Legal and Ethical Considerations in the Treatment of Psychosis

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A variety of legal and ethical issues surround any decision about the treatment of patients with psychosis. These issues have come to the forefront with the introduction of the atypical antipsychotic agents. The law defines the minimum expected level of conduct for a health care professional, and where the law ends, ethics begin. Adverse drug reactions are a leading cause of death in the United States, and medication error is a common reason for liability claims against health care professionals. Patients alleging negligence must prove that the health care professional owed a duty to the patient, that the duty was breached, that the patient was injured, and that the breach of duty was the legal cause of the injury. Professional ethics are governed by various models for ethical decision making. The principles model, which can be readily applied to the patient with mental illness, is based on the ethical principles of beneficence, nonmaleficence, autonomy, utility, and justice.

(J Clin Psychiatry 1999;60[suppl 19]:59–65)

Health care professionals treating patients with mental illness recognize that a variety of legal and ethical issues surround the decision on specific treatment for each patient. Additionally, they recognize that a variety of forces are responsible for creating these issues. Perhaps most notable among these forces currently are advances in the overall clinical approach to the treatment of psychosis and in the therapeutic entities available for the treatment of psychosis. An example of advances in the clinical approach to treatment is the recent growth in privately and publicly developed clinical practice guidelines, and an example of advances in therapeutic entities is the recent introduction of the atypical antipsychotics.

Advances, whether in the clinical approach to treatment or in the treatments available, force the health care professional to reevaluate how existing patients are being treated and decide if a change in treatment is appropriate. These advances force the health care professional who is treating newly diagnosed patients to consider whether, and to what extent, it is appropriate to adopt a new method of treating a particular medical condition. For example, the introduction of atypical antipsychotic agents not only provided health care professionals with another therapeutic weapon, but also created new points on the decision tree. The health care professional has to decide whether to continue treating existing patients with the older typical antipsychotic drug products or switch patients to the newer atypical antipsychotics. When therapy is initiated for newly diagnosed patients, the health care professional must choose between a typical or an atypical antipsychotic agent.

Any decision on how to treat a specific patient with psychosis is surrounded by numerous considerations, each of which must be weighed by the health care professional possessing the authority and the responsibility to make the decision. The foremost consideration revolves around deciding which drug to try first in light of the patient's clinical presentation, e.g., whether the patient has been previously treated, or is currently being treated, with an antipsychotic drug or whether the patient is newly diagnosed. In today's managed care environment, perhaps the most likely next consideration would be whether the newer atypical antipsychotic drug products have been placed on the drug formulary for the managed care or other public or private insurance plan. If the drug is not on the formulary, but the health care professional believes the atypical drug product should be the therapy of choice for the individual patient, ethical considerations then arise, as discussed below. Today, with the attention being paid to accreditation, credentialing, provider profiling and report carding, practice guidelines, quality assurance standards, and cost efficiency in the delivery of health care services, the most common consideration in any patient care decision may well be the desired outcome of the treatment. In addition, legal and ethical considerations are common to every patient care decision. The legal considerations primarily in-

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Presented at the symposium "Antipsychotic Agents: Clinical, Economic, and Legal Considerations in the Treatment of Psychosis," held October 19–20, 1998, in Washington, D.C., and supported by an unrestricted educational grant from Eli Lilly and Company.

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volve understanding and complying with state and federal statutes and agency regulations, and where applicable, adhering to the law created by judicial decisions.

A number of state and federal statutes exist for the purpose of protecting persons with mental illness, and a number of cases concerning the rights of persons with mental illness have been decided by the courts, as have cases regarding the liability of health care professionals who are treating these patients. One series of decisions concerns the general rights of persons with mental illness, and specifically, the rights of these persons with respect to treatment for their mental illness, such as the right to refuse treatment under certain circumstances. Judgments involving tardive dyskinesia or other extrapyramidal symptoms (EPS) are of particular concern to health care professionals who treat patients with psychosis. The second series of decisions concerns the duty owed by health care professionals to their patients with mental illness and the resulting liability that may be imposed for failing to fulfill the duty. The concept of standard of care, which will be discussed in greater detail below, is of particular importance in this area.

