

Pharmacy Ethics: A Case-Based Introduction

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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.

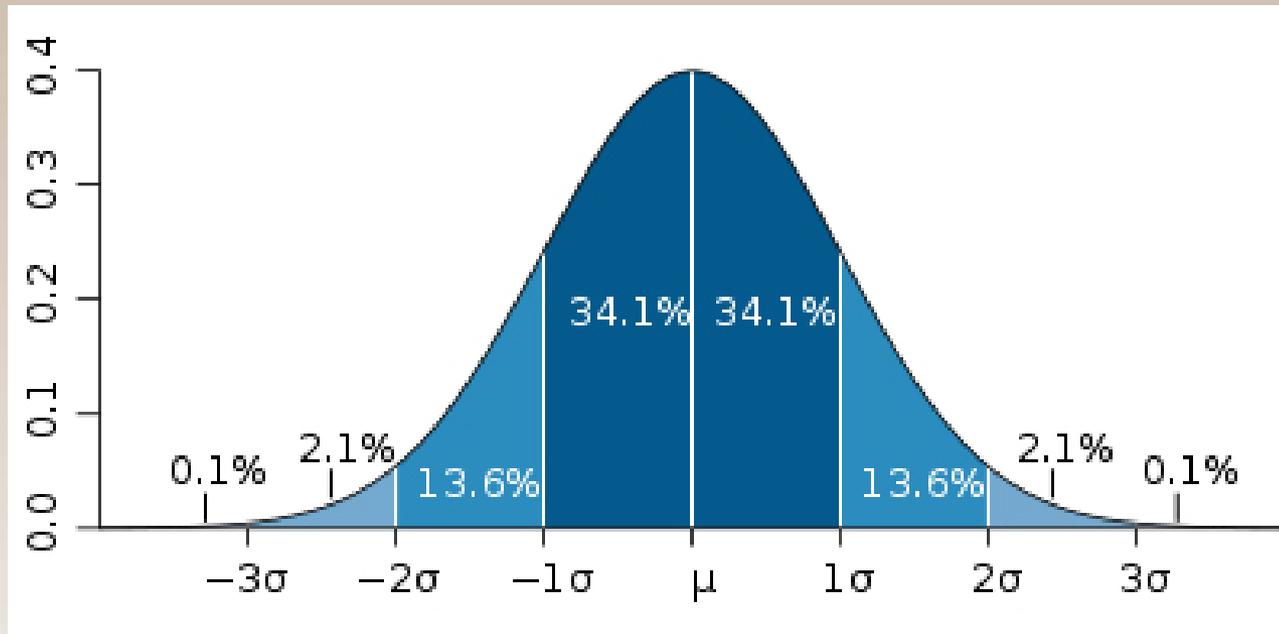
Ethics and Law

- 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



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?

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)
- 1986-88 disciplinary rate range: 1.49 actions/1000 to 45.61 actions/1000. See <http://oig.hhs.gov/oei/reports/oai-01-89-89020.pdf> (accessed 07-16-12).

Reason for Disciplinary Actions

Percent	Alleged violation
19.5%	Uncategorized (<1% each): Default on health education loan or scholarship obligations; failure to obtain informed consent; failure to provide medically reasonable or necessary items or services; filing false records or falsifying records; immediate threat to health or safety; improper or inadequate supervision or delegation; malpractice; misleading, false, or deceptive advertising or marketing; negligence; nolo contendere plea; other - not classified; practicing beyond the scope of practice; submitting false claims; substandard or inadequate care; unable to practice safely; unauthorized administration of medication
19.5%	Violation of federal or state statute or regulation
10.4%	Diversion of controlled substance

