## Legal Cases That Raise Ethical Issues

Jesse C. Vivian David B. Brushwood

## SIMILARITIES AND DIFFERENCES BETWEEN LAW AND PROFESSIONAL ETHICS

The disciplines of law and ethics share many similar characteristics while fulfilling separate, but occasionally overlapping functions. In behavioral terms, and at a very basic level, laws set forth the minimal expectations of conduct demanded by a governing society. Failure to adhere to the mandates of those laws results in governmentally brokered punishment. Professional ethics function to provide behavioral guidelines. Enforcement, however, is more often achieved by a voluntary commitment to follow those guidelines in dealing with the people who partake of the services offered by individual members. Sanctions for failing to adhere to professional standards are usually limited to warnings or, at worst, group ostracism. Both law and professional ethics deal with the identification and formalization of group values expressed as behavioral rules. In law, the rules are embodied in legislative codes, statutes, or as declarations from the courts. Professional ethics are most often found in codes of ethics or standards of conduct. However, it is important to keep in mind that while nearly every law is founded upon a moral principle, not every ethical value becomes law.

Jesse C. Vivian, B.S. Pharm., JD, is Professor of Pharmacy Practice at Wayne State University College of Pharmacy and Allied Health Professions, Detroit, MI 48202-3489. David B. Brushwood, JD, is Professor of Pharmacy Health Care Administration at the University of Florida College of Pharmacy, Gainesville, FL 32610-0496.

[Haworth co-indexing entry note]: "Legal Cases That Raise Ethical Issues." Vivian, Jesse C. and David B. Brushwood. Co-published simultaneously in the Journal of Pharmacy Teaching (The Pharmaceutical Products Press, an imprint of The Haworth Press, Inc.) Vol. 6, No. 1/2, 1997, pp. 1-17; and: Teaching and Learning Strategies in Pharmacy Ethics, Second Edition (ed: Amy Marie Haddad) The Pharmaceutical Products Press, an imprint of The Haworth Press, Inc., 1997, pp. 1-17. Single or multiple copies of this article are available for a fee from The Haworth Document Delivery Service [1-800-342-9678, 9:00 a.m. - 5:00 p.m. (EST). E-mail address: getinfo@haworth.com].

#### TEACHING STRATEGY: THE CASE METHOD

Students often become confused in trying to apply (or differentiate) legal and ethical principles to a set of facts that requires a decision about what type of conduct is either mandated (by law) or expected (as a professional standard). This situation is exacerbated because, unfortunately, pharmacy law is sometimes taught as if it were a body of knowledge with specific rules that are intended to be learned and obeyed, else the consequences will be swift and severe. But neither the law nor ethics provides a cookbook set of rules where there is only one right answer to every question or issue. Alternative solutions are almost always available in both disciplines. Of course, one answer may be better than other alternatives. The value of contrasting the similarities and differences between the facts and legal outcomes of two or more situations in arriving at the best solution to a dispute has been the basic tenet of the case law method of teaching in law schools for a number of years. This method teaches law students to analyze many arguably applicable laws and select the ones that are better suited to a given set of facts. This approach is also useful in helping students understand pharmacy ethics. The similarities and distinctions between legal standards and professional ethics can be useful in contrasting alternative forms of conduct that might be available to a pharmacist in any given situation.

Utilization of actual cases that have been decided by a jury or court can be instructive in showing students how objective observers value and rank certain behaviors. The case method of teaching is also valuable in showing that the law, like ethics, is not so much about applying  $\alpha$  rule to a set of facts as choosing the *best* rule over many otherwise applicable alternatives. The case method also supports the notion that professional ethics is not only about values and mores but, through the use of multiple examples, is a useful tool in prioritizing values in resolving conflict when alternative actions are available.

#### SOURCES OF CASES

Ethical responsibility is best understood when principles are applied to facts. Historical cases are useful in applying theoretical principles of right and wrong conduct to real situations with a demonstrated outcome. Case law can supply a realistic set of facts for teachers to build upon in trying to illustrate otherwise abstract ideas. There is nothing magic or better about using case law as a source of teaching material. Often times, the best

teaching cases are those that the instructor has had a personal involvement with because, if for no other reason, the emotions attached to the memory of the facts are real and heartfelt. Emotional involvement with a set of facts is a great strategy for getting students to focus on the difficulties associated with ethical decision-making. Yet there is an inherent limitation in relying on our own experiences as a source for situations useful in demonstrating the principles we want to teach. For example, principles of confidentiality may prevent us from revealing too many details about a particular case. Or, because a case is of a local character, students may know something about the parties or facts that could bias their judgment. Perhaps the greatest limitation is that most of us just don't have enough involvement with compelling cases that make good teaching examples. As an alternative, instructors may rely on hypothetical cases based on a loose set of facts. This approach runs the risk of being too contrived. Skeptical students may be put off by the unrealistic character of some made-up cases.

