Slide 1

**Ethics and Professionalism**

2015 NYSCHP Annual Assembly
April 24-26, 2015
Bruce D. White

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**Disclosure**

- None to disclose

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**Objectives**

- Define ethics and law and clarify differences and similarities between the two.
- Explain normative ethics and show how ethical and legal violations and consequences relate to one other.
- Use a normal distribution curve to highlight standards and ethical and legal boundaries.
- Illustrate normative ethics conceptually with examples of ethical-unethical and legal-illegal conduct.
Ethics and Law

• What does **ethics** mean?
• How are ethics and morality related?
• What does **law** mean?
  – “a rule of conduct established by custom, agreement, or authority”
  – “a binding custom or practice of a community: a rule of conduct or action prescribed or formally recognized as binding or enforced by a controlling authority”

Standards and Normative Ethics

• How are ethics and law related?
  – Standards?
  – Establish conduct minimums?
  – Created and enforced by some authority?
• Professional ethics? Codes of ethics?
• What does **normative ethics** mean?
• How does normative ethics relate to ethical and legal professional standards?

Normal Distribution Curve
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How many health care licensees are disciplined each year by the boards? Why?

• Pharmacy? NABP Clearinghouse received 4324 disciplinary action reports in 2011 (65% pharmacists [2810 cases]; 35% pharmacy technicians [1514 cases])
• Nursing?
• Medicine?

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Pharmacy Disciplinary Actions

• 173,000 pharmacists in 2011
• Recall difficulties with reporting, analyzing
• NABP reported disciplinary rate for 2011 ~1.6% (16.24 actions per 1000 licenses)

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Reason for Disciplinary Actions

<table>
<thead>
<tr>
<th>Reason</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alleged violation</td>
<td>19.5%</td>
</tr>
<tr>
<td>Default on health education loan or scholarship</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Failure to provide medically necessary or reasonable care or services</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Filing false records or falsifying records submitted through submission of a claim for reimbursement or payment</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Diversion of controlled substance</td>
<td>19.5%</td>
</tr>
<tr>
<td>Narcotics violation</td>
<td>10.4%</td>
</tr>
<tr>
<td>Violation of federal or state statute or regulation</td>
<td>9.6%</td>
</tr>
<tr>
<td>Substandard or inadequate care</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Unable to practice safely</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Unauthorized administration of medication</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Other</td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>
**Reason for Disciplinary Actions**

<table>
<thead>
<tr>
<th>Percent</th>
<th>Alleged Violation</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.2%</td>
<td>Error in prescribing, dispensing, or administering medicine</td>
</tr>
<tr>
<td>6.7%</td>
<td>Abuse of alcohol or other substance</td>
</tr>
<tr>
<td>5.1%</td>
<td>Criminal conviction</td>
</tr>
<tr>
<td>4.3%</td>
<td>Failure to comply with CE or competency requirements</td>
</tr>
<tr>
<td>3.7%</td>
<td>Final</td>
</tr>
<tr>
<td>3.7%</td>
<td>Disciplinary action taken by another federal, state or local licensing authority</td>
</tr>
<tr>
<td>2.5%</td>
<td>Violation of or failure to comply with licensing board order</td>
</tr>
<tr>
<td>2.4%</td>
<td>Unauthorized dispensing or prescribing of medication</td>
</tr>
<tr>
<td>2.4%</td>
<td>Practicing without a valid license</td>
</tr>
<tr>
<td>1.3%</td>
<td>Allowing or aiding unlicensed practice</td>
</tr>
</tbody>
</table>

**Board Sanctions Imposed**

<table>
<thead>
<tr>
<th>Percent</th>
<th>Sanction</th>
</tr>
</thead>
<tbody>
<tr>
<td>19.7%</td>
<td>Probation of license</td>
</tr>
<tr>
<td>14.8%</td>
<td>Administrative or publicly available fine or monetary penalty</td>
</tr>
<tr>
<td>14.8%</td>
<td>Revocation of license</td>
</tr>
<tr>
<td>12.5%</td>
<td>Suspension of license</td>
</tr>
<tr>
<td>11.0%</td>
<td>Voluntary surrender of license</td>
</tr>
<tr>
<td>10.7%</td>
<td>Voluntary surrender of license with conditions or limitations or restrictions of license</td>
</tr>
<tr>
<td>10.0%</td>
<td>Voluntary surrender of license with conditions or limitations or restrictions of license in conditional or restricted practice</td>
</tr>
<tr>
<td>9.0%</td>
<td>License restored or reinstated (complete and conditional)</td>
</tr>
<tr>
<td>9.0%</td>
<td>Reprimand or censure</td>
</tr>
<tr>
<td>3.0%</td>
<td>Summary or emergency suspension of license</td>
</tr>
</tbody>
</table>

**Normal Distribution Curve**
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What are we really talking about?

• “When Is a Pain Doctor a Drug Pusher?”
• “The Death of Heath Ledger”
• “Michael Jackson Death: Judge Refuses to Sequester Jury in Trial”
  – Los Angeles Times, August 25, 2011

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What are we really talking about?

ille Banner

Prescription mix-up kills 3-year-old girl

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What is an ethical dilemma?