DISTINGUISHING BETWEEN LEGAL AND ETHICAL CONSIDERATIONS

Quite often, articles are published concerning either the legal or ethical considerations surrounding some current issue in health care, but the 2 are of equal importance in the care of patients with mental illness, particularly psychosis. The law defines the minimum expected level of conduct, and where the law ends, ethics begins. To illustrate this concept, suppose that a patient with mental illness reports that he or she is being evicted from a place of residence and asks for the help of the health care professional. While the law may not require the health care professional to intervene, ethical principles may be viewed to require the health care professional to take some action. And if the health care professional takes action out of a deep sense of regard for ethical principles, the question may then become, when will the ethical duty be fulfilled and satisfied? In other words, where does one draw the line once the action taken exceeds the minimum required by the law and enters into the realm of ethical duty? Continuing the same example, suppose that the health care professional takes action, but the patient is nevertheless evicted from his or her place of residence. Certainly, it may be reasonable to expect the health care professional to spend the time necessary to make a few telephone calls to involve someone who can address the eviction. On the other hand, it may not be reasonable to expect the health care professional to invite the patient to live in his or her home. While it may be easy to draw the line between 2 extremes, as in this example, making judgments in the areas in between the extremes—the gray area—is not as easy.

In distinguishing between law and ethics, former U.S. Supreme Court Chief Justice Earl Warren stated:

> In civilized life, Law floats in a sea of Ethics. Each is indispensable to civilization. Without Law, we should be at the mercy of the least scrupulous; without Ethics, Law could not exist. Without ethical consciousness in most people, lawlessness would be rampant. Yet without Law, civilization could not exist, for there are always people who in the conflict of human interest, ignore their responsibility to their fellowman.
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> In the Law beyond the Law, which calls upon us to be fair in business, where the Law cannot demand fairness; which bids us temper justice with mercy, where the Law can only enforce justice; which demands our compassion for the unfortunate, although the Law can only give him his legal due, each of us is necessarily his own Chief Justice. In fact, he is the whole Supreme Court, from which there lies no appeal. The individual citizen may engage in practices which, on the advice of counsel, he believes strictly within the letter of the law, but which he also knows from his own conscience are outside the bounds of propriety and the right. Thus, when he engages in such practices, he does so not at his peril—as when he violates the Law—but at peril to the structure of civilization, involving greater stakes than any possible peril to himself.[1]

Some health care professionals may claim that ethics can be reduced to law. In other words, if one acts within the bounds of law, and fulfills all of the law's requirements, then one has discharged all ethical obligations. Such a philosophy does not serve the best interest of either the patients or the health care professions. This is demonstrated in the earlier example of the evicted patient, where it was seen that beyond the law's requirements there can exist an ability to act on behalf of the patient.

AN OVERVIEW OF LEGAL AND ETHICAL CONSIDERATIONS

In today's health care system, a number of parties are involved in the process of selecting and dispensing medication. As with treatment for many medical conditions, the treatment of the patient with psychosis may involve many if not all of the parties listed in Table 1. Indeed, sometimes the fact that so many different parties are involved in taking care of a patient is often overlooked. Some may question why patients, caregivers, and advocacy organizations are listed together with health care professionals. For decades, only 3 parties were truly involved in the medication use process: the physician prescribing the medication, the pharmacist dispensing the medication, and the patient using the medication. And historically, the patient's role in this process was very limited, since the patient usually had little knowledge about the medication. But today, patients actively seek information about their medications, and

Table 1. Parties Involved in Drug Therapy

Physicians
Nurse practitioners and physician assistants
Nurses
Pharmacists
Prescription benefit managers/managed care organizations
Pharmaceutical manufacturers
Patients
Patient fiduciaries and other caregivers
Consumer advocacy organizations
Federal and state government agencies
Private health care associations

pharmacists are now required by state and federal laws to provide patient and caregiver counseling about medications. In the area of psychosis, caregivers and advocacy organizations are extremely important and play an ever increasing role in achieving the desired therapeutic outcome. Clearly, to not consider these parties with the health care professionals fails to recognize the valuable ally they represent.