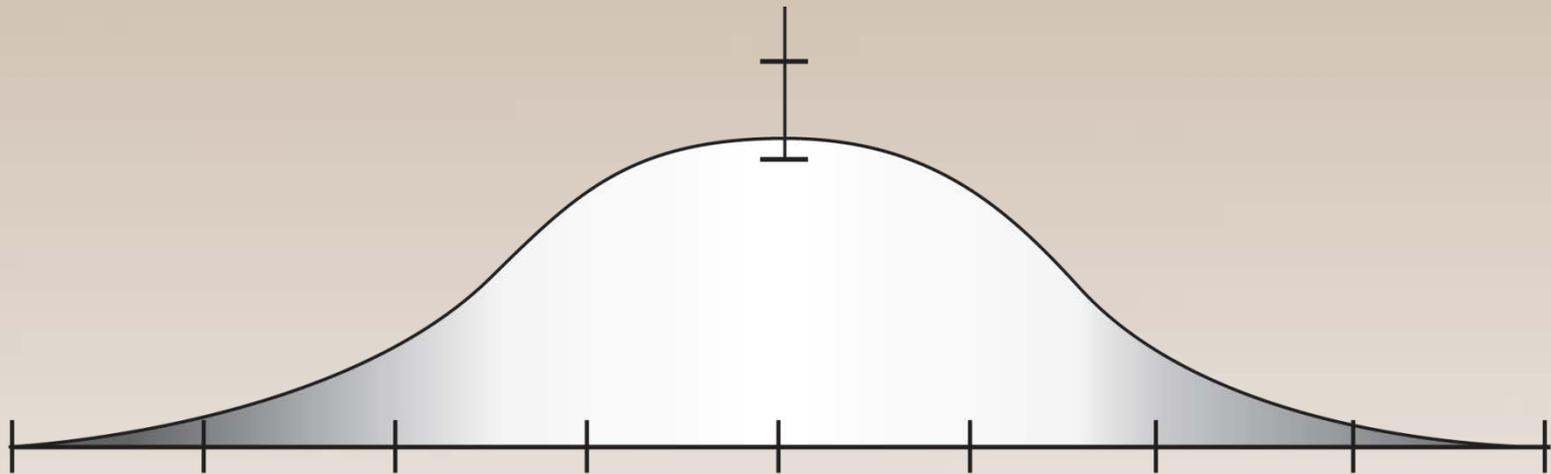
Reason for Disciplinary Actions

Percent	Alleged violation
7.2%	Error in prescribing, dispensing, or administering medicine
6.7%	Abuse of alcohol or other substance
5.1%	Criminal conviction
4.3%	Failure to comply with CE or competency requirements
3.7%	Fraud
3.7%	Disciplinary action taken by another federal, state or local licensing authority (license revocation, suspension, or other action)
3.4%	Violation of or failure to comply with licensing board order
2.5%	Unauthorized dispensing or prescribing of medication
2.4%	Practicing without a valid license
1.3%	Allowing or aiding unlicensed practice

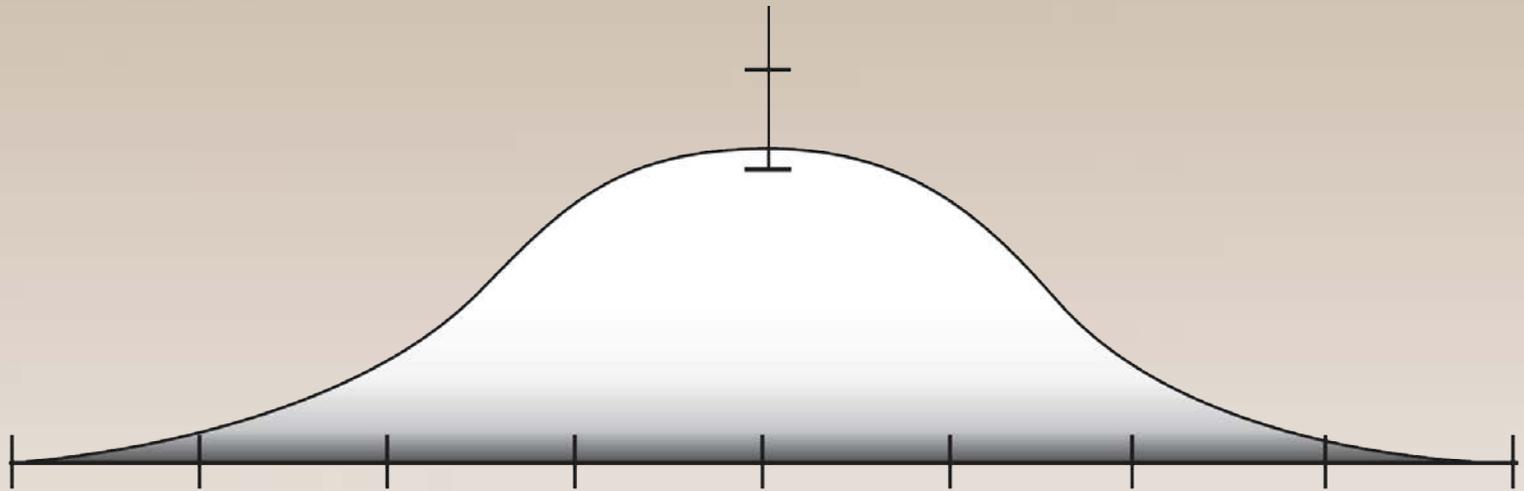
Board Sanctions Imposed

Percent	Sanction
19.7%	Probation of license
14.8%	Administrative or publicly available fine or monetary penalty
12.5%	Revocation of license
11.0%	Suspension of license
10.7%	Voluntary surrender of license
10.0%	Unclassified sanction (<3%): denial of initial license; denial of license renewal; extension of previous action; licensure restoration or reinstatement denied; limitation or restriction of license; other licensure action - not classified; reduction of previous action
9.2%	License restored or reinstated (complete and conditional)
9.0%	Reprimand or censure
3.0%	Summary or emergency suspension of license