• It may turn on the individual question: “Should I do this?” This is a question that implicates “normative ethics.”
• Normative ethics involves recognized (“cherished”) personal and societal values and principles expressed as accepted behavioral “norms.” Typically, values inform choices (decision making) and principles inform rules (standards setting).
What is an ethical dilemma? [continued]

- Common virtues include: honesty, truth-telling, fidelity, loyalty, confidentiality, and privacy.
- Commonly recognized principles in professional ethics include: autonomy (respect for persons), beneficence (attempting good), nonmaleficence (avoiding harm), and justice (being fair).

What is an ethical dilemma? [continued]

- Principles are implicated in normative ethics and ethical theories: (1) virtue ethics (Aristotle [Greek, 383-322 BCE] and St. Thomas Aquinas [Italian, 1225-1274]); (2) deontological [duty-based] ethics (Kant [German, 1724-1804]); and teleological [consequentialist, utilitarian] ethics (Bentham [English, 1748-1832]; Mill [English, 1806-1873]).

What is an ethical dilemma? [continued]

- The various ethical theories implicate: motive(s) and intent (emphasized in virtue theory); intent and act(s) (emphasized in value theory); and outcome(s) and consequence(s) (emphasized in action theory).
- Recall that once a decision is made and actions taken, outcomes are not always predictable.
What is an ethical dilemma? [continued]

• The various ethical theories implicate: motive(s) and intent (emphasized in virtue theory); intent and act(s) (emphasized in value theory); and outcome(s) and consequence(s) (emphasized in action theory).

• Recall that once a decision is made and actions taken, outcomes are not always predictable.
What is an ethical dilemma? [continued]

- Normative ethics also includes reflection about approaches to individual decision making (e.g., feminist ethics, pragmatic ethics, relativistic ethics, casuistry [case-based or paradigm case analysis], and narrative ethics).

- “All ethical dilemmas involve a clash of cherished values embodied in long-held principles. For any person in a dilemma it is difficulty to prioritize these cherished values, for example, telling the truth and saving lives, because they both seem to be highly prized and sometimes irreconcilable. Finding the right balance among these and other values is the heart of the moral life.” (Thomasma, 2003)
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So then, do these fact patterns present ethical dilemmas?

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“Abbott Settles Marketing Lawsuit”  
(Schmidt & Thomas, 2012)

- “Abbott [a highly regarded pharmaceutical manufacturer illegitimately marketed [Depakote] for schizophrenia and agitated dementia, even though it was approved only for treatment of seizure disorders, or mania associated with polar disorder … .”
- “The company trained its sales representatives to promote Depakote to nursing homes as a way to sedate patients without running afoul of a federal law intended to prevent overdose of certain medications.”

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Ethical Question (Schmidt & Thomas, 2012)

To what extent should drug manufacturers systematically expand their markets to unapproved uses when there is doubtful benefit to patients?
“Diabetes Drug Maker Hid Test Data, Files Indicate” (Harris, 2010)

• “Not only was Avandia [a SmithKline Beecham diabetes drug] no better than Actos [a Takedas Pharmaceuticals diabetes drug competitor], but the study provided clear signs that it was risker to the heart. But instead of publishing the results, the company spent the next 11 years trying to cover them up … .”

Ethical Question (Harris, 2010)

At what point should pharmacists and drug companies be more open and transparent about emerging risks and side effects that patients might encounter while taking their products?

“Approval for Drug That Treats Melanoma” (Pollack, 2011)

• “The first drug shown to prolong the lives of people with the skin cancer melanoma won approval from the Food and Drugs [sic, Drug] Administration … .”

• “In [a] randomized clinical trial, patients with metastatic melanoma treated with Yervoy lived a median of about 10 months, compared with 6.4 months for patients in a control group … .”

• “Bristol-Myers [the manufacturer] said it would charge $120,000 for a complete course of treatment, which consists of four infusions over a three-month period.”
Ethical Question (Pollack, 2011)
Should very expensive drugs be offered to individual patients when the benefits are marginal? If so, who should bear the expense?