As one examines the legal and ethical considerations, many, if not all, of these parties may be involved in any given situation. Therefore, in addition to evaluating the effects a decision may have on the patient, one must also evaluate the potential effects on the other parties involved. While at first glance, one might believe that too many parties are involved, if these parties work together with the single-minded goal of improving the care provided to the patient, then many benefits may be realized. Because multiple parties are present, the opportunity for true interdisciplinary care is present. By cooperating, each member of the health care team can assist the others in carrying out the duties imposed by the legal and ethical considerations in treating the patient with psychosis.

The Legal Considerations

As readers of the professional and lay press, health care professionals have likely seen the articles describing the medication error problem that, over the last few years, have appeared with an alarming regularity. According to an article in *U.S. News and World Report*[2]: Patients are more likely to die from prescription medication than from an accident, pneumonia, or diabetes. Adverse drug reactions may be the fourth ranking cause of death in the United States, just behind heart disease, cancer, and stroke. More than 2 million Americans become seriously ill every year because of adverse reactions to correctly prescribed medications taken properly, and more than 100,000 die from those reactions. One in 15 patients hospitalized in the United States can expect to suffer a serious reaction to prescription or over-the-counter drugs, and about 5% will die from the reaction. A series of reports in *The Journal of the American Medical Association*[3–5] found that the chances of getting the wrong drug or the wrong dosage of a drug at 2 leading hospitals was nearly 1 in 50, with about 1 in 100 patients at real risk from such mistakes. Of 70 preventable mistakes in one study,[4] 44 caused serious or life-threatening reactions. Another study[5] attributed most errors to physicians and nurses who had inadequate information on either the drug or the patient.

Table 2. Median Jury Awards in Medical Malpractice Cases[a]

Type of Case	Median Award ($)
Childbirth	1,300,000
Medication error	621,000
Misdiagnosis	508,000

[a]Data from reference 8.

Medication errors in elderly patients were the subject of 2 major studies. In the first of these,[6] nearly 8.5 million, or 5%, of elderly patients' visits to their physicians resulted in one or more inappropriate medications being prescribed. On November 17, 1997, the federal government reported that up to one fifth of nursing home patients are receiving inappropriate medications, placing them at risk of such serious side effects as falls and delirium, according to a report in *Drug Topics*,[7] which also noted studies by the U.S. Department of Health and Human Services showing that 20% of patients were taking drugs that were judged inappropriate for the diagnosis.

Medication error is the fourth most common allegation in primary care malpractice lawsuits; the first 3 are improper or incomplete treatment, failure to diagnose, and delay of treatment.[8] In malpractice lawsuits, the most frequently cited medication errors are allergic reactions, side effects, excessive dose, incorrect dose, drug interaction, and use of a contraindicated drug. The median jury award for a medication error is $621,000 (Table 2). This information should be considered whenever the medication therapy of a patient with mental illness is being evaluated.

In 1993, the Physician Insurers Association of America (PIAA) reported a study of 393 medication error claims from 23 medical malpractice insurance companies (Tables 3 to 6).[9] The total indemnity payment on the 393 claims was $47,443,655, and the mean payment per claim was $120,722. The majority of claims were made in the specialties of internal medicine (30.3%) and family practice (29.0%), and the most common causes of medication error claims were incorrect dose, inappropriate drug, failure to monitor side effects, communication failure, failure to monitor blood drug levels, and lack of knowledge of drug. Death occurred in 83 patients.