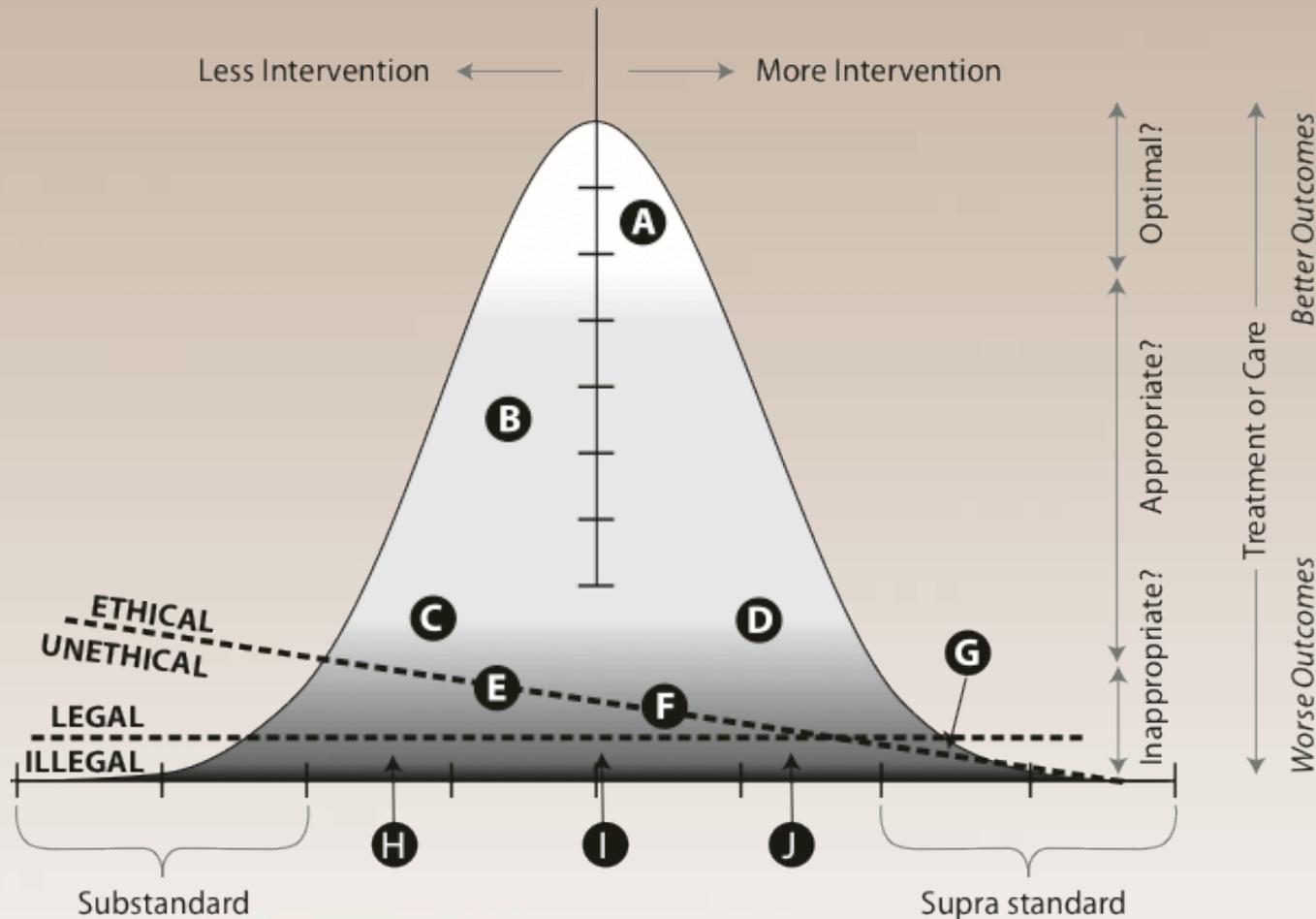
Normal Distribution Curve



Normal Distribution Curve



Normative Behaviors “Curve” or Ethics Continuum



What are we really talking about?



What are we really talking about?

- “When Is a Pain Doctor a Drug Pusher?”
 - New York Times Magazine, June 17, 2007
- “The Death of Heath Ledger”
 - New York Times, January 22, 2008
- “Michael Jackson Death: Judge Refuses to Sequester Jury in Trial”
 - Los Angeles Times, August 25, 2011

What are we really talking about?



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]

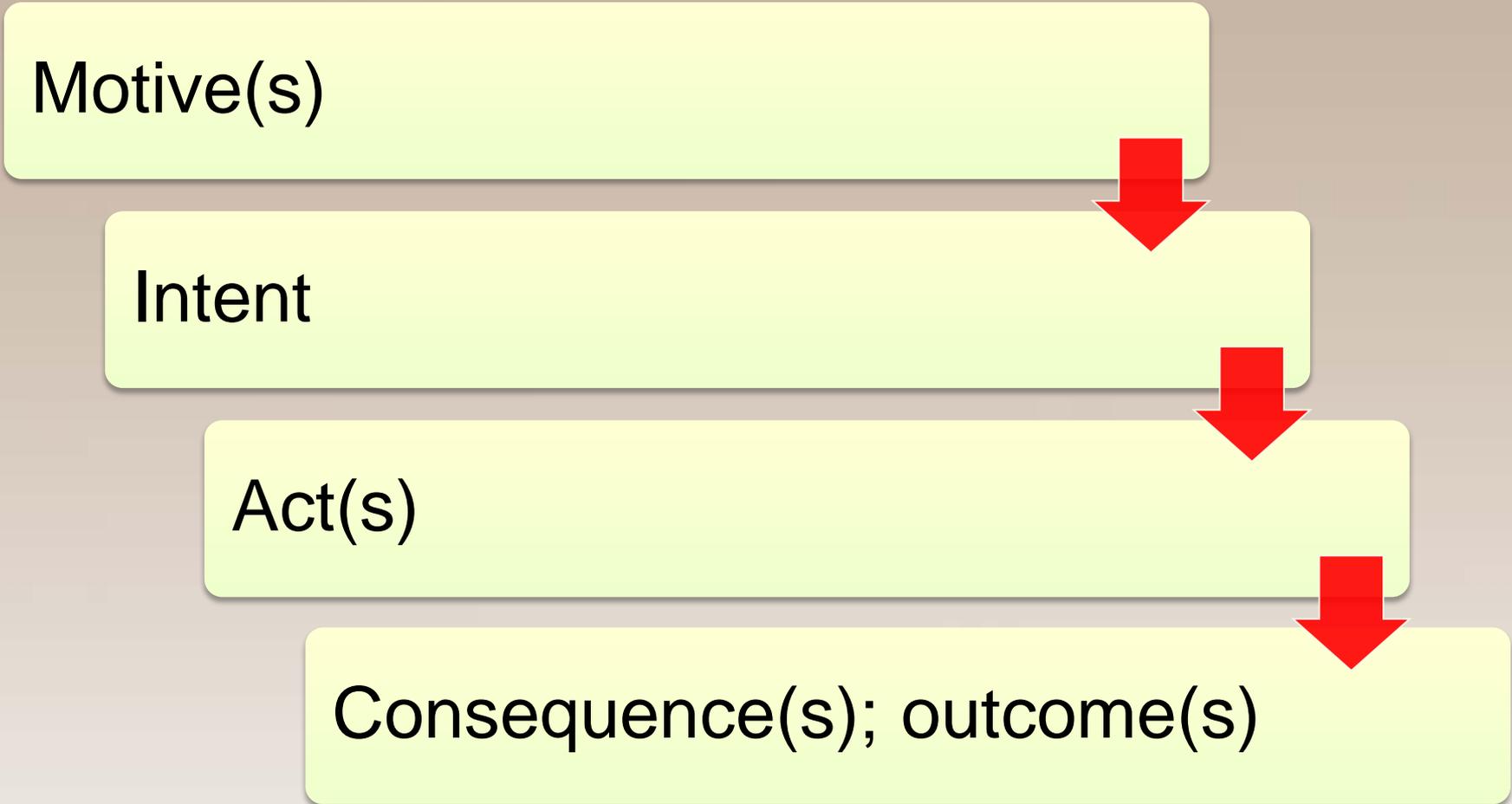
- Principles are implicated in normative ethics and ethical theories: (1) virtue ethics (Aristotle [Greek, 383-322 BC]) and St. Thomas Aquinas [Italian, 1225-1274]); (2) deontological [duty-based] ethics (Kant [German, 1724-1804]); and teleological [consequentialist, utilitarian] ethics (Bentham [English,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

