Pharmacy Ethics

BD White, Albany Medical College, Albany, NY, USA

© 2014 Elsevier Inc. All rights reserved.

Introduction

Ethics is not simply about making right rather than wrong decisions, or about right versus wrong actions or conduct. Ethics is the study of trying to make life better; it involves analyzing the decisions that individuals and groups make in hopes of effecting better decisions rather than worse ones and reaching better outcomes rather than less satisfactory ones (Ingram and Parks, 2002: 5–6). Ethics analysis includes an examination of the values individuals and groups hold as more important than others within the context of a specific situation and at an identified time and place (Ashcroft et al., 2005: 1–6).

Ethics is a subfield of philosophy. Ethicists ask questions in an effort to help improve the decision-making process as measured against some standard. Naturally, ethicists ask questions about many disciplines within society that impact quality of life (such as medicine, law, engineering, and public policy). Scholars refer to this subset of ethics as applied ethics. Pharmacy ethics is the study of ethics as applied to pharmacy practice and to the safe and effective delivery of drugs to patients, primarily through pharmacists and pharmaceutical manufacturers. Of course, there are other decision makers and actors (those who carry out their own or others’ decisions) who impact pharmacy ethics: physicians who prescribe medicines, nurses who administer medicines, pharmacies and hospitals that make drugs available, pharmacy owners and wholesalers who supply drugs, insurance companies who administer prescription drug plans, state and federal authorities who regulate pharmacy practice, and lawyers and judges who help resolve legal disputes involving drugs, to name only a few.

Because of its wide impact on individual patients’ quality of life, pharmacists and pharmaceutical manufacturers should give considerable thought to ethics and good decision making at the micro and macro levels (White, 2007). At the micro level, one may be referencing the decision making between one patient and one pharmacist; at the macro level one may be considering how the ethical practice of pharmacy impacts the greater community. In today’s environment, individuals are sometimes disadvantaged personally when decisions are made for society’s shared benefit or good. Macrolevel ethical decisions typically implicate public policy and justice determinations and often involve allocations and rationing by policy makers. Pharmacists and pharmaceutical manufacturers deal with macro ethical decision making cooperatively by trying to influence legislators, regulators, and elected and appointed officials collectively by lobbying lawmakers and supporting specific candidates for executive offices. Of course, assessment of ethical decision making at the micro and macro levels requires different analysis tools since the goals at each level are often so dissimilar.

The recent thought leader shift in pharmacy ethics education is relatively new (Bliss, 2008). Thirty years ago, the ethical questions pharmacy students considered in class typically dealt with business ethics issues, such as whether or not pharmacies should offer tobacco or alcohol products for sale, whether or not pharmacies should stock and sell generic drug products, and whether or not a recent graduate should work for a ‘chain pharmacy’ such as Walgreens (Smith et al., 1991). Curiously, it may be that the question of selling tobacco products in pharmacies has still not yet been resolved satisfactorily even though the American Pharmacists Association officially condemned the practice in 2010 (American Pharmacists Association, 2010). One needs only to cite a recent campaign organized by the Capital District Tobacco Free Coalition to have ‘tobacco free pharmacies’ in Albany, New York neighborhoods (Figure 1) (Capital District Tobacco-Free Coalition) to illustrate this point. As late as 1994, a leading textbook on pharmacy ethics in its Introduction to the First Edition stated that pharmacy ethics has traditionally held a very small place in the scheme of pharmaceutical education, if only relegated to a dean intoning the APHA [American Pharmacists Association] Code of Ethics to his senior pharmacy students on the eve of their graduation.