The legal considerations related to use of antipsychotic drug products are essentially the same as for any drug product. Thus, more can be learned by examining the legal considerations for drug products in general than by examining only drug products used to treat psychosis, and then by applying the fundamental principles to the drug products used to treat psychosis. Certainly, one can discuss a potential liability claim against a physician if tardive

Table 3. Medication Error Claims by Physician Specialty in 393 Reports of Medication Errors[a]

Specialty	Error Claims (%)
Internal medicine	30.3
Family practice	29.0
General surgery	5.3
Obstetrics/gynecology	5.3
Orthopedic surgery	5.3
Pediatrics	4.3
Dermatology	3.6
Psychiatry	3.6
Other specialties	13.3

[a]Data from reference 9.

Table 4. Causes of Medication Error Claims in 393 Reports of Medication Errors[a]

Cause	Error Claims (N)[b]
Incorrect dose	111
Inappropriate drug	98
Failure to monitor side effects	81
Communications failure	71
Failure to monitor blood drug levels	52
Lack of knowledge of drug	52

[a]Data from reference 9.
[b]In some reports, there were multiple claims.

Table 5. Drugs Most Commonly Involved in Medication Error Claims in 393 Reports of Medication Errors[a]

Drug	Error Claims (N)
Antibiotics	54
Glucocorticoids	45
Analgesics	38
Nonsteroidal anti-inflammatory drugs/aspirin	28
Topicals/eye drugs	26
Cardiac/antihypertensives	20

[a]Data from reference 9.

Table 6. Primary Injuries Resulting From Medication Errors in 393 Reports of Medication Errors[a]

Central nervous system complications
Allergic reactions
Cutaneous injuries
Cardiac complications
Respiratory problems
Bleeding
Death[b]

[a]Data from reference 9.
[b]Occurring in 83 of 393 reports.

dyskinesia develops in a patient who has been treated long term with antipsychotics, but it is more important to discuss the fundamental, underlying problems that cause this situation to occur.

The legal standard of care is essential in determining whether a health care professional has liability to a patient for an alleged injury. The concept arises through the legal theory of liability known as negligence. The patient alleging negligence by a health care professional must prove the traditional 4 elements of the negligence theory. First, the patient must prove that the health care professional owed a duty to the patient. Second, it must be proved that the health care professional breached the duty owed because of an error or omission. Third, it must be proved that the conduct of the health care professional was the *proximate cause* of the patient's injury. This element requires the patient to prove that the conduct was the *cause-in-fact* of the injury, and that it was reasonably foreseeable to the health care professional that the conduct involved could result in injury. Finally, the patient must prove actual injury.

The standard of care relates to the first 2 elements of the theory and is used to determine whether the health care professional owed a duty and whether the duty was breached. In its simplest terms, standard of care is nothing more than asking the question, "What would the reasonably prudent health care professional have done under like and similar circumstances?" In essence, the answer to this question becomes the standard of care against which the health care professional charged with negligence is measured.

Several sources may be used in an effort to identify the standard of care applicable to any particular situation—testimony of expert witnesses, clinical practice guidelines, package inserts from the pharmaceutical manufacturer, and references from the medical literature. Perhaps the most recognized of the sources is the expert witness who offers an opinion on what the health care professional involved should have done under the circumstances. While all these sources are commonly used, none is absolute proof of the standard of care. In the end, it will be left to the trier-of-fact, such as a jury, to determine the most convincing source or sources offered and whether the health care professional involved breached the standard of care. As such, health care professionals should always consider how their conduct may be viewed if presented to a jury.