Motive(s)

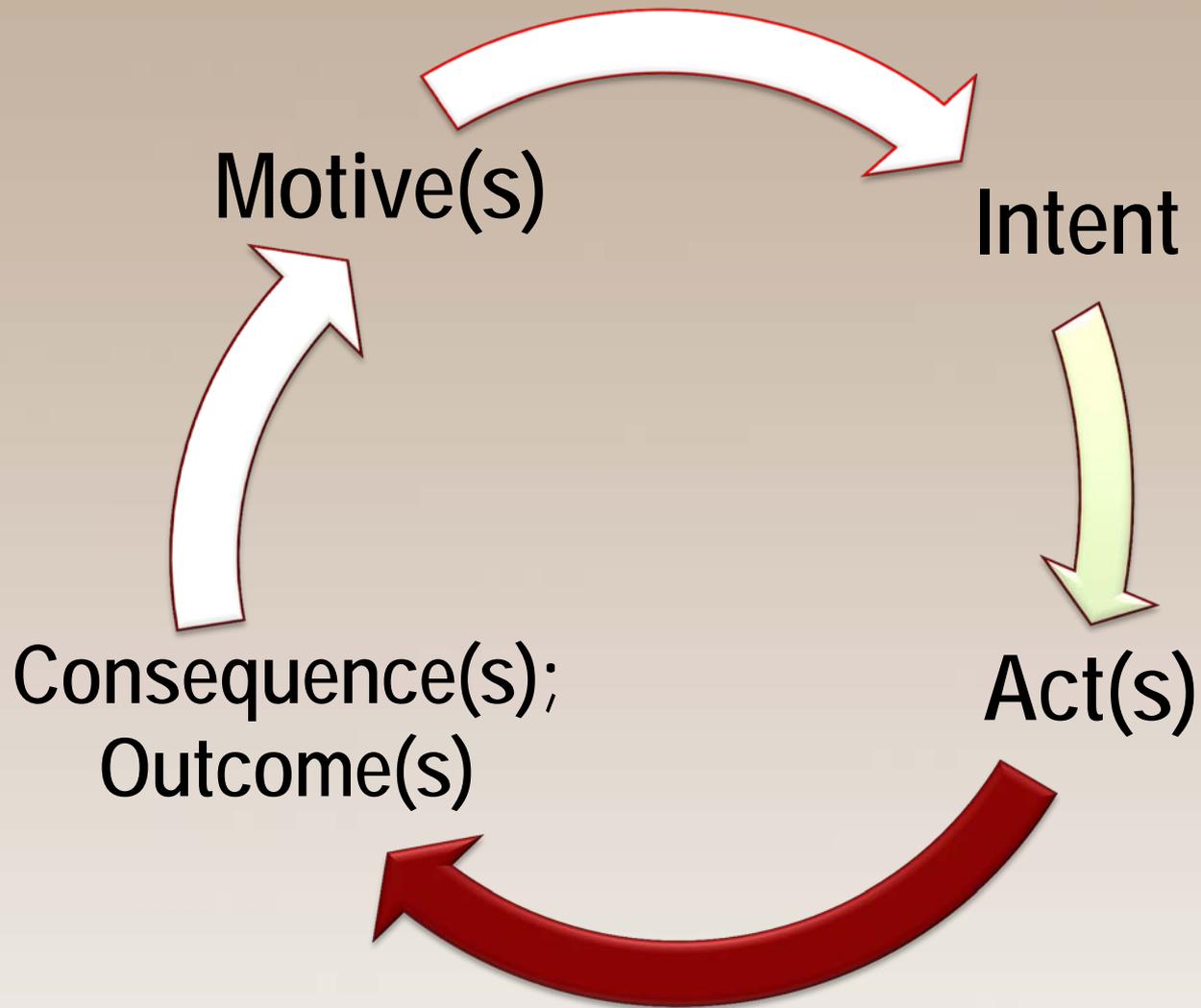


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graph TD; A[Motive(s)] --> B[Intent]; B --> C[Act(s)]; C --> D[Consequence(s); outcome(s)];
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Intent

Act(s)

Consequence(s); outcome(s)



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 reaction?