(Buerki and Vottero, 2002: xiii)

Just a few of today’s news media headlines and accompanying quotations from these stories herald some of the

Figure 1 Capital District Tobacco-Free Coalition campaign poster for tobacco-free pharmacies.
dilemmas that patients, pharmacists, drug manufacturers, and regulators confront:

1. “Abbott Settles Marketing Lawsuit” (Schmidt and Thomas, 2012)
   a. “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 … .”
   b. “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.”
2. “Diabetes Drug Maker Hid Test Data, Files Indicate” (Harris, 2010)
   a. “Not only was Avandia [a SmithKline Beecham diabetes drug] no better than Actos [a competitor diabetes product], 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 … .”
3. “Approval for Drug That Treats Melanoma” (Pollack, 2011)
   a. “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 … .”
   b. “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 … .”
   c. “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.”
4. “U.S. Scrambling to Ease Shortage of Vital Medicine” (Harris, 2011)
   a. “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.”
   b. “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.”
   c. “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.”
   a. “[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.”
   a. “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.”
   b. “[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.’”
7. “Medical Examiner Rules [Heath] Ledger’s Death Accidental” (Barron, 2008)
   a. “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 … .”
8. “Ohio County Losing Its Young to Painkiller’s Grip” (Tavernise, 2011)
   a. “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.”
   b. “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.”
   a. “Florida has long been the nation’s center of the illegal sale of prescription drugs: Doctors here bought 89 percent of all the Oxycodone 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.’”
   b. “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.”
   c. “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.”
10. “Polo Ponies Were Given Incorrect Medication” (Thomas, 2009)
   a. “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 … .”
   b. “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 . . . .

11. “Nursing Home Investigation Finds Errors by Druggists” (Tidesky, 2012)
   a. "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."
   b. “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.”

12. “Ex-pharmacist gets 51 months for Medicaid Fraud” (Ex-pharmacist Gets 51 Months for Medicaid Fraud, 2011)
   a. “[The pharmacist] submitted claims [for over $3.5 million from 2006 to 2010] to the Indiana Medicaid Program for prescriptions that were never given to patients.”

13. “Complaint: Pharmacist refuses to fill prescription about abortion concern” (Gupta, 2011)
   a. “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.”
   b. “The prescription at the center of this is methergine. It’s used to prevent bleeding after childbirth or an abortion.”
   c. “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.”
   d. “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’.”

   a. "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.”

   (Clearly, this case does not involve a pharmacist per se. However, one is left to wonder how the camp counselor came to possess a prescription drug unless supplied by one with legal authority to prescribe, dispense, or deliver such a product.)
   a. “[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.”
   b. “[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.”

Each of these headlines or news item titles illustrates an ethical dilemma. Although the fact situation described in each is different, there are easily identifiable, unifying ethical themes or principles involving individual and corporate character (virtue), being honest and telling the truth (veracity), respecting patient privacy in professional communications (confidentiality), meeting professional or societal responsibilities faithfully and competently (fidelity), honoring individual self-determination and voluntary informed consent (patient autonomy), acting to maximize good (beneficence), working to minimize harm (nonmaleficence), allowing for equal opportunity and resource allocation fairness and equity (justice), and assuring just state action and fair public policy determinations (again, justice) (Veatch and Haddad, 2008: 9–16).

Ethical Questions and Standards
Specific Issues Framed as Ethical Questions

As emphasized, all these headlines and quotations have safe and effective drug delivery concerns to patients (both at the micro and macro levels) and decision making in common. When framed as broader questions, it may be clearer that these headlines unquestionably reveal ethical dilemmas:

- To what extent should drug manufacturers systematically expand their markets to unapproved uses when there is doubtful benefit to patients? (Case 1)
- 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? (Case 2)
- Should very expensive drugs be offered to individual patients when the benefits are marginal? If so, who should bear the expense? (Case 3)
- 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? (Case 4)
- Should drug manufacturers be permitted to market prescription-only medicines directly to consumers, arguably artificially driving demand and increasing the likelihood of inappropriate use? (Case 5)
- 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? (Case 6)
- Are physicians prescribing too many pain medications, or too few? Correspondingly, are pharmacists failing to
appropriately monitor patient pain killer use? (Cases 7, 8, and 9)