Health care professionals should actively practice risk management in the course of patient care. In the context of medication therapy, risk management focuses on preventing adverse events and outcomes and includes knowing the indications, contraindications, risks and benefits, adverse reactions, and toxicity of the Food and Drug Administration–approved drugs that physicians prescribe. An understanding of the various types of drug reactions should result in significant reduction or elimination of liability concerns.[10]

Specific to antipsychotic drug therapy is the issue of communication with the patient. The most significant question revolves around the mental competence of the patient, or where applicable, the patient's caregiver. How does the physician document that the patient understands the choice of medication therapy or that the patient fully appreciates the risks and benefits of treatment? These same questions may be applicable when a caregiver is in-

Table 7. Models for Ethical Decision Making

Model	Description
Duty	Best described as a consensus list of shoulds or shalls adopted by health care professionals, e.g., a code of ethics
Shared decision making	Health care professional determines the indications for medical treatment, which are then reviewed and discussed with the patient; each is allowed to express preferences and note concerns with various options for medical treatment; model based on what many believe is an inappropriate assumption—that the professional and patient are equally empowered in the decision-making process
Principles	Based on assertion that ethical problems only arise when conflicts between personal and professional principles (considerations worthy of deep respect in life and practice) appear; when health care professionals act professionally, they should do so with deferential regard to deep-seated principles

volved. At a minimum, notations should be recorded in the chart or other medical record maintained on the patient. These notations can be very valuable at a later time when trying to recollect events. A related issue is obtaining informed consent, either from the patient or from the caregiver. In the area of mental illness, one must also consider the role of a conservator or other patient representative. Written, informed consent from a patient or patient's representative, as is needed for surgical procedures, is seldom required at the start of drug therapy. Nonetheless, a notation in the chart or medical record summarizing the conversation with the patient or the patient's representative, as well as any observations related to perceived understanding and the granting of consent to initiate the medication therapy, is recommended.

As with virtually all medical conditions, the presence of psychosis presents the health care professional with choices of treatment, which may be influenced by several factors, such as whether the patient is institutionalized or an outpatient and whether the patient is able to function independently without caregivers. Components of treatment for the patient with psychosis may include supportive counseling and medication therapy as well as other recognized medical treatments. As the health care professional considers the choices of treatments available, active discussions about the choices and their relative risks and benefits should be conducted with the patient. Through such discussions, a decision can be made as to the most appropriate, and therefore hopefully most beneficial, treatment to employ.

Once a mode of treatment is selected, the decision-making process may still continue. For example, if the choice of treatment is medication therapy, the health care professional must then decide between one drug product versus another drug product. Specific to treating the patient with psychosis, this will involve choosing between the typical and atypical antipsychotics. When this decision is reached, the actual drug product to use will then need to be determined, using the factors that have been discussed above. As one proceeds along a decision tree or clinical pathway on how to treat a particular patient, all alternatives must be considered, and it must be ascertained that the patient or patient's representative understands those alternatives. Notations about this process should be continuously recorded in the chart or other medical record.

With respect to the choice of medication therapy, one should incorporate the knowledge gained from the PIAA study[9] of medication errors in the initiation and continuing management of the medication therapy. When therapy begins, it is essential to make certain that the drug product to be used is indicated for the mental illness involved and that it is being used in the proper dosage. Then a plan for continuing follow-up and management, which are essential, should be designed to avoid the problems identified in the PIAA study, such as the failure to monitor for side effects and failure to monitor drug levels, where appropriate.

The Ethical Considerations

Recognizing the purpose of a system of ethics is an appropriate beginning point to this discussion on ethical considerations. Three primary purposes for a professional system of ethics are generally recognized:

1. To illuminate and affirm the professional as an independent, responsible, and accountable individual who respects the rights of those individuals served by the profession.
2. No matter how broadly and detailed laws and regulations are written, there remain areas that must be covered by a system of voluntary self-discipline—the system of ethics.
3. To reconcile professional interests with the interests of society.

It is also appropriate to note why a professional ethic is important in the health care professions. First, it is one of several generally accepted criteria that serve to distinguish a profession from other occupations or businesses. Second, professionals are given certain legal prerogatives by society, such as a license to practice the profession. In return, the profession accepts responsibility to maintain a standard of conduct that goes beyond mere conformity to law or technical skill.