What is an ethical dilemma? [continued]

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

What is an ethical dilemma?

[continued]

- “[A]ll ethical dilemmas involve a clash of cherished values embodied in long-held principles. For any person in a dilemma it is difficult 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)

So then, do these fact patterns present ethical dilemmas?

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

- “Abbott [a highly regarded pharmaceutical manufacturer] illegally 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.”

J

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?

J

“Diabetes Drug Maker Hid Test Data, Files Indicate” (Harris, 2010)

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

J

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?

J

“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.”

D

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?

D

“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 illnesses, 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.”

C

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?

C

“Better Drug Ads, Fewer Side Effects” (Spatz, 2011)

- “[T]he 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.”

D

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?

D

“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.’”

D

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?

D

“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”

F, J

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?

F, J

“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.”

F, J

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?

F, J

“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 89 percent of all the [o]xycodone sold in the country last year. At its peak, so many out-of-staters 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.”

F, J

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?

F, J

“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.”

F

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?

F

“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.”

E

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?

E

“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.”

H

Ethical Question (Ex-pharmacist, 2011)

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

H

“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.’”

Ethical Question (Gupta, 2011)

May pharmacists refuse to dispense some prescriptions because to do so would violate their consciences?

“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.”

A

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?

A

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

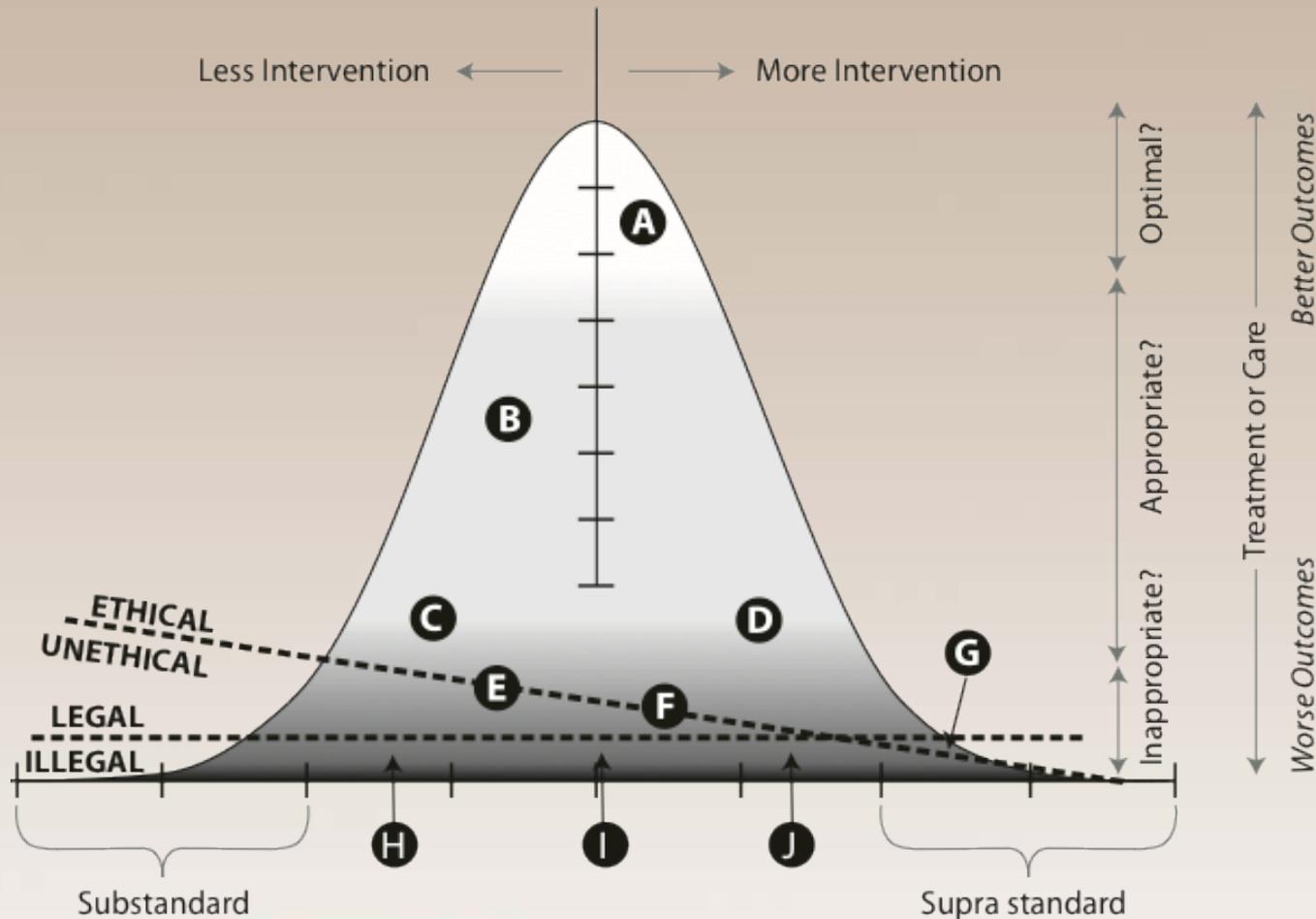
- “[S]tate laws often prohibit a non-licensed professional from dispensing ... medication. If a camper experiences [an] emergency in the wilderness or in a remote location without access to professional medical help, a counselor may be the only person in a position to render critical assistance.”
- “[I]f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