U.S. Scrambling to Ease Shortage of Vital Medicine” (Harris, 2011)
• “Federal officials and lawmakers, along with the drug industry and doctors’ groups, are rushing to find remedies for critical shortages of drugs to treat a number of life-threatening diseases, including bacterial infection and several forms of cancer.”
• “So far this year [2011], at least 180 drugs that are crucial for treating childhood leukemia, breast and colon cancer, infections and other diseases have been declared in short supply – a record number.”
• “Heather Bresch, president of the generic drug giant Mylan, says the shortages grow out of a sweeping consolidation of the generic drug industry into a few behemoths that compete only on price and have foreign plants that are rarely inspected.”

Ethical Question (Harris, 2011)
Are pharmaceutical companies obligated to manufacture some drugs – particularly life-saving drugs or generic drugs that are widely used – when there is no reasonable expectation to recover even operating margin or make a modest profit?
“Better Drug Ads, Fewer Side Effects” (Spatz, 2011)

- The evidence on the public benefits of broadcast direct-to-consumer drug advertising is mixed. Employers who pay the health insurance bills complain that the ads drive up unnecessary use of medical care and steer patients to expensive brand names and away from generics. Doctors report feeling pressured to prescribe the most heavily advertised products. The drug industry and allies among patient organizations point out that, for many chronic conditions, the real issue is underuse of effective medicines and that generic drug use is at its highest levels ever.

Ethical Question (Spatz, 2011)

Should drug manufacturers be permitted to market prescription only medicines directly to consumers, arguably artificially driving demand and increasing the likelihood of inappropriate use?

“New Law Bans Mail-Order Drug Mandates” (Hartocollis, 2011)

- The bill barred insurers or employers from forcing patients to use mail-order plans for prescription drugs, except for plans negotiated by unions. Instead, consumers would be guaranteed the choice of having their prescriptions filled either through mail-order or at the local drugstore, without any added copayments or fees.
- A spokesman for Express Scripts, a large mail-order drug supplier, said that mail-order delivery to people’s homes of drugs for chronic illnesses was still the cheapest option with the least potential for error, and that to the extent that that has been diminished, “drug costs will go up.”
Ethical Question (Hartocollis, 2011)
Should insured patients have the option of purchasing chronic disease medicines at a local or neighborhood pharmacy rather than through mail order pharmacies — which usually costs less with fewer dispensing errors — without incurring any added expense or paying a premium?

“Medical Examiner Rules [Heath] Ledger’s Death Accidental” (Barron, 2008)
• “The actor Heath Ledger died accidentally ‘from the abuse of prescription medications’ — specifically, six kinds of painkillers, sleeping pills and anti-anxiety drugs — a spokesperson for the New York City medical examiner said ….”

Ethical Question (Barron, 2008)
Are physicians prescribing too many pain medications, or too few? Correspondingly, are pharmacists failing to appropriately monitor patient pain killer use?
“Ohio County Losing Its Young to Painkiller’s Grip” (Tavernise, 2011)

• “In Ohio, fatal overdoses more than quadrupled in the last decade, and by 2007 had surpassed car crashes as the leading cause of accidental death, according to the [state’s] Department of Health.”

• “We’re raising third and fourth generations of prescription drug abusers now,” said Chief Charles Horner of the Portsmouth police, who often notes that more people died from overdoses in Ohio in 2008 and 2009 than in the World Trade Center attack in 2001.”

Ethical Question (Tavernise, 2011)
Are physicians prescribing too many pain medications, or too few? Correspondingly, are pharmacists failing to appropriately monitor patient pain killer use?

“Florida Shutting ‘Pill Mill’ Clinics” (Alvarez, 2011)

• “Florida has long been the nation’s center of the illegal sale of prescription drugs: Doctors here bought 80 percent of all the oxycodone sold in the country last year. At its peak, so many out-of-state patients flocked to Florida to buy drugs at more than 1000 pain clinics that the state earned the nickname ‘Oxy Express.’”

• “With the help of tougher laws, officials have moved aggressively this year to shut down so-called pill mills and disrupt the pipeline that moves drugs north. In [2010], more than 400 clinics were either shut down or closed their doors.”

• “Prosecutors have indicted dozens of pill mill operators, and nearly 80 doctors have seen their licenses suspended for prescribing mass quantities of pills without clear medical need.”
Ethical Question (Alvaraz, 2011)

Are physicians prescribing too many pain medications, or too few? Correspondingly, are pharmacists failing to appropriately monitor patient pain killer use?

