

Update on Legal Issues Associated With Tardive Dyskinesia

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Of the various drug therapies, antipsychotic medication presents some novel twists to old issues in law and psychiatry. From what is known, its benefits are high but so are its risks, notably the risk of tardive dyskinesia in the case of the neuroleptics. Presented here for consideration are legal issues of standard of care, informed consent, the right of institutionalized patients to refuse treatment, statute of limitations, and causal nexus.
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What is the appropriate therapy for a diagnosis? The writer Jay Neugeboren relates the history of his brother Robert, who spent most of his life, since age 19, in mental hospitals and psychiatric wards in and around New York City:

Robert's diagnosis has changed frequently in the past 30 years, depending largely upon which drugs have been successful in keeping him calm, stable, or compliant. He was schizophrenic when enormous doses of Thorazine and Stelazine calmed him; he was manic depressive (bipolar) when lithium worked; he was manic-depressive-with-psychotic symptoms, or hypomanic, when Tegretol or Depakote (anti-convulsants), or some new antipsychotic or antidepressant—Trilafon, Adapin, Mellaril, Haldol—promised to make him cooperative; and he was schizophrenic (again) when various doctors promised cures through insulin coma therapy or megadose vitamin therapy or gas therapy. At the same time, often in an attempt to minimize side effects, other drugs were poured into him: Artane, Benadryl, Cogentin, Kemadrin, Symmetrel, Prolixin, Pamelor, Navane. . . .¹

It is not for lawyers to educate the medical profession on diagnosis or treatment or on tardive dyskinesia (TD). Their task rather is to apply general principles of law to what is known about a particular disorder and treatment. The court looks to standards or guidelines set out by the profession and to the experts (as proffered by the litigants) to inform it of the standard of care. Without expert testimony, a malpractice suit is dismissed.²

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In recent years, physicians in all areas of medicine have expended substantial efforts in setting out standards specifying treatments for particular illnesses. These standards or guidelines provide a means to judge the treatment provided by a physician. A departure from a widely accepted clinical standard may be presumptive evidence of lack of due care, but expert testimony is still required to introduce the standard and establish its source and its relevancy. The courts allow