.
- Unauthorized refills.
A newly hired pharmacist is working a weekend shift in a community pharmacy. The pharmacy manager instructs the pharmacist to use the “slow times” to return to stock all the Rxs that have not been picked-up for at least two weeks from the time the Rxs were filled. The new pharmacist inquires about the proper way to reverse the insurance claims for the Rxs being returned to stock. The pharmacy manager responds, “Don’t bother. Nobody will know the difference.”
Discussion of Medicare Case

What the pharmacy manager has instructed the newly hired pharmacist to do is not only an example of Medicare fraud, but it is unethical as well because it violates the ethical principles of veracity and patient autonomy (billing this to the patient’s Medicare account without patient’s knowledge). It also harms society in general because it adds unnecessary and inappropriate costs to an already strained Medicare budget. The new pharmacist is faced with a dilemma: If he follows the manager’s orders, it will be a clear violation of ethics, but disregarding the wishes to the manager could put the new pharmacist’s job in jeopardy.

Ernest Mario School of Pharmacy
Duties/Rights of Stakeholders as a Model for EDM

- Patients
- Physicians and other healthcare providers
- Pharmacist colleagues
- Employer
- Society at large (e.g., the healthcare system)
- Self/Family
- The profession (its reputation)

Each stakeholder has ethical rights and duties. It is often necessary to decide which stakeholder’s rights (or duties) take precedence. Often, the patient’s rights are most important, but sometimes it might be appropriate to yield to other stakeholders.
Long-established and Accepted Ethical Principles ("Virtues") as a Model for EDM

- **Beneficence:** "Caring." "Doing good."
- **Nonmaleficence:** "First do no harm."
- **Autonomy:** Self-determination, human dignity, respect for the individual.
- **Utility:** The end result should be useful to patients and to society.
- **Justice:** Impartiality in applying beneficence and distributing resources.
- **Veracity:** Truthfulness, candor.
- **Fidelity:** Keeping your word. Maintaining confidentiality.
Beneficence/Nonmaleficence

- “Do good” (Beneficence)
- “Do no harm” (Nonmaleficence)
- Hippocrates – 4th Century B.C. – introduced these ethical principles.
- The first precept and fundamental starting point for any discussion of ethics.
- Not everyone agrees on the good to be done or the harm to be avoided.
- The best answers are not innately known; must be arrived at through EDM. Involves the correct use of practical reasoning.

Ernest Mario School of Pharmacy
“Do good.”
“Do no harm.”

- Two sides of the same ethical coin.
- The individual pharmacist’s approach to ethical practice will be largely affected by which one of these he/she considers to be more important.
- “Do good” comes before “Do no harm.”
- The “harm” of an excessive “First do no harm:” (might be an excuse for doing nothing). Doing nothing might itself be the cause of harm. For example, not taking a needed medication.
Codes of Ethics Model for EDM:  
*The 1994 APhA/ASHP Code*

- Codes are based on broad consultation and consensus among a broad spectrum of the profession.
- Codes are based on moral principles, *i.e.*, Ethics (or “Virtues”).
- The 1994 Code is strikingly different from the previous (1969) code and previous codes.
The Pharmacy Code of Ethics

I. Covenantal relationship between pharmacist and patient.

- There is a social contract between the pharmacist and the patient
- The pharmacist is fully committed to patient’s welfare.
- The pharmacist is the professional who assists patients to make the best use of medications.
- The patient is always the #1 stakeholder.
The Pharmacy Code of Ethics

II. The pharmacist promotes the good of every patient in a compassionate, caring, confidential manner.

- Beneficence/Nonmaleficence (caring).
- Confidentiality (and privacy) – absolute ethical imperatives.
The Pharmacy Code of Ethics

III. The pharmacist respects the autonomy and dignity of every patient.

- Autonomy – the patient must give implicit “informed consent to take or not take a medication.”
- Counseling – effective communication with cultural competency.
- Shared decision-making is important.
- Informed refusal is also the patient’s right (based on autonomy).

Ernest Mario School of Pharmacy
The Pharmacy Code of Ethics

IV. A pharmacist acts with honesty and integrity in professional relationships.

- Veracity (e.g., placebo therapy only appropriate in controlled investigational drug trials as long as patients in the trials are not subjected to any harm.).
- Counseling (full disclosure/duty to warn).
- Avoid work conditions that impair professional judgment or compromise the best interests of the patient. (e.g., “no time to counsel patients”)

Ernest Mario School of Pharmacy
The Pharmacy Code of Ethics

V. A pharmacist maintains professional competence.

• *Integrity in all aspects of Continuing Professional Education.*

VI. A pharmacist respects the values and abilities of colleagues and other providers.

• *Knows when to refer a patient to another practitioner.*

• *Dealing with impaired colleagues (must offer help, but ultimately solve the problem in the interest of patients).*

• *Recognizing one’s own limitations.*
VII. A pharmacist serves individual, community, and societal needs.

- The patient comes first, but there are also other stakeholders: employers, the overall health care system, society.
- Prudent resource utilization.
- Participation in public policy decisions related to health care reform and global health.
VIII. A pharmacist seeks justice in the distribution of health care resources.

- **Distributive justice (fairness and reasonableness in the allocation of all resources).**
- **Scarce resources.**
- **Very expensive drugs (society, employers must also be considered in addition to the patient).**
- **Formulary decisions (must carefully consider all stakeholders).**
Coupon and Discount Programs

- Designed to lure patients from one pharmacy to another.
- Disruptive of the pharmacist-patient relationship.
- Increases probability of errors from the transfer of new Rxs multiple times.
- Prevents the establishment of a complete medication profile (duplicative therapy, Drug-Drug interactions).
- Programs such as $4 generics may be legal but are questionable ethically.