To assist those governed by a system of ethics, there exist various models for ethical decision making. Three of these models are particularly relevant to a discussion of treatment of the patient with psychosis (Table 7).

In the duty model, the focus is on expectations for conduct as established by a profession. The most common form for establishing these expectations is in a code of ethics. In addition, some professions have adopted standards of practice. However, such standards typically focus more

on specific patient care issues than on ethical conduct. In any event, health care professionals should review any expectations for conduct that may have been established by relevant state and national professional bodies and, to the degree appropriate, make sure their regular course of professional conduct meets these expectations.

The concepts of informed consent and assumption of the risk are at the heart of the shared decision-making model. In essence, the health care professional completely informs the patient, and together they make a decision. Of course, this model can be difficult to apply in treating the patient with psychosis because of underlying questions of mental competency of the patient to understand the information that is shared and to participate in the decision-making process. The model is based on what may be an inappropriate assumption that the professional and the patient are equally empowered in the decision-making process.

The principles model, which is based on the assertion that ethical problems arise only when conflicts between personal and professional principles (considerations worthy of deep respect in life and practice) appear, can be readily applied to the patient with mental illness. In this model, deferential regard to the deep-seated principles of beneficence, nonmaleficence, autonomy, utility, and justice (Table 8) should be at the heart of all professional actions. To demonstrate application of these principles, think back to the example of the patient about to be evicted from his or her place of residence. The principle of beneficence, which is the belief that the failure to benefit others when in a position to do so violates social and professional duties, could be argued in support of a position that the health care professional had an ethical duty to intervene and try to remove harm. Consider also patients who need all of their income for necessities and do not have public or private health care insurance and cannot afford medication therapy. The principle of beneficence could again be argued in support of a position that the health care professional should devote the time necessary to attempt to locate the medication. For example, a number of pharmaceutical manufacturers have established assistance programs for just such patients.

The principle of nonmaleficence calls upon health care professionals to first do no harm. Health care professionals may have a number of choices when deciding on a treatment to be rendered to a patient. Depending on the situation, all treatment options may be associated with some risk of harm. The principle of nonmaleficence could be argued in support of a position that the health care professional strives to utilize the treatment option that poses the least risk of harm, so long as it achieves the desired therapeutic outcome. For example, when selecting a typical or an atypical antipsychotic for a patient with psychosis, physicians have to weigh the long term risk of tardive dyskinesia into the decision. In a randomized, double-blind comparison of the incidence of tardive dyskinesia in patients with schizophrenia, the relative 1-year risk was 7.45% in the haloperidol-treated patients and 0.52% in the olanzapine-treated patients.[11]

Table 8. Principles Model of Ethical Decision Making

Beneficence	Whatever is done in practice is done for the patient's good
Nonmaleficence	Whatever is done in practice is done so as to cause as little harm to the patient as possible
Autonomy	Patients are involved in making their own health decisions
Utility	End result seems useful to the individual and society
Justice	Fairness is promoted in the system

The principle of autonomy can be troublesome in application to the patient with mental illness. The most general idea of personal autonomy—derived from the Greek *autos* (self) and *nomos* (rule, governance, or law)—is that of self-governance or being one's own person without constraints imposed by another person's action or by psychological or physical limitations. The autonomous person determines his or her course of action. Health care professionals generally have an inherent desire to help patients and lead them toward productive and happy lives, but unfortunately this inherent desire cannot be forced on patients without treading on the principle of autonomy. In other words, the principle of autonomy recognizes that patient who does not wish to accept the treatment or who is not responsible in using the treatment. It is the patient's right to remain untreated unless the patient is at risk of causing harm to self or, particularly, to others. Fortunately, there exists in the law procedures to obtain assistance in dealing with such a patient.