On the other hand, cases that have been reported in the legal literature are a matter of public record, so confidentiality is not an issue. Their geographic distribution makes it unlikely that any student will know any of the individuals in the case. If an instructor wishes to conceal the identity of the litigants, then this can be easily accomplished through the use of pseudonyms. Another advantage of actual court cases is that they come complete with a description of facts, an outline of the key issues, and an analysis of the issues. The legal analysis may be useful only as background, or it may be useful in ethics teaching as a challenge for students to determine whether the legal result is ethically supportable.

It should be noted that there are limitations on the use of case law as well. As not every ethical principle is reflected in a law, there may not be any court cases available to illustrate a specific point. Further, depending on the age of a case or the law that the case was decided under, the legal and/or ethical points discussed may be out of date or diametrically opposed to contemporary ideas of professional behavior. This requires instructors to be current in understanding legal and ethical principles and filter out those cases that might mislead students. Even outdated, but "classic" cases, however, may be useful in tracing changed attitudes about ethical behavior.

#### CASES INVOLVING ETHICAL AND LEGAL PRINCIPLES

What follows is a list of cases that may serve as the basis for a productive discussion of pharmacy ethics. When available, cases with differing

#### 4 TEACHING AND LEARNING STRATEGIES IN PHARMACY ETHICS

outcomes on similar facts or issues have been chosen to help instructors and students see how judges and juries differ in values assessment. These cases are intended to represent a diverse array of opinions on various issues while having realistic applicability to pharmacy education. Not every case directly involves a pharmacist; the issues considered in the opinion, however, should have equally important impact on the practice of pharmacy. The list is not exhaustive and does not purport to deal with the full range of ethical challenges pharmacists may encounter. Where appropriate, citation has been made to a federal statute or administrative rule; these references have particular relevance to the ethical issue under consideration.

Each case includes a reference to an official court citation to an opinion which can be found in any academic library. In addition, these cases are available on nearly every on-line legal database. Most cases are briefly described to help instructors decide which cases best suit their needs. Hopefully, the synopses will be useful in helping those who are not used to reading judicial opinions wade through the often technical and confusing legalese to ferret out the salient legal and ethical principles. While each of these cases involved a number of different legal issues, the arrangement offered here attempts to highlight a central and common point.

#### **PROFESSIONAL DUTIES**

## The Duty to Counsel (a/k/a "The Duty to Warn")

Riff v. Morgan Pharmacy, 508 A. 2d 1247 (P-A. Super. 1986). This case reviews a jury verdict against a pharmacy for failure by the pharmacist to inform a patient about the need to limit the use of Cafergot® suppositories. The court rejects the pharmacy's argument that "a pharmacy is no more than a warehouse for drugs and that a pharmacist has no more responsibility than a shipping clerk who must dutifully and unquestioningly obey the written orders of omniscient physicians." The court concludes that a pharmacist is a member of the health-care team, and that in health care there is a safety net of overlapping responsibilities.

Dooley v. Revco, 805 S.W. 2d 380 (Tenn. App. 1990). The appeal in this case presents the issue of whether the lower court was correct in dismissing a malpractice case brought against a pharmacy for failure of the pharmacist to counsel the patient about drug interactions. The court states that legal duty of one person to another person is correlative to a right vested in the other person. A duty rests on everyone to use due care under

the attendant circumstances, and negligence is doing what a reasonable and prudent person would not do under the given circumstances. The lower court was reversed, and the case was sent back for further proceedings against the pharmacy.

Heredia v. Johnson, 827 F. Supp. 1522 (D. Nev. 1993). Pursuant to a prescription, the pharmacy dispensed ear drops to a patient suffering severe otitis media with bullous myringitis. The manufacturer's package insert contained an express warning against using the product in the presence of a perforated ear drum. That warning was not passed on to the patient who used the medication as directed. The patient experienced a perforated ear drum and suffered permanent brain damage. On the failure to warn claim against the pharmacy, the court held that a question of fact exists as to whether the pharmacy was negligent in carrying out its duty of due care. In light of this case, one might also consider the federal statute, commonly referred to as OBRA-90 (Omnibus Budget Reconciliation Act of 1990, P.L. 101-508 §,4401:42 USC § 1396r-8(g)), imposing a counseling duty on pharmacists with respect to Medicaid patients. In contrast, one might consider also these cases holding pharmacists do not owe patients a duty other than to "dispense as prescribed." Stebbins v. Concord Drugs, 164 Mich Approximately 204: 516 N.W. 2d 381 (1987); Walker v. Jack Eckerd Corp., 434 S.E. 2d 63 (Ga. App. 1993).