Ethical Questions (Mock, 2004)

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

G

Normative Behaviors “Curve” or Ethics Continuum



Normative Ethics Curve Areas

Area	Ethical?	Legal?	Intervention?	Care?	Outcomes?
A	Yes	Yes	Neutral	Optimal	Best
B	Yes	Yes	Less or More	Appropriate	Better
C	Yes	Yes	Less	Borderline	Better
D	Yes	Yes	More	Borderline	Better
E	Maybe	Yes	Less	Inappropriate	Worse
F	Maybe	Yes	More	Inappropriate	Worse
G	Yes	No	More	Debatable	Better
H	No	No	Less	Inappropriate	Worst
I	No	No	Neutral	Inappropriate	Worst
J	No	No	More	Inappropriate	Worst

Cases and Examples

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

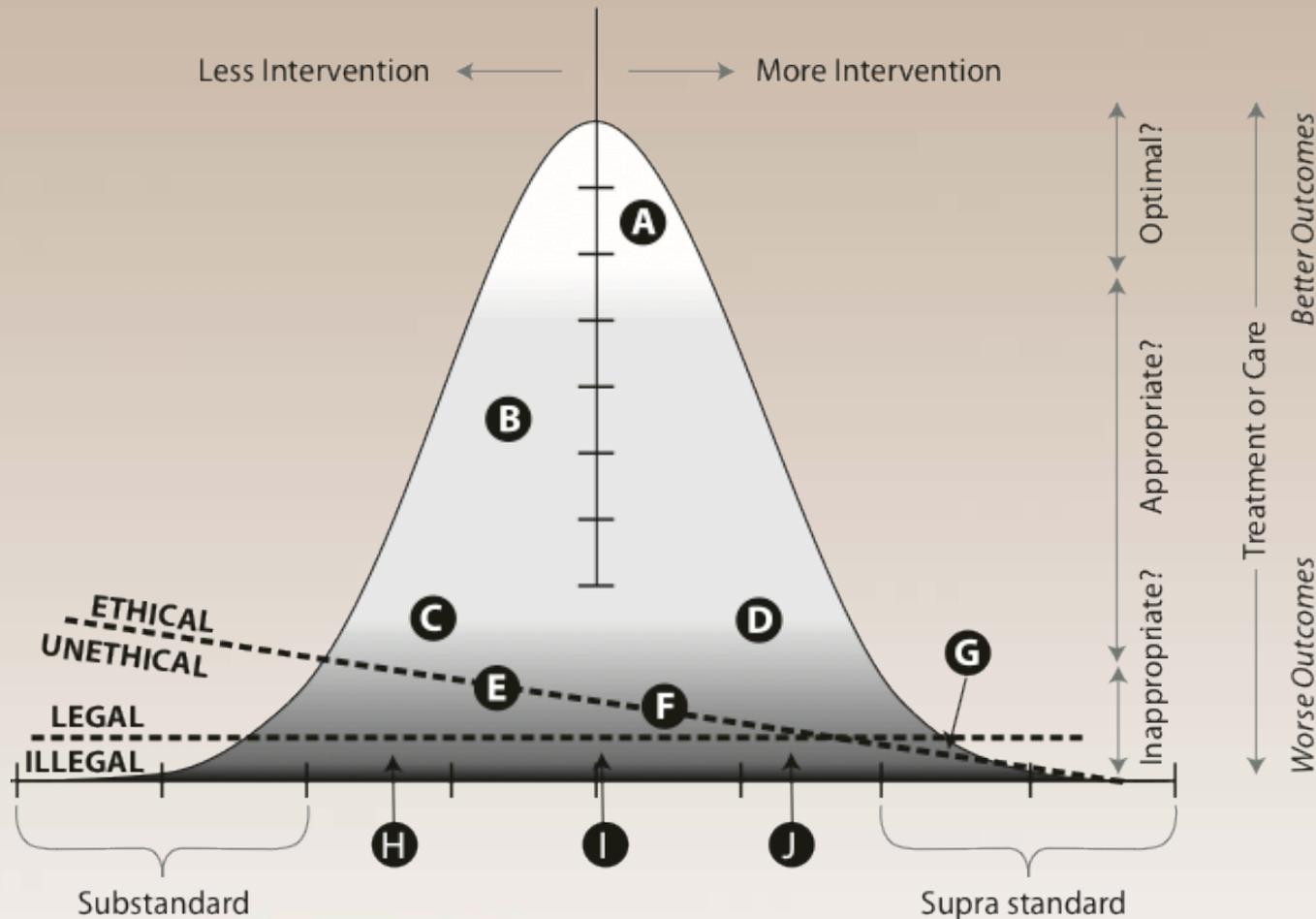
Criminal Conduct

- 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

"Actionable Error" and Law

Unactionable Error	Actionable Error		
Professional Error (Administrative)	Ordinary Negligence (Civil)	Gross Negligence (Civil)	Intentional Error (Criminal)
Unintentional	Unintentional	Unintentional	Intentional
Fails to meet standard of care	Fails to meet standard of care	Clearly violates standard of care	Clearly violates a standard of care
Subject to regulatory oversight; usually public prosecution	Private prosecution	Private prosecution	Public prosecution
Nominal or technical injury	Injury	Usually severe injury	Intentional injury
Nominal damages	General and special compensatory damages	Compensatory damages and punitive damages	Intentional damage
Evidence standard: preponderance or clear and convincing	Evidence standard: preponderance	Evidence standard: preponderance	Evidence standard: beyond a reasonable doubt

Normative Behaviors “Curve” or Ethics Continuum



How do we deal with malpractice?