Ethical Question (Thomas, 2009)

“Polo Ponies Were Given Incorrect Medication” (Thomas, 2009)

- “A Florida pharmacy acknowledged Thursday that it had incorrectly mixed a medication given to the 21 polo horses that died [April 19, 2009] at the United States Open Polo Championship....”
- “The incident is likely to renew questions about the safety of compound [sic, compounding] pharmacies, which are sometimes used by veterinarians to mix hard-to-find drugs.”

Ethical Question (Thomas, 2009)

Is pharmacist malpractice – by definition, action involving a pharmacist who allegedly failed to meet the established standard of care – inherently unethical?
“Nursing Home Investigation Finds Errors by Druggists” (Udesky, 2012)

Pharmacists responsible for reviewing the medication of patients in California nursing homes routinely allowed inappropriate and potentially lethal prescriptions of antipsychotic medications, and failed to correct other potentially dangerous drug irregularities, according to recent state investigations.

A 1982 anti-kickback law requires nursing homes to pay a fair rate for pharmacy services to discourage consulting pharmacists from endorsing or extending the prescriptions of expensive, and potentially dangerous, drugs. A majority of the nursing homes where the state found patients who were inappropriately prescribed antipsychotic medications were paying below average fees for pharmacy services.

Ethical Question (Udesky, 2012)

Is pharmacist malpractice – by definition, action involving a pharmacist who allegedly failed to meet the established standard of care – inherently unethical?

“Ex-pharmacist gets 51 months for Medicaid Fraud” (2011)

• "[The pharmacist] submitted claims [for over $3.5 million from 2006-2010] to the Indiana Medicaid Program for prescriptions that were never given to patients."
Ethical Question (Ex-pharmacist, 2011)

How should regulators (and society) deal with pharmacists who engage in unprofessional and unethical behavior?

“Complaint: Pharmacist refuses to fill prescription about abortion concern” (Gupta, 2011)

- "A new Idaho law enacted in 2010 is designed to protect medical professionals by allowing them to refuse health care services that conflict with their religious, moral, or ethical principles."
- "The prescription at the center of this case is methergine. It’s used to prevent bleeding after childbirth or an abortion."
- "According to Planned Parenthood, the Walgreens pharmacist asked if their patient had an abortion. The nurse says she cited federal patient privacy laws and refused to answer."
- "The pharmacist said, ‘Well, if you’re not going to tell me that and she had an abortion. I’m not going to fill this prescription.’"
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“The Immunizing Pharmacist”
(Mienkovich, 2011)

• “Pharmacists have, by now, overcome most legal obstacles to the right to immunize patients and have overwhelmingly demonstrated their value by increasing patient immunization rates. As the most accessible healthcare professionals, pharmacists are poised to provide immunizations to millions of people who visit pharmacists each week.”

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Ethical Question (Mienkovich, 2011)

Since the benefit appears to be so great as compared to risk, should all pharmacists be trained to give immunizations to adults and children?

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“Administering Emergency Prescription Drugs: Legal Implications and Policy Considerations” (Mock, 2004)

• “[S]tate laws often prohibit a non-licensed professional from dispensing … medication. If a camper experiences an emergency in the wilderness or in a remote location without access to professional medical help, a counselor may be the only person in a position to render critical assistance.”

• “[I]f a counselor makes an independent determination that a camper needs an emergency prescription drug and administers that drug, he could be technically violating the law.”
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**Ethical Questions (Mock, 2004)**

How might pharmacists expand their scope of practice appropriately, ethically?

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**Normative Behaviors “Curve” or Ethics Continuum**

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**Normative Ethics Curve Areas**

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<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Yes</td>
<td>Yes</td>
<td>Neutral</td>
<td>Optimal</td>
<td>Best</td>
</tr>
<tr>
<td>B</td>
<td>Yes</td>
<td>Yes</td>
<td>Less</td>
<td>Appropriate</td>
<td>Better</td>
</tr>
<tr>
<td>C</td>
<td>Yes</td>
<td>Yes</td>
<td>More</td>
<td>Inappropriate</td>
<td>Worse</td>
</tr>
<tr>
<td>D</td>
<td>Yes</td>
<td>Yes</td>
<td>More</td>
<td>Borderline</td>
<td>Better</td>
</tr>
<tr>
<td>E</td>
<td>Yes</td>
<td>Yes</td>
<td>Less</td>
<td>Inappropriate</td>
<td>Worse</td>
</tr>
<tr>
<td>F</td>
<td>Maybe</td>
<td>Yes</td>
<td>More</td>
<td>Inappropriate</td>
<td>Worse</td>
</tr>
<tr>
<td>G</td>
<td>Yes</td>
<td>No</td>
<td>More</td>
<td>Inappropriate</td>
<td>Worse</td>
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<tr>
<td>H</td>
<td>No</td>
<td>No</td>
<td>Less</td>
<td>Inappropriate</td>
<td>Worse</td>
</tr>
<tr>
<td>I</td>
<td>No</td>
<td>No</td>
<td>More</td>
<td>Inappropriate</td>
<td>Worse</td>
</tr>
<tr>
<td>J</td>
<td>No</td>
<td>No</td>
<td>More</td>
<td>Inappropriate</td>
<td>Worse</td>
</tr>
</tbody>
</table>
Slide 61