## Duty to Detect/Prevent Drug Interactions

Baker v. Arbor Drugs, 544 N.W. 2d 727 (Mich. App. 1996). The patient was taking Parnate® to treat depression. He was given a prescription for Tavist-D® (at the time, a prescription-only drug) that was filled at the same pharmacy that regularly dispensed the Parnate®. The pharmacy chain advertises that its computers and pharmacists regularly check prescriptions for drug-drug interactions and that patients can rely on the safety of the systems it employs. The patient suffered a stroke as a result of the Parnate®/Tavist-D® interaction. He later committed suicide, leaving a note to his wife indicating that he did not want to be a burden to her. The pharmacist on duty when the prescription was dispensed testified that, based on a label indication, the computer had detected a drug-drug interaction but she had not seen the warning screen because a pharmacy technician overrode it. The trial court's dismissal on the negligent failure to warn claims were reinstated on appeal based in large part on the chain's advertising claims for safety. For an interesting comparison, see Laribee v. Super X Drug Corp., 1987 Westlaw 14054 (Ohio Ct. App. 1987) where the plaintiff was harmed after she used Macrodantin® dispensed from the defendant pharmacy on prescription over a prolonged period of time. In support of her claim that the pharmacy owed her a duty to warn against the overuse of medications, she submitted several advertisements from the pharmacy indicating that its pharmacists alert patients to dangers associated with the use of drugs they dispense. The court held that while the ads could create justifiable reliance in the minds of consumers that they would be warned of potential adverse reactions, there is no duty to warn of open and obvious dangers. Here the facts showed that the plaintiff regularly refilled the prescription early and consumed the drugs at a much faster rate than called for in the directions. Hence, the pharmacy was not liable.

Johnson v. Walgreen Co., 675 So. 2d 1036 (Fla. Approximately. 1996). The patient had a history of hypertension, insomnia, and depression treated by several different physicians who prescribed multiple medications. All prescriptions were dispensed from one pharmacy. Along with an over-the counter drug recommended by the pharmacist, the prescription drugs interacted fatally. The undisputed cause of death was drug toxicity. State law defines "dispensing," in part, as an assessment by a pharmacist that prescriptions have been checked for interactions and safety. The appellate court dismissed the negligence claims against the pharmacy on the basis that the statute does not create a private cause of action to maintain a lawsuit; instead, it is to be used by the state agency that licenses pharmacists for administrative remedies against pharmacists who fail to adhere to its requirements.

## Duty to Detect/Prevent Drug Addiction

Orzel v. Scott Drugs, 449 Mich. 550 (1995). The pharmacy dispensed amphetamines to the patient on forged and highly questionable "prescription." The patient had a long history of drug abuse both before and after the pharmacy dispensed the medications. He admitted that he knew the prescriptions were forged, stolen, and otherwise obtained by unlawful methods. He sued the pharmacy claiming that it should have known he was addicted and taken steps to prevent him from obtaining the illegal drugs. A jury awarded \$3.8 million in damages but reduced the amount by 50% for the plaintiff's comparative negligence in obtaining the prescriptions illegally. The trial court judge vacated the entire award against the pharmacy on the theory that a plaintiff's own illegal acts bars recovery against a defendant that causes harm as a result of the unlawful conduct. Although the appeal court reinstated the jury verdict, the state supreme court affirmed dismissal based on the plaintiff's "wrongful conduct." The opinion contains a lengthy discussion of the relative merits (or demerits)

of wrongful conduct on the part of a drug addict and a pharmacist who supplies the drugs negligently.

Kintigh v. Abbott Laboratory, 200 Mich. App. 92; 503 N.W. 2d 657 (1993). The plaintiff purchased large quantities of Schedule V cough syrups containing codeine over-the-counter during a prolonged period of time from 12 different pharmacies. He sued the pharmacies and pharmacists claiming breach of professional duties to detect and prevent his substance abuse problem. Both the trial and appeals courts dismissed the claims, finding that pharmacists do not owe any duty to identify drug addicts or monitor their over-the-counter drug use.