The image shows a newspaper clipping from the Nashville Banner. The masthead at the top reads "Nashville Banner" in large blue letters. Below it, on the left, is the text "48 pages, 6 sections" and on the right, "TODAY'S NEWS TODAY". The main headline is "Prescription mix-up kills 3-year-old girl" in large, bold black font. Below the headline is the sub-headline "Doctor: VUMC pharmacy confused cancer drugs". The byline reads "By Bill Snyder, Banner Senior Medical Writer". The article text describes a 3-year-old girl who died from complications after receiving an overdose of chemotherapy. It quotes Dr. John N. Lukens, director of pediatric oncology at the medical center, stating that the girl was given the wrong anti-cancer medicine because of an error in the hospital pharmacy. The article also mentions that the girl was being treated for a recurrence of a rhabdomyosarcoma and that the pharmacy had mixed up the drugs. The article concludes with a note to see page A-2 for more details.

Nashville Banner

48 pages, 6 sections TODAY'S NEWS TODAY

Prescription mix-up kills 3-year-old girl

Doctor: VUMC pharmacy confused cancer drugs

By Bill Snyder
Banner Senior Medical Writer

A 3-year-old Mississippi girl who was being treated for cancer at Vanderbilt University Medical Center has died from complications after apparently being given an overdose of chemotherapy, one of her doctors says.

"This was absolutely devastating to everybody," says Dr. John N. Lukens, director of pediatric oncology at the medical center of the Saturday death.

Steps are being taken "so nothing like this will happen again," Lukens says.

The girl, whose name was not released by the medical center to protect her family's privacy, was being treated for a recurrence of a rhabdomyosarcoma, an aggressive tumor in the back of her nasal cavity and mouth.

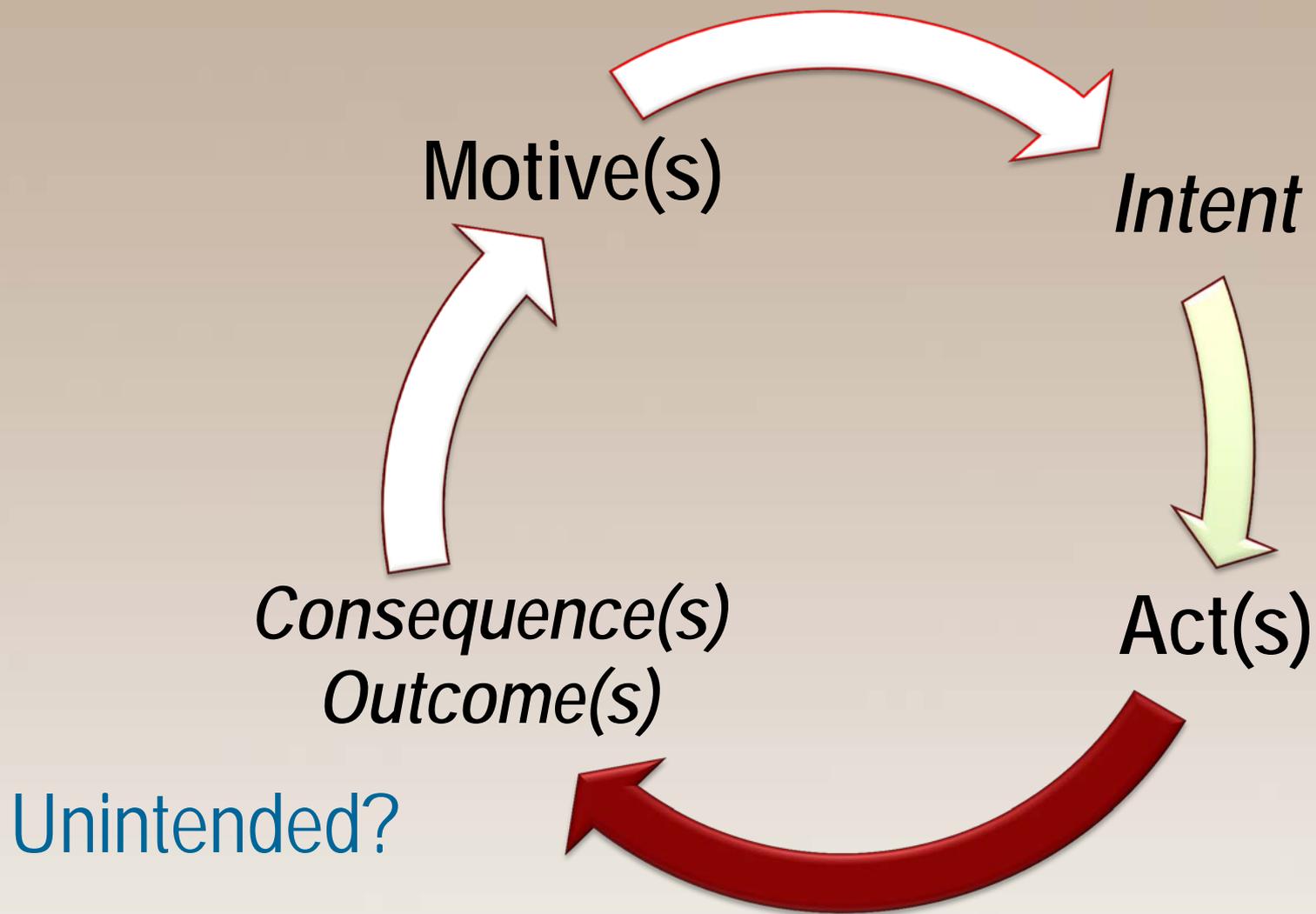
Although she was receiving three anti-cancer drugs and was responding to treatment, she had less than a 20 percent chance of being cured, Lukens says.