Cases and Examples

<table>
<thead>
<tr>
<th>Area</th>
<th>Case or Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Providing immunizations to patients</td>
</tr>
<tr>
<td>B</td>
<td>Providing typical pharmaceutical care services, meeting the standard of care</td>
</tr>
<tr>
<td>C</td>
<td>Providing a drug to a patient when the benefit is marginal</td>
</tr>
<tr>
<td>D</td>
<td>Failing to provide a drug when there is little or no profit</td>
</tr>
<tr>
<td>E</td>
<td>Pharmacy malpractice, eg, offering inferior pharmacy consultation services</td>
</tr>
<tr>
<td>F</td>
<td>Pharmacy malpractice, eg, dispensing prescription medicines erroneously</td>
</tr>
<tr>
<td>G</td>
<td>Dispensing a prescription medicine in an emergency</td>
</tr>
<tr>
<td>H</td>
<td>Clearly criminal, eg, providing controlled substances improperly</td>
</tr>
<tr>
<td>I</td>
<td>Risking serious injury, eg, conscientiously refusing to fill a prescription</td>
</tr>
<tr>
<td>J</td>
<td>Clearly criminal, eg, billing for services not provided</td>
</tr>
</tbody>
</table>

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Criminal Conduct

- Prescribing controlled substances illegally
  - Registered as a practitioner
  - For a "legitimate medical purpose"
  - In the "usual course of professional practice"
  - Pharmacist's "corresponding responsibility"
- Fraud, waste, and abuse
  - Billing for services not rendered
  - Providing unnecessary services

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“Actionable Error” and Law

<table>
<thead>
<tr>
<th>Unactionable Error</th>
<th>Actionable Error</th>
<th>Intentional Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional Error</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Administrative)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unintentional</td>
<td>Unintentional</td>
<td>Intentional</td>
</tr>
<tr>
<td>Subjects to</td>
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<td></td>
</tr>
<tr>
<td>public prosecution</td>
<td>public prosecution</td>
<td></td>
</tr>
<tr>
<td>Nominal ortechnical</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Injury</td>
<td>Usually excess injury</td>
<td>Intentional injury</td>
</tr>
<tr>
<td>General and special compensation damages</td>
<td>Conspiring damages and punitive damages</td>
<td>Intentional damages</td>
</tr>
<tr>
<td>Evidence standard of care and clear and convincing</td>
<td>Evidence standard of care and clear and convincing</td>
<td>Evidence standard of care and clear and convincing</td>
</tr>
<tr>
<td>Evidence standard of care and clear and convincing</td>
<td>Evidence standard of care and clear and convincing</td>
<td>Evidence standard of care and clear and convincing</td>
</tr>
</tbody>
</table>
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Personal or professional Lapses?
- Lying on applications?
- Cheating on examinations?
- Having inappropriate relations with patients? With staff?
- Failing to recognize boundaries?
- Inappropriate behaviors?
- Failing to meet professional obligations?

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Virtues
- Honesty
- Truth-Telling
- Fidelity
- Loyalty
- Confidentiality
- Privacy

Act(s)

Consequence(s)

Outcome(s)

Motive(s)

Virtues
- Honesty
- Truth-Telling
- Fidelity
- Loyalty
- Confidentiality
- Privacy

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Motive(s) ("self-actualization")
("Why do that?")

**Intrinsic**
- Self-esteem (self-regard, self-respect, self-regard, self-integrity)

**Extrinsic**
- Peer recognition, prestige, and honor (pride)
- Money
- Revenge and justice
- Altruism ("Is pure altruism possible?")
How do we deal with plagiarism?


Fundamental Review of the Pharmaceutical Society of Great Britain's Code of Ethics

- Make the care of patients your first concern.
- Exercise your professional judgment in the interests of patients and the public.
- Show respect for people.
- Encourage patients to participate in decisions about their care.

Fundamental Review of the Pharmaceutical Society of Great Britain's Code of Ethics [continued]

- Develop your professional knowledge and competence.
- Be honest and trustworthy.
- Take responsibility for your working practices.

Objectives

• Define ethics and law and clarify differences and similarities between the two.
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