Lasley v. Shrakes Country Club Pharmacy, 880 P. 2d 1129 (Ariz. App. 1994). A pharmacy supplied glutethimide and codeine to the patient on prescriptions from a physician over a 30-year period. He sued the pharmacy for failing to warn him of the addictive properties of the drugs and failing to refuse to fill the prescriptions when it knew or should have known that he was addicted. He supplied an affidavit from an expert witness that referred to the American Pharmaceutical Association's Standards of Practice as evidence of a pharmacist's duty to advise patients of the addictive nature of drugs. The state supreme court analyzed cases from several other states and concluded that pharmacists owe a general duty of due care to their patients. As to the question of whether pharmacists may be liable for failing to warn against and/or prevent drug addiction, the court ruled that it would be up to a jury to decide the specific standard of care.

#### PROFESSIONAL RIGHTS/PREROGATIVES

Professionals and Patients for Customized Care v. Shalala, 56 F. 3d 592 (5th Cir. 1995). The plaintiff-pharmacists appealed from a district court ruling that Food and Drug Administration Compliance Policy Guide 7132.16 (CPG 7132.16) is not a substantive rule and therefore is not subject to the Administrative Procedure Act's notice-and-comment requirement. The holding is affirmed. According to this court, the CPG is an advisory memo to FDA field agents designed to differentiate between pharmacies engaged in traditional compounding and those which engage in manufacturing activities in violation of the FDA regulations. The court expresses the opinion that the CPG does not alter the rights of pharmacists to engage in contemporaneous compounding but seeks to curtail the activities of pharmacists who attempt to thwart the NDA and "new drug"

approval process administered by the FDA under the guise of compounding.

#### INFORMED CONSENT

Canterbury v. Spence, 464 F. 2d 772 (D.C. Cir. 1972). This is a primer on informed consent. The patient was operated on for back pain, and alleges that he never was told the risks of the procedure. The court states, "True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each." The court discusses three standards for the materiality of a risk: 1) the physician-oriented standard, 2) the patient-oriented objective standard, and 3) the patient-oriented subjective standard.

Precourt v. Frederick, 481 N.E. 2d 1144 (Mass. 1985). A patient developed aseptic necrosis as the result of the systemic use of Prednisone<sup>®</sup>. The court recognizes a right of action for failure to obtain informed consent. The court notes that the materiality of information about a potential injury is a function not only of the severity of the injury, but also of the likelihood that it will occur.

#### INFORMED REFUSAL

Rivers v. Katz, 504 N.Y.S. 2d 74 (App. Div. 1986). Involuntarily committed mental patients commenced a legal action to obtain declaration of their right to refuse medication. The court holds that neither mental illness nor institutionalization can stand as justification for overriding an individual's fundamental right to refuse antipsychotic medications. A patient's right to have the final say in respect to decisions regarding medical treatment extends to mentally ill persons, who are not to be treated as persons of lesser status or dignity because of their illness.

Washington v. Harper, 494 U.S. 210 (1990). An inmate in the Washington State Penitentiary sued the institution, contending that he had a right to have a judicial review of his medical situation before he could be administered psychotropic medications against his will. The court quoted entries from the patient's chart such as "because of his lack of participation in therapy it is recommended that the involuntary medication policy continue in use." The supreme court concludes that the decision to use medication is a medical decision, therefore review of forced administration of medica-

tion by a medical board is sufficient, without the need for review by a legal body such as a court or administrative agency.

State v. McAfee, 385 S.E.2d 651 (Ga. 1989). A quadriplegic who was incapable of spontaneous respiration requested that he be allowed to turn off his ventilator, and that he be provided a sedative to alleviate the pain which would occur when the ventilator was disconnected. The court recognizes that the patient has a right to refuse medical treatment. This right extends to a right to be free from pain at the time the ventilator is disconnected. The right to have a sedative administered before the ventilator is disconnected is a part of his right to control his medical treatment.