- May pharmacists refuse to dispense some prescriptions because to do so would violate their consciences? (Case 10)
- Is pharmacist malpractice – by definition, action involving a pharmacist who allegedly failed to meet the established standard of care – inherently unethical? (Cases 11 and 12)
- How should regulators (and society) deal with pharmacists who engage in unprofessional and unethical behavior? (Case 13)
- Since the benefit appears to be so great as compared to risk, should all pharmacists be trained to give immunizations to adults and children? (Case 14)
- How might pharmacists expand their scope of practice appropriately, ethically? (Case 15)

Many of these ethical dilemmas are also legal cases. Law may be defined as a formally recognized binding rule of conduct that is enforceable by a governmental authority (White, 2007: 227–229). One cardinal difference between ethics and law is that a violation of law may lead to the community imposing a monetary civil penalty, a criminal fine, or confinement. Violation of an ethical standard may result in private or public censure and personal embarrassment but not in state-sanctioned fine or imprisonment. This critical distinguishing characterization may be represented in two questions: (1) “What should the pharmacist do?” (the ethical question); and (2) “What must the pharmacist do?” (the legal one) (Mullan and Brown, 1996).

Common to both ethics and law, however, is retrospective assessment and critique of professional judgment. Typically, an action with its resulting consequence must have occurred before one may look back and conclude that the action and outcome were unethical or ethical and illegal or legal. In fact, Aristotle said centuries ago that one should not ultimately decide whether or not a person had lived a ‘good life’ until after the individual’s death (Ingram and Parks, 2002: 101–110). One of the key values of ethics conversation and discussion about difficult cases is to think prospectively about what actions might be appropriate or inappropriate before one actually confronts an ethical dilemma.

Standards and Normative Ethics

However, the central question remains: how might pharmacists and pharmaceutical manufacturers resolve ethical dilemmas while maintaining patient and society trust? Might a general statement about appropriate conduct suffice? Will such an accepted statement be generalizable or universally applicable given the diversity of the facts and the individuals involved? Is a short, direct statement – such as the one that follows – really adequate to help with questionable cases?

Traditionally, ethical decision-making analysis involves reviewing and evaluating the outcomes or consequences of a decision or action, the actor’s unique involvement or a specific act(s), the intent of the actor or decision maker in taking action, and the motive(s) of the decision maker or actor. The great philosophers and ethicists through the ages have underscored these various unique elements to better understand and explain the nature of good and morally acceptable decision making (Ingram and Parks, 2002). Aristotle thought that character and virtue were important because he believed virtuous persons of good character would make better decisions. St. Thomas Aquinas believed that God had created a ‘natural law,’ which established standards that governed good actions; Hobbes suggested that social contract theory helped refine any notions of natural law. Kant understood that much turned on the intent and ‘good will’ of the actor and the ‘rules’ governing behaviors in society. Bentham and Mill opined that perhaps the ultimate outcomes or consequences of an action are the more important consideration in decision making. Nietzsche questioned the motives of man and expressed concern about the hypocrisy he saw in the moral reasoning or some. Rawls asserted that a just, democratic society would minimize the risks of chance and opportunity to promote a civil order that protects any disadvantaged. Regardless, the four key factors usually stressed in ethics questions – motive, intent, acts, and consequences – may not be linear but rather circular (see Figure 2) since they are interdependent and feedback in a loop or cycle.

Clearly, one simply using a set of principles as a guide – whether from the great philosophers or from a professional code of ethics articulated by practitioners (such as the one promulgated by the American Pharmacists Association) – only goes so far in helping to resolve ethical dilemmas (Fink, 2007).