On the night of July 8 or early July 9, after being admitted to Vanderbilt for a second course of chemotherapy, she was given the wrong anti-cancer medicine because of an error in the hospital pharmacy, he says.

She had been prescribed carboplatin but "the pharmacist pulled cisplatin off the shelf," mixed a higher than usual dose of the drug and put it in a bag labeled carboplatin, Lukens says.

Hospital staff "felt they had been given the drug that had been ordered," he says.

Please see OVERDOSE, page A-2



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?

Virtues

Honesty

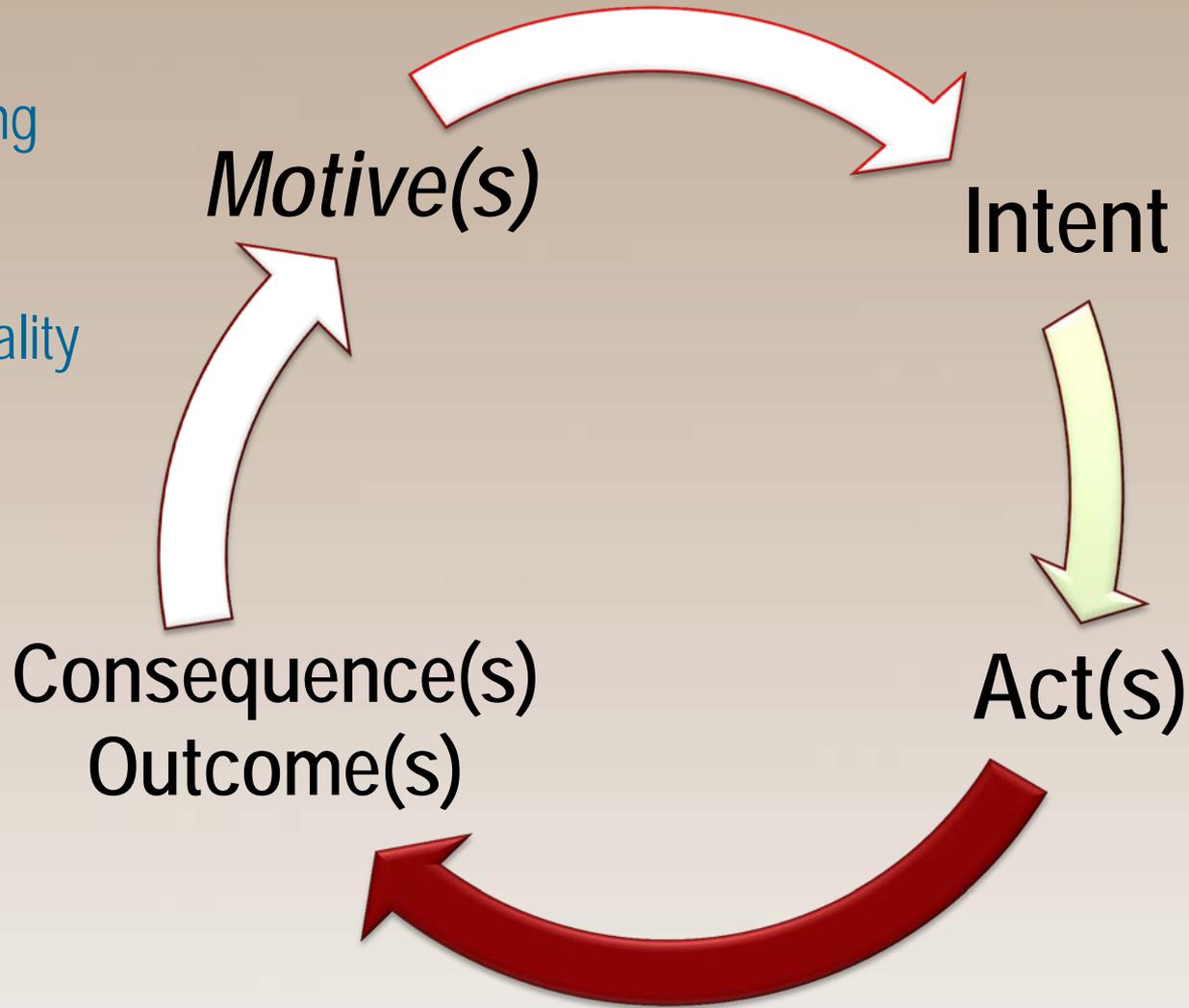
Truth-Telling

Fidelity

Loyalty

Confidentiality

Privacy



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?

- Bellack JP. Emotional intelligence: a missing ingredient? J Nurs Educ. 1999;38:3-4.
- Latif DA. Emotional intelligence: is it a missing ingredient in pharmacy education? [Viewpoint]. Amer J Pharm Educ. 2004;68(2):Article 56.
- Latif DA. Retraction: “Emotional intelligence: is it a missing ingredient in pharmacy education?” [Letters]. Amer J Pharm Educ. 2004;68(4):Article 106.

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.

– Wingfield J, Badcott D. *Pharmacy Ethics and Decision Making*. London: Pharmaceutical Press, 2007.

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.

Questions? Comments?

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