#### **MEDICATION RECORDS AND PRIVACY**

Doe v. Southeastern Pennsylvania Transport Authority (SEPTA), 72 F. 3d 1133 (3rd Cir. 1995). The plaintiff was employed by a publicly owned and operated bus company, SEPTA, that provided a prescription drug benefit to its employees through pharmacies that elected to participate in the plan. The defendant pharmacy submitted claims for payment to the bus company for dispensed prescriptions. The claims forms included the patient's name and the name of the dispensed drug. During a review of the claims, a human resources director learned that the plaintiff was taking AZT; she asked a staff physician what the drug was used for and learned that the physician knew the plaintiff was HIV-positive. The plaintiff was awarded \$125,000 by a jury in his complaint against the company for its unconstitutional invasion of his privacy. The award was reversed on appeal. The higher court ruled that while prescription drug records do come within the constitutionally protected zone of privacy, publicly owned agencies have a right to this information to insure taxpayers that employee benefits are being properly utilized. After initiation of this lawsuit, the pharmacy changed its claims form, deleting the drug names before submission to the employer as a means of better protecting patient confidentiality.

Evans v. Rite-Aid, 451 S.E. 2d 9 (S.C. App. 1994). A pharmacy employee falsely told colleagues and friends that the plaintiff had obtained a prescription to treat a venereal disease. The plaintiff brought suit against the pharmacy for breach of confidentiality, outrage, and negligent supervision of its employees. Dismissal of the claims was upheld on appeal. The state does not recognize any statutory or common law duty of confidentiality or privilege between a pharmacist and its patients.

Whalen v. Roe, 429 U.S. 589 (1977). This case is a challenge to the legally authorized accumulation of information on prescribing of Schedule

II drugs on a centralized computer at the New York State Department of Health. The court concludes that the law authorizing information collection and storage does not impair any privacy interest in avoiding the disclosure of personal matters, or any privacy interest in making independent decisions as to drug use. However, the dissemination of information to individuals not authorized to receive it could impair such a privacy interest.

Green v. Superior Court, 33 Cal. Rptr. 604 (Ct. App. 1963). Pharmacists' records were subpoenaed in a divorce case where the father sought to prove the mother an unfit parent due to her excessive drug use. The pharmacists refused to disclose the information, citing the right of confidentiality because: 1) physicians do not usually dispense their own prescribed drugs but must rely upon pharmacists, 2) use of some drugs is exclusively for the treatment of specific ailments, 3) in such cases knowledge of the drug dispensed would reveal the patient's confidentially communicated information to the doctor, and 4) to protect the communication privilege not to disclose information in a court of law must be extended to the pharmacist. The court disagrees with the pharmacists, and holds the pharmacists in contempt for failure to provide the information requested.

#### EXPERIMENTATION

Mink v. University of Chicago, 460 F. Supp. 713 (N.D. Ill. 1978). One thousand women were given diethylstilbestrol (DES) as part of an experiment, but were not told they were part of an experiment, nor were they told that the pills administered to them were DES. The court concludes that the women may bring a lawsuit alleging that injuries they suffered from exposure to DES were due to their failure to give informed consent. The university and the drug manufacturer that conducted the experiment had a duty to notify the woman of risks inherent in the use of the drug when the university and manufacturer became aware of the relationship between the drug and cancer. One could also compare the FDA's regulations on Institutional Review Boards (IRBs) and drug testing (45 CFR § 46.111) with the findings of this case.

Pierce v. Ortho Pharmaceutical Corp., 417 A. 2d 505 (N.J. 1980). A physician employed by a pharmaceutical manufacturer objected to research on a pediatric and geriatric liquid formulation of a drug for diarrhea, because the formulation contained saccharin. The physician contended that several ethical codes prevented her from participating in such research, because at that time there was a question concerning whether saccharin caused cancer. The court concludes that a drug manufacturer has

the right to conduct research, as long as necessary steps are taken to protect human subjects of experimentation by following FDA guidelines. Since the manufacturer had followed all requirements, and was going to submit an Investigational New Drug Exemption to the FDA prior to experiments with human subjects, the court did not agree with the physician's view.

#### NONTRADITIONAL THERAPIES

People v. Privitera, 141 Cal. Rptr. 764 (App. Div. 1977). A physician and several others were convicted by a jury of conspiracy to sell an unproved drug, laetrile, intended for the alleviation or cure of cancer. The court holds that the privacy right set forth by the California Constitution is not just a shield against threats to personal freedom imposed by modern surveillance and data collection activities, but rather encompasses fundamental and compelling interests of cancer patients to choose or reject medical treatment on the advice of their physicians. This right can be abridged only by a compelling need. The requirement that only approved medications can be used for cancer patients does not bear a rational relationship to the object of protecting the public from fraudulent medical treatment, thus it does not overcome the right to privacy.