The principles of utility and justice can be demonstrated by recalling the earlier discussion concerning new advances in therapy, e.g., for a patient who has been treated for years with typical antipsychotics. Utility, which can be translated as "usefulness," represents the view that what is right is that which is most useful and the ultimate goal of society should be to produce the greatest possible balance of value over nonvalue. According to this principle, any decision is justified if it produces more good than the alternatives would produce. The principle of utility could be argued to require that the health care professional at least evaluates whether a new treatment advance would be more useful—in terms of providing more therapeutic benefit and/or less risk of harm—than the existing therapy. Of course, this point is not unique to the treatment of the patient with psychosis and calls for reevaluation when any advance in treatment becomes available. The principle of justice, best described in terms of fairness, states that one acts justly toward a person when that person has been given what is due or owed—thus what he or she deserves—and can legitimately claim. If the health care professional decides that the patient would benefit from the

new treatment, but learns that this treatment is not yet included in the patient's insurance benefits nor is the patient able to pay for the treatment, the principle of justice should be considered. Under the principle of justice, it could be argued that the health care professional may have an ethical duty to advocate for inclusion of the advanced treatment on the formulary. The principle of justice can be used to complement the argument that the health care professional owes this advocacy to the patient.

CONCLUSION

A number of legal and ethical considerations surround the treatment of the patient with psychosis, and this review was intended to stimulate the health care professional to think about these issues. With the knowledge gained through this review, the health care professional should better understand the causes of liability claims related to medication therapy and be in a position to apply this knowledge to treating patients with psychosis and other medical conditions. Also recognized now is the importance of documenting the process undertaken to reach the decision on the treatment to be implemented, as well as the follow-up and monitoring of the patient after treatment has been initiated.

Health care professionals have always been attentive to and respectful of their legal duties to patients, but beyond the legal duties, there are ethical duties. Certainly, determining the exact conduct required to fulfill an ethical duty may not be as clear as the conduct required to fulfill a legal duty. Perhaps one way to address this dilemma is for the health care professional to ask himself or herself, immediately after the patient visit is concluded, "Did I do all that I could for that patient?" An affirmative answer to the question will serve the health care professional well in responding to any allegation that the applicable legal and ethical duties were not fulfilled.

Drug names: haloperidol (Haldol and others), olanzapine (Zyprexa).

Disclosure of off-label usage: The author of this article has determined that, to the best of his knowledge, no investigational information about pharmaceutical agents has been presented herein that is outside Food and Drug Administration–approved labeling.

REFERENCES

1. Warren E. Special Address to the Lewis Marshall Award Dinner of the Jewish Theological Seminary of America. Nov 11, 1962; New York, NY
2. Double-Checking the Doctor. US News and World Report. July 17, 1995:70
3. Lazarou J, Pomeranz BH, Corey PN. Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. JAMA 1998; 279:1200–1205
4. Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events: implications for prevention. JAMA 1995; 274:29–34
5. Leape LL, Bates DW, Cullen DJ, et al. Systems analysis of adverse drug events. JAMA 1995;274:35–43
6. Aparasu RR, Fliginger SE. Inappropriate medication prescribing for the elderly by office-based physicians. Ann Pharmacother 1997;31:823–829
7. Ferguson WL Jr, Wilson DB. Medication errors: lessons in law. Drug Topics Jan 19, 1998:84–93
8. Still JG. A physician insurer's perspective on managing the patient using NTI drugs. In: At Risk: A Multi-Disciplinary Discussion of Clinical, Economic, and Legal Issues Associated With Narrow Therapeutic Index Drugs. Rockville, Md: PIAA; 1998:35–39
9. Physician Insurers Association of America. Medication Errors Study, 1993. Rockville, Md: PIAA; 1993
10. Gibofsky A. Legal issues in allergy and clinical immunology. J Allergy Clin Immunol 1996;98(6, pt 3):S334–S338
11. Beasley CM, Dellva MA, Tamura RN, et al. Randomized double-blind comparison of the incidence of tardive dyskinesia in patients with schizophrenia during long-term treatment with olanzapine or haloperidol. Br J Psychiatry 1999;174:33–38