Ernest Mario School of Pharmacy
19-Minute Wait Times for Prescriptions

- “The 19-minute Promise” – Save Mart Supermarkets in California.
- Excessive pressure on pharmacists will increase probability of errors.
- Makes prescription just a commodity.
- Some Rx-related “problems” can’t be resolved in 19 minutes.
- Serious concerns from an ethical point of view.

Ernest Mario School of Pharmacy
“Free Antibiotics”

- Promotion advertised by many supermarket chains.
- Can lead to overuse and encourage development of antibiotic resistance, compromising the public health. Patients may tend to overuse the antibiotics, thinking that anything that is “free” must not be very potent.
- Patients will put greater pressure on physicians to prescribe antibiotics knowing that they are “free.” (Desire to get “something for nothing”)
- Implies that antibiotics are “quick fixes.”
- Destroys the pharmacist’s role in promoting more careful use of antibiotics.
- “Free antibiotics” will compromise the prescribing of the optimal antibiotic.
- Difficult to justify ethically.

Ernest Mario School of Pharmacy
Pharmacist Counseling and Pharmacist’s Duty to Warn

- Results of State Court Cases are inconsistent and vary by jurisdiction.
- Implications of the Code of Ethics: Duty to warn of serious side effects.
- Most courts have yet to rule that pharmacists have a duty to warn, but practice standards are changing.
- Pharmacists should not rely on inconsistent legal standards.
- OBRA-90 and Medicare Part D Regulations encourage counseling by the pharmacist.
- The potential for Pharmacist liability beyond accurate dispensing exists; the ethical obligation always exists.
- Deciding when the ethical obligation requires proactive counseling is a decision the pharmacist needs to make.
Proactively Counseling all Patients about **Driving**
when taking Rx-meds

- Opioids
- Benzodiazepines
- Drugs that may cause dizziness or fainting
  (especially among elderly patients - e.g., many antihypertensives)
- Hypnotics
- Tort liability against pharmacist is a possibility by injured third parties for failure to warn.
- Consider the ethical issues.
Tobacco Sales in Pharmacies

- Ethical issues
- “Chain pharmacy (professes to be) moving into the health care business.” (APhA, 2008). If so, sale of tobacco is very questionable ethically.
- Many Independent Pharmacies provided leadership by removing cigarettes in the past.
- Opinion of California pharmacists and adult Americans: Broad support for removal of tobacco products from pharmacies.
- Ban of tobacco sales in “drugstores” – Boston and San Francisco
- Unfair ruling in San Francisco, allowing supermarket and Big Box Pharmacies, e.g., Wal-Mart to sell tobacco products.

Ernest Mario School of Pharmacy
On-Line Pharmacies

- Ryan Haight Act – 2008:
  - Internet can be used to continue an existing provider-patient relationship, but not to create such a relationship.
- VIPPS (Verified Internet Pharmacy Practice Site) - NABP
  - VIPPS = 15; Out of Compliance = 79
  - 71 issue drugs without a valid Rx
  - 36 with address outside the U.S. (not subject to Ryan Haight Act).

Ernest Mario School of Pharmacy
Placebos

- Traditional definition of placebos: “sugar pills to fool the patient”
- Ethical consideration of the use of traditional placebos
- Extent of Physician use of “Placebos” – extensive based on “new definition”
- A new “definition” of Placebo – use of analgesics or similar drugs when there is no need
- Placebos in investigational drug studies (clinical trials)
Expensive Drugs and the Cost of Extending Life

- Examples of “expensive drugs”
  - Lapatinib (Tykerb)
  - Trastuzumab (Herceptin)
  - Cetuximab (Erbitux)
  - Lenalidomide (Revlimid)
- Ethical dilemmas – must consider effects on patient – effects of payer and health system.
- “4th Tier” – pay a % of cost of very expensive drugs
- Medicare Part D: Help patients to avoid the doughnut hole
- Increasing drug costs suggest that considering costs in treatment decisions does not violate professional ethics.
A Pharmacist’s Right of Refusal to Fill Prescriptions or Dispense Medications

- Emergency Contraception
- Assisted Suicide or Lethal Injection
- Palliative Sedation
- Fertility Drugs
- Oral Contraceptives

- December 2008 – President Bush’s Federal Rule – right of healthcare workers to refuse b/c religious or moral objections – being reversed by President Obama.
Professional Judgment in Dispensing Drugs

• Refusal for moral reasons presents a fundamental ethical dilemma complicated by State/Federal Laws and employer policies.

• N.J.A.C. 13:39-7.13 – Pharmacist shall have the right to refuse to fill a Rx if in h/h professional judgment: The Rx is outside the scope of practice...; sufficient reason to question the validity...; to protect health and welfare of the patient.

• N.J.S.A. 45:14-60 – pharmacist has right to change to different dosage form as long as prescriber is informed of the change.
Confidentiality of Prescription Information

- An ethical obligation
- Challenges in maintaining confidentiality may become greater because of electronic storage and transmission of patient specific information.
- Routine disclosure: between healthcare providers for treatment; patient gives written authorization; 3\textsuperscript{rd} party audits or State or Federal inspections.
- Rare exceptions: whenever one or more innocent victims could be seriously harmed.
- Antiretroviral prescriptions present ethical challenges. (Should unsuspecting sexual partners be informed?)

Ernest Mario School of Pharmacy
Pharmaceutical Industry Drug Marketing Issues

- Gifts to prescribers or formulary decisions makes are prohibited because they may compromise independent decision making.
- Meals – unless trivial – prohibited.
- CPE – must be completely free of any potential commercial influence in bias.
- Direct to Consumer Advertising – may result in patients putting excessive pressure on prescribers for inappropriate therapy.

Ernest Mario School of Pharmacy