Custody of a Minor, 393 N.E. 2D 836 (Mass. 1979). The parents of a child with acute lymphocytic leukemia sought judicial permission to withdraw their child from court ordered chemotherapy, and administer to the child laetrile, large doses of vitamins A and C, enzyme enemas, and folic acid. The court notes that family autonomy is not absolute, and it may be limited where it appears that parental decisions will jeopardize the health or safety of a child. The court upholds the court ordered chemotherapy, because the "metabolic therapy" the parents sought to have the chemotherapy replaced with was not only medically ineffective, but was poisoning the child.

Tuma v. Board of Nursing, 593 P. 2d 711 (Id. 1979). A nurse was suspended from professional practice for "unprofessional conduct" based on her having told a terminally ill cancer patient about laetrile as an alternative to chemotherapy. The nursing board concluded that this action had interfered with the physician-patient relationship. The court describes what it believes is meant by the phrase "unprofessional conduct." Then it concludes that the phrase cannot be used to support the suspension of a nurse's license for discussing alternative treatments with a patient.

#### WHISTLEBLOWING

Kalman v. Grand Union Company, 443 A. 2d 728 (N.J. Super. 1982). A pharmacist was fired for objecting to an illegal action by his employer. The court reviews that objection, and concludes that it is based on the regulations relevant to pharmacists and on the American Pharmaceutical Association Code of Ethics rather than on the pharmacist's own personal values or conscience. The objection is in vindication of a clear mandate of public policy, therefore the pharmacist has a right to sue the employer for wrongful discharge.

DeAnda v. St. Joseph Hospital, 671 F. 2d 850 (5th Cir. 1982). A pharmacist was discharged from employment at a hospital, allegedly for complaining of racial discrimination in hiring practices of the hospital's director of pharmacy. The court rules that in an action of this type, the burden is first with the pharmacist to show that she was discharged after complaining about hospital policy. The burden then shifts to the hospital to show that there is a legitimate nondiscriminatory reason for the discharge. If such evidence is produced, the burden then shifts back to the pharmacist to demonstrate that the nondiscriminatory basis for the action was mere pretext for discrimination.

# PROVIDER/PATIENT VALUE CONFLICTS: CONSCIENCE CLAUSES

Brownfield v. Daniel Freeman Marina Hospital, 256 Cal. Rptr. 240 (App. Div. 1989). A rape victim was brought to a hospital emergency room. Her mother arrived soon thereafter and inquired about the availability of the "morning-after pill." The hospital personnel refused to provide information because it was a Catholic hospital. The court concludes that the "conscience clause" within the state abortion law does not apply, because the "morning-after pill" is not an abortifacient drug, but a pregnancy prevention treatment. Also, the refusal to provide information about the "morning after pill" violates the patient's right to decide about therapeutic options.

Janaway v. Salford Health Authority, 3 All England Reports 1079 (1988). A secretary/receptionist was terminated from employment at a hospital for refusing to type letters concerning abortion. A statutory conscience clause protects those who refuse to participate in abortions from any adverse action. The court discusses the application of conscience clauses to hospital personnel who are not attending the patient. It con-

cludes that the word "participate" refers to those who are actually taking part in treatment. Therefore, the conscience clause does not apply to a secretary/receptionist.

#### **PROCREATIVE FREEDOMS**

Hugh Carey v. Population Services International, 431 U.S. 678 (1977). This case challenged the constitutionality of a New York statute which made it a crime for anyone to sell condoms to minors, for anyone but pharmacists to sell condoms to adults, and for anyone to advertise condoms. The case reviews the right to privacy concept as it has developed through the landmark case of Roe v. Wade. The court rules that procreative freedom is based on the right to privacy, which is a fundamental right. A fundamental right can only be infringed by a law if there is a compelling interest. In this case, the interest in having condom users informed by pharmacists as to the proper use of condoms was not compelling, since there was no evidence that pharmacists were in fact educating condom purchasers about proper use.

Hayes v. Shelby Memorial Hospital, 726 F. 2d 1543 (11th Cir. 1984). In this case the court was asked to determine whether a hospital can fire an x-ray technician when she becomes pregnant, to protect the pregnant employee's fetus from potentially harmful radiation, and to protect the hospital's finances from potential litigation. The court considers the possibility that facially neutral policies may nevertheless have a disproportionate impact on women. The hospital lost this case because it failed to consider less discriminatory alternatives to firing the technician.

#### RIGHT TO DIE/ASSISTED SUICIDE

Quill v. Vacco, 80 F. 3d 716 (2nd Cir. 1995). A state law banning physician-assisted suicide is unconstitutional. Physicians who are willing to do so may prescribe drugs to be self-administered by mentally competent patients who seek to end their lives during the final stages of a terminal illness.