After giving initial thought to character, virtue, and principles, it may be helpful to ask the next question: “How might a good pharmacist or a good drug manufacturer resolve an ethical dilemma at hand?” (Veatch and Haddad, 2008: 9–16). As it happens, this shows a marked similarity to the legal standard that pharmacists are obligated to meet in everyday practice: “what might the reasonably prudent pharmacist do under like or similar circumstances?” (Abood, 2010: 370–388). Or somewhat differently, what might a reasonably prudent pharmacist ‘normally’ do when confronting an ethical dilemma?
dilemma? Using a normative ethics approach involves a case-based analysis rather than one based on principles or perceived duties. Casuistry – case-based reasoning – is the foundation of the common law. The method looks to established precedents as a way of resolving disputed cases with similar fact patterns. In applied ethics, casuists attempt to establish the professional ethical norm as lawyers and judges seek to identify the legal standard of care.

Normative Ethics in Pharmacy Illustrated

Often when scientists hear ‘normative,’ they think of a normal curve, the Gaussian curve, or ‘bell-shaped’ curve, which shows a normal distribution of data points (see Figure 3). Those familiar with the normal curve will recall that about 68% of the distribution falls within one standard deviation from the mean, about 95% within two standard deviations. In the normal curve, about 4–5% of the distribution is beyond two standard deviations. Curiously, medical boards and pharmacy boards typically discipline about 5% of licensees annually (Kohatsu et al., 2004).

Given the definition of normative ethics, the normal distribution curve, and the likelihood that about 5% of pharmacists may be disciplined annually, one might use the normal curve to illustrate pharmacy ethics decision making, the difference between optimal and inappropriate behaviors and outcomes, the lines between ethical and unethical and illegal conduct, and the relationship between law and ethics? In developing a diagrammatic representation of a normative ethics curve, one might blacken the extreme tails of the curve – those areas more than two standard deviations from the mean, about 5% of the distribution – to represent inappropriate conduct that is condemned by the license boards and society (Figure 4). Then, without modifying the area under the curve, one might redistribute the black and gray areas under the curve from the tails to the base (Figure 5). These black and graying areas might represent illegal and unethical behaviors or outcomes, behaviors or outcomes that result in pharmacist disciplinary actions such as criminal conviction with fines or imprisonment, license revocation, license suspension, probation, public or private censure or reprimand, and civil liabilities. The transitional gray and lighter and white areas under the curve – about 95% of behaviors or outcomes – what happens in the vast majority of professional drug delivery encounters and interactions – are above the black and darker areas and represent legal and ethical behaviors and outcomes. The gray areas nearer the base might depict questionable behaviors and conduct that might be condemned by practicing pharmacists but – for whatever reason – not be the subject of board disciplinary action or criminal or civil prosecution.

Figure 6 more completely describes the areas under this normative ethics curve. Using the median to divide the curve based on intensity of action, one may split it into right and left halves. The right half indicating more versus less pharmacist intervention or activity necessary to produce an outcome, the left half indicating less versus more activity required for a specific result. The very top of the curve (the whitest area) represents those activities in which very little pharmacist or drug manufacturer intervention would produce a result or outcome with very significant or maximal individual or society benefit. The extreme right ‘tail’ of the curve would represent supra standard care (as opposed to substandard care on the extreme left), in which more pharmacist or drug manufacturer intervention would result in very bad outcomes. (Note that supra standard on this curve is still substandard, or inappropriate; supra is used to distinguish extreme exertion to produce a bad outcome.) This area to the extreme right, may be intentional, deliberate, planned, organized, relatively complicated, or complex activity that would lead to the very worst possible outcomes for patients. The extreme left side of the curve represents little or no pharmacist or drug manufacturer intervention or activity that also results in bad consequences to the individual patient or society. On the extreme right, the pharmacist does too much and poor consequences result; on the extreme left, the pharmacist does too little or nothing with similarly poor outcomes resulting. At the black base of the normative ethics curve, the consequences are very bad (criminal) and at the top the outcomes are maximized (optimal) with little effort.

In the interest of fair-minded observation and discussion, one might readily acknowledge that since more ‘actions’ involve doing rather than not doing (in essence, an asymmetric
distribution) perhaps the normative curve should be skewed to the left (rather, ‘left-tailed’ or a negative skew) as in Figure 7? Perhaps it is unreasonable to even discuss more or less active involvement in a normative ethics curve representation at all, since the pharmacist or drug manufacturer consciously or actively thinks about doing less before actually doing more or less in the way of physical activity anyway? Most would say that thinking and planning involve as much of an ‘active’ process as would be required in actually engaging in conduct. These comparisons are valid intellectual exercises, but the fact remains that about 4–5% of health care providers are disciplined each year and about 4–5% of a normal distribution lies farther than two standard deviations from the mean, or ‘norm.’

Moreover, one should understand from the outset that a description of a normative ethics curve is for illustration purposes only. There are no data points to graph on this curve. In fact, there are not single events (e.g., acts or outcomes) to plot. Each one decision may lead to countless other decisions or acts, much like a chain reaction when splitting an atom. When any one decision is made, it is impossible to predict with any precision what might have or what series of other decisions or acts or consequences might follow. Such is the nature of decision making. If the decision maker or actor knows with certainty the outcome of a proposed intervention, any issues about what should be done might be less important.

To further the illustration value of a normative ethics curve in pharmacy ethics, one might use the letters A through J to identify specific areas under the curve and showcase fact situations that match these areas. Additionally, to help explain the relationship between law and ethics, one might use dotted lines near the base of the curve to delineate illegal from legal behavior or conduct, and just above that demarcation, a second dotted line to differentiate unethical from ethical behavior or conduct. (Note that the illegal–legal line perhaps should be more close to the base since only about 4–5% of disciplinary resolutions fall below that standard; however, for representation purposes within the graph, the line is not to scale.) In Figure 6, the illegal–legal and unethical–ethical boundary lines are represented as linear; they may just as easily have been portrayed as undulating to represent the difficulty in settling on one point versus another when there are differences of opinion among reasonable pharmacists about characterizations. Moreover, in Figure 6 these lines are not parallel but angled to allow for the possibility that some technically illegal conduct in fact may be ethical (labeled as area under the curve G). Table 1

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</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 or more</td>
<td>Appropriate</td>
<td>Better</td>
</tr>
<tr>
<td>C</td>
<td>Maybe</td>
<td>Yes</td>
<td>Less</td>
<td>Borderline</td>
<td>Better</td>
</tr>
<tr>
<td>D</td>
<td>Maybe</td>
<td>Yes</td>
<td>More</td>
<td>Borderline</td>
<td>Better</td>
</tr>
<tr>
<td>E</td>
<td>Maybe</td>
<td>Maybe</td>
<td>Less</td>
<td>Inappropriate</td>
<td>Worse</td>
</tr>
<tr>
<td>F</td>
<td>Maybe</td>
<td>Maybe</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>Debatable</td>
<td>Better</td>
</tr>
<tr>
<td>H</td>
<td>No</td>
<td>No</td>
<td>Less</td>
<td>Inappropriate</td>
<td>Worst</td>
</tr>
<tr>
<td>I</td>
<td>No</td>
<td>No</td>
<td>Neutral</td>
<td>Inappropriate</td>
<td>Worst</td>
</tr>
<tr>
<td>J</td>
<td>No</td>
<td>No</td>
<td>More</td>
<td>Inappropriate</td>
<td>Worst</td>
</tr>
</tbody>
</table>
summarizes the areas under the normative ethics curve with comparative descriptions.

The 15 cases used to introduce this pharmacy ethics discussion earlier may be used to further explain the areas under the normative ethics curve. The darker areas at the base of the curve – the clearly illegal and unethical areas, whether to the extreme right or left – offer less opportunity for disagreement since these are the notorious cases that are more widely reported in the media as terribly wrong. Case 12 – the criminal conviction of a former pharmacist who billed Indiana Medicaid for services and products that were not provided – may be a good example of area under the curve H. Cases 1 and 2 – two cases that involve drug companies who devised relatively complicated and sinister plans either to market drug products illegally or hide important data that might cause serious patient injury – are examples of behavior or conduct in area under the curve J. Thinking in terms of motive–intent–act–outcome (recall Figure 2), motive – reprehensible motive – appears to be a predominant feature of cases 1, 2, and 12. Greed or excessive profit appears to have motivated the actors in all three of these cases. Normative ethics – or reasonably prudent pharmacists or drug manufacturers – could never condone such behaviors nor defend actors engaged in such conduct.