Compassion in Dying v. Washington, 79 F. 3d.790 (9th Cir. 1995). A state statute prohibiting physicians from prescribing medications to end the lives of terminally-ill, competent patients is unconstitutional as violative of the due process clause of the Fourteenth Amendment to the Constitution.

#### 14 TEACHING AND LEARNING STRATEGIES IN PHARMACY ETHICS

Although neither of these cases directly mentions pharmacists, the holdings have very significant impact on the profession because both cases decriminalize physician *prescribing* of drugs for patients wishing to end their lives. While these cases establish a legal right to prescribe medications for this purpose, questions still exist as to the legality and ethics of pharmacists *dispensing* drugs for suicidal uses.

#### **BUSINESS ETHICS**

#### **Ownership Restrictions**

Liggett v. Baldridge, 278 U.S. 105 (1928). The United States Supreme Court held that a Pennsylvania statute requiring pharmacies to be owned 100% by pharmacists and barring corporations from having any pharmacy ownership interest is unconstitutional as a violation of the equal protection and due process clauses. The opinion discusses the importance of pharmacists in protecting the public health by providing safe drugs but reasons that corporate ownership of a pharmacy does not threaten public safety.

North Dakota Pharmacy Board v. Snyder's Drug Stores, 414 U.S. 156 (1973). In this case, the United States Supreme Court reversed in earlier holding in Liggett and holds that a law in North Dakota limiting the ownership of pharmacies to organizations that have at least 51% vested in a pharmacist is constitutional. The net effect of the state statute is to prohibit chain store pharmacies. The court concludes that a pharmacist would be more likely to observe the business of pharmacy with an intelligent eye than a casual investor who looked only to the standing of the stock in the market. The conclusion is that pharmacist-only ownership protects the public health.

For an interesting contrast to the above two cases, see the Opinion of the Attorney General of Michigan (OAG No. 6676, March 12, 1991) finding the state's Pharmacy Ownership Act, requiring at least 25% of a licensed pharmacy be owned by a pharmacist, is unconstitutional as a violation of the due process and equal protection clauses of the Constitution because the original purpose of the statute, to protect the health and welfare of the citizens, is no longer fulfilled and there are other, less restrictive means of assuring quality pharmacy practice. The net effect of this opinion is that the state Board of Pharmacy cannot deny a pharmacy license application where a pharmacist has no ownership of the pharmacy.

### Advertising

American Pharmaceutical Association v. Department of Justice, 467 F. 2d 1290 (6th Cir. 1972). The APhA Code of Ethics forbade advertising by pharmacists. Two pharmacists were notified to appear before the APhA Judicial Board to answer charges of unethical conduct based primarily on the advertising practices of their employers. The court briefly reviews the contention that a limitation on advertising is an antitrust violation. Underlying the case is the question whether a ban on advertising protects the public, or instead protects pharmacists from the economic effects of competition. The court concludes that the APhA should produce documents requested by the Department of Justice, so that action against APhA could proceed.

Smithkline Beecham v. Johnson & Johnson-Merck, 906 F. Supp. 178 (S.D. NY 1995) (Opinion) and (Slip Op. 95 Civ. 7688 HB, Dec. 6, 1995 as amended Dec. 12, 1995), 1995 U.S. Dist. Lexis 18184 (Order). Manufacturers of Pepcid AC® and Tagamet HB® sued each other for false and misleading advertisements under the Lanham Act. The trial court enjoined both manufacturers from making unsupported claims of superiority and assertions that one or the other product is preferred by physicians and/or pharmacists.

#### Contractual Issues

Shepard's Pharmacy v. Stop and Shop, 37 Mass. App. 516; 640 N.E. 2d 1112 (1994). Pharmacist negotiated the sale of his pharmacy to a chain. A few days before the scheduled closing a second chain made the pharmacist a substantially higher offer. The pharmacist refused to sell to the first chain. However, an advertisement announcing the sale appeared in a local newspaper with a picture of the pharmacist and a statement that he would stay on as the new manager. As a result of the ad, the second chain learned of the pending sale and withdrew its offer. Suit was brought against the first chain for unfair and deceptive business practices, economic coercion in announcing the sale before being completed, interference with business opportunities, emotional distress, and invasion of privacy for publishing his picture without permission. The jury awarded \$750 on finding interference between the pharmacist and his customers, but no interference between the pharmacist and the second chain. The judge awarded the pharmacist \$750,000 for invasion of privacy and doubled the amount under state law, finding the conduct was willful. Nearly \$57,000 in attorney fees was also awarded. Reversed on appeal because the evidence did not support a finding that the first buyer's conduct "attained a level of rascality that would raise an eyebrow of someone injured in the rough and tumble world of commerce."

## **Benefits Management**

Preferred Rx v. American Prescription Plan, 46 F. 3d 535 (6th Cir.), 1995 U.S. App. Lexis 2239 (Feb. 7, 1995). In exchange for a \$25 membership fee and an assignment of benefits agreement with plaintiff, patients' "copay" was waived on prescriptions filled by defendant's mail-order pharmacy. Plaintiff and defendant entered into an exclusive dealing contract whereby defendant billed plaintiff for each prescription at the average wholesale price (AWP) and plaintiff billed the patients' insurance company at its retail price, approximately 30-40% higher than AWP. After deducting the copay the insurance companies paid plaintiff. On learning that the defendant was doing business with other benefits administrators and competing against plaintiff for customers, plaintiff brought breach of contract and fraud suit. Jury awarded \$1.12 million in compensatory damages and \$1 million in punitive damages. Approximately \$61,000 was awarded on a counterclaim against plaintiff. In all major respects the verdict was affirmed on appeal.

## **Employment Freedom**

Slipepcevich v. Caremark, (Slip Op. 95 C 7286, Jan. 8, 1996), 1995 U.S. Dist. Lexis 110 (N.D. Ill.). Pharmacist was employed in a mail-order pharmacy under a written contract that prohibited his employment with a competitor for one year after termination from the defendant pharmacy if the competitive employment could involve disclosure of confidential information or trade secrets. He quit and took a job with a competing mail-order pharmacy. The former employer sought to bar the new employment in court, claiming that everything the pharmacist knows about mail-order pharmacy he learned in the course of his prior work. The trial court dismissed the claims noting that there was no allegation that the pharmacist took files, stole customers, or used any secret information. The court concluded that the noncompetitive clause was overly broad and would not be interpreted to prevent gainful employment in a competitive marketplace absent evidence of an actual breech of its prohibitions.

## **Marketplace Competition**

Domel v. Aetna Life and Casualty, 1995 U.S. Dist. Lexis 7049, (N.D. Cal.), May 10, 1995. Independent pharmacy brought federal antitrust

claims against insurance company and participating pharmacies after being excluded from pharmacy services provider panel. The district court dismissed all claims and characterized the exclusive provider network as having *de minimus* effects on competition and little more than an inconvenience to patients who are directed to other pharmacies.

Wal-Mart Stores v. American Drugs, 319 Ark. 214 (1995). Arkansas Supreme Court reversed lower court rulings in favor of independent pharmacies and held that chain stores pattern and practice of selling health and beauty items and prescription drugs does not violate state Unfair Practices Act absent evidence that conduct is intended to injure or destroy competition. According to the court, the statutory prohibition against predatory pricing does not bar "loss leader" sales in highly competitive market-places.

In Re: Brand Name Prescription Drugs Antitrust Litigation, 867 F. Supp. 1338 (N.D. Ill. 1994) (Denial of Summary Judgment), 1994 U.S. Dist. Lexis 16658, November 15, 1994 (Class Action Certification) and 1996 U.S. Dist. Lexis 8817, June 24, 1996 (Partial Settlement Approved). Over 4,000 independent and chain community pharmacies brought suit against approximately 45 brand-name drug manufacturers for discriminatory pricing policies favoring institutional and managed-care pharmacies. On June 23, 1996, a partial settlement involving eleven defendants was approved by the trial court awarding plaintiffs over \$300 million. The involved defendants agree to eliminate "class of trade" pricing. The settlement does not affect claims against other defendants or pharmacies who opted out of the settlement.

#### SELECTED READINGS

Abood RR, Brushwood DB. Pharmacy practice and the law. Gaithersburg, MD: Aspen Publishers; 1994.

Buerki RA, Vottero LD. Ethical responsibility in pharmacy practice, rev. ed. Madison, WI: American Institute of the History of Pharmacy; 1996.

Mullan K, Brown JM. The relationship between ethics and the law. In: Weinstein, BD; Ethical issues in pharmacy. Vancouver, WA: Applied Therapeutics; 1996.

Smith M, Strauss S, Baldwin HJ, et al. eds. Pharmacy ethics. New York: Pharmaceutical Products Press; 1991.