Area under the curve I may be a little more difficult to illustrate with case examples: illegal, unethical behavior in which the pharmacist or drug company is almost passive and still there is a bad outcome (or potentially bad outcome) to patients. Opinions among professionals about normative ethics may vary widely on this point. Restated, it is almost as if the pharmacist stands idly by – not intervening when acting is possible – with a bad (or arguably bad) outcome resulting. Might case 13 be one such example? In this case, the pharmacist – reasonably suspecting that the patient had had an elective abortion since the call came from a Planned Parenthood nurse practitioner – refused to dispense a prescription for methergine. Methergine (methylergometrine) is a vasoconstrictor and often used in obstetrics to control bleeding after a delivery or spontaneous or induced abortion. The pharmacist refused to dispense the prescription invoking reliance on a 2010 statute enacted by the Idaho legislature. The law allowed health care professionals to refuse services when such performance would conflict with religious, moral, or ethical principles (Strauss, 2011). When asked by the pharmacist if an abortion was involved in the care, the nurse practitioner cited federal privacy protection laws in refusing to share information about the patient’s treatment. The pharmacist did not dispense the prescription. The nurse practitioner filed a complaint with the Idaho State Board of Pharmacy. After an investigation, the board of pharmacy “found no violations of state laws the board is tasked with enforcing” (Dooley, 2011). Since the state pharmacy board held the action was not illegal (the point on the curve perhaps should be above illegal–legal line), but the debate will still continue about whether or not the action was above the unethical–ethical line. One wonders if there might have been a different result had the patient died shortly after from blood loss. Regarding the illegal–legal bar in a similar fact pattern, Illinois attempted to make refusal to dispense contraceptives illegal by regulation (White, 2007: 85–109). An Illinois circuit court eventually overturned this law but public sentiment certainly remains for pharmacists to offer services even when performance violates conscience (Yeakley, 2011). Briefly back to case 13, as an aside, one might question the ethical behavior of the nurse practitioner since federal privacy protections do not prohibit the transmission of important health information from one provider to another when necessary for patient care and coordination (Health Information Privacy, n.d.).

Area under the normative ethics curve A represents little decision making or minimal activity on the part of the pharmacist or drug manufacturer with optimal outcomes. Might case 14 be an example for this area under the curve? In recent years, pharmacists have been providing immunization services (particularly flu vaccines) directly to adult patients in local community pharmacies. Studies report that pharmacist immunization programs to be highly effective (Wick, 2006). It should be noted that pharmacists providing direct, hands-on patient care is a recent innovation in health care delivery and for some pharmacists touching a patient is considered unprofessional, unethical, and illegal (Etchells, 2012). Regardless, area under the curve A shows that ethical dilemmas may occur even with presumably optimized outcomes. For example, if immunizing pharmacists is a good idea, should not all pharmacy schools offer the training as part of their curricula, or why should pharmacists not also offer immunizations to children as well as adults?

Area B under the normative ethics care represents the vast majority or bulk of decision making and activity in everyday pharmacy practice and ethics. Conduct and outcomes are clearly legal and ethical appropriate care. Behaviors in this area under the curve provide indisputably good patient care.

Areas under the normative ethics curves C and D represent decisions and behaviors that are approaching a gray area: legal and ethical, but with clinical outcomes that might be better. Cases 3, 5, and 6 may be examples of actions in which pharmacists were engaged but produced less than satisfactory outcomes in the minds of some. Case 3 illustrates a unique justice issue in that the metastatic melanoma patient who received Yervoy lived about three-and-a-half months longer than the melanoma patient who did not, but at a drug delivery cost of at least $120 000. One might ask if this is a ‘better’ outcome, even for the patient who lived a few weeks longer, when the collective community was – for all practical purposes – financially responsible for the cost. Case 5 questions the appropriateness of offering direct-to-consumer advertising for prescription drugs when the practice appears to drive up costs and create artificial demand. Case 6 considers the fairness of allowing patients to have choice in obtaining chronic disease prescription either by mail order more cheaply rather than at the local pharmacy and without directly incurring any additional costs. Case 4 – in which the drug manufacturers elected not to act by making some essential products available because there is very little profit to offset production costs – is similarly problematic because of justice or equity concerns. All four of these cases illustrate how government acted or failed to act, directly or indirectly, in controlling or regulating drug supply.

At the unethical–ethical boundary are areas under the curves E and F. Area E dealing with less rather than more intervention; F dealing with the related more rather than less intervention. Might case 11 be an example of a pattern that fits within E and cases 7–10 fit within F? Some pharmacy law and
ethics teachers would say that the fact situations described in cases 7, 8, and 9 are already within the illegal area (Abood, 2010: 219–221). Cases 7, 8, and 9 highlight the inappropriateness of physicians prescribing and pharmacists dispensing some controlled substances prescriptions. By federal regulation, if a pharmacist dispenses a prescription for a controlled substance not for a legitimate medical purpose or not in the usual course of professional practice, he or she has failed to meet a legal standard. These laws are regulations promulgated by Drug Enforcement Administration; violators are subject to sanction and criminal prosecution.

Perhaps an extreme example of this type of problem – involving a doctor not a pharmacist – may be illustrated with the unfortunate death of entertainer Michael Jackson when his physician, Dr Conrad Murray, administered the hypnotic propofol intravenously whenever the patient requested a drug for intractable insomnia (Moore, 2011). Dr Murray was convicted of involuntary manslaughter in a California criminal court and was sentenced to 4 years in prison (Medina, 2011).

Cases 10 and 11 deal with pharmacy malpractice and professional standards of care issues. Case 10 – in which a veterinary compounding pharmacy error resulted in the accidental deaths of 21 polo ponies – details how the pharmacist or pharmacists incorrectly filled the prescription. Case 11 – in which pharmacy investigators alleged that consultant pharmacists engaged by several California nursing homes failed to identify potentially dangerous situations of overprescribing or drug interactions or side effects – shows how malpractice may occur when pharmacists fail to meet the required standard of care by inattention or inaction.

Area under the normative ethics curve G is a special situation, decision making or action that is illegal but still considered ethical by reasonably prudent pharmacists. Case 15 may be an example of this type of ethical dilemma. Even though the fact situation of case 15 does not involve a pharmacist directly, there are examples to illustrate area G behavior from pharmacy practice. Emergency delivery of prescribed drugs to patients without prescriber authorization may be one. In some jurisdictions, state legislatures have recognized this problem by enacting specific statutes to permit pharmacists to deliver an emergency supply of a drug (most often a medicine for a chronic disease such as high blood pressure or diabetes) when a refill has not been formally authorized and the prescriber has not been contacted after good faith effort (Tennessee Code Annotated § 63-10-207, 2010). One should note, however, that this remedy is in effect one law creating an exception to mandatory compliance with another law. However, one should recall that a state law exception might not serve as a waiver or defense when a federal law is viewed as controlling (Abood, 2010: 172–173). But this may be more a legal issue rather than an ethical one.

**Emerging Pharmacy Ethics Challenges**

Any attempt to describe pharmacy ethics briefly is certain to be critiqued by scholars learned in philosophy or applied ethics and by pharmacy law and ethics teachers. No abbreviated overview can possibly give adequate consideration to relevant topics fully, nor competently predict emerging future pharmacy ethics challenges. Pharmacy law and ethics is an evolving field that will undoubtedly grow because of its importance in assuring a better quality of life to patients and because of the expanding complexities in the drug delivery supply chain and health care system.

Moreover, a short discussion of normative ethics – particularly one professing to use a diagram of a normative ethics curve with illustrative cases from pharmacy practice – may be misleading in several respects. Educators and practitioners will and should disagree about where a particular case or fact pattern may fall under the curve. Ethical assessment is more subjective than not; ethics analysis requires a different way of thinking other than that used in pharmacy calculations, pharmaceutical or physical chemistry, or even pharmacology with its normal physiological response variations. As one article has said, “the plurality of human beings makes it complicated to translate ... values into general rules of conduct” (Dessing and Flameling, 2003). Standards of acceptable and unacceptable professional behavior and society’s responses change over time. One needs only to recall an episode involving a pharmacist in Frank Capra’s 1946 holiday classic It’s a Wonderful Life to illustrate this fact of life (Goodrich et al., 1946). Mr Gower, the fictional Bedford Falls pharmacist, went to jail for 20 years in George Bailey’s alternative universe because he ‘poisoned a kid’ when he negligently misfilled a prescription. It is quite unusual for a pharmacist to be prosecuted criminally today for negligence, even when a patient death occurs accidentally (Vivian, 2009).

Ethics analysis too is situational, or contextual. Each case is factually unique. Again, using the case of Mr Gower to illustrate the point, there were two critical factors that may have played into whether or not the local prosecutor decided to seek a prison term for the death of the child (stated also, whether there were mitigating or aggravating factors that were taken into consideration). It appears that Mr Gower had just received a telegram advising him of his son’s sudden death from influenza. The pharmacist appears grief stricken and distracted on one scene. And, in another segment, he appears to be drinking. What all of these facts add to the ebb and flow of events is unclear. But in the end, Mr Gower did dispense the wrong medication and a child died. With this dire consequence, some may rightfully ask what else really matters.

Health care professionals are obligated to act in patients’ best interests. They must place the patients’ well-being above self-interests (Pellegrino, 2007). In taking an oath of service, health care providers ‘profess’ to care for individuals ‘professionally,’ meeting professional norms in the process. Practitioners also must use professional judgment (Aristotle’s *phronesis*, or ‘practical wisdom’) when deliberating about difficult moral situations and acting in patients’ best interests. In summary, ethics and good decision making turn on professional trust:

> Good health care requires partnership between providers and the public. Trust constitutes a key element of this partnership – and trust depends on a widespread belief that the principles of honest public service prevail in health care. Patients must feel confident in the trustworthiness of their providers to seek care, reveal sensitive information, submit to treatment, or participate in research. (Greenwald, 2010)
Acknowledgments

The author gratefully acknowledges the thoughtful and helpful reviews of the manuscript by the following pharmacy law and ethics professors: Richard R. Aboud, BSPharm, JD, Professor of Pharmacy Practice, Thomas J. Long School of Pharmacy and Health Sciences, University of the Pacific, Stockton, California; David B. Brushwood, BSPharm, JD, Professor of Pharmaceutical Outcomes and Policy, College of Pharmacy, University of Florida, Gainesville, Florida; Robert A. Buerki, PhD, Professor of Pharmacy Practice and Administration, College of Pharmacy, The Ohio State University, Columbus, Ohio; Joseph L. Fink, III, BSPharm, JD, Professor of Pharmacy Law and Policy and Kentucky Pharmacists Association Professor of Leadership, College of Pharmacy, University of Kentucky, Lexington, Kentucky. He also deeply appreciates their friendship.

References

American Pharmacist Association, July/August 2010. Discontinuation of the sale of tobacco products in pharmacies and facilities that include pharmacies. J. Am. Pharm. Assoc. NS 40 (4), 471.


Relevant Website

www.pharmacist.com – American Pharmacists Association (APhA).

Elsevier Reference Module in Biomedical Sciences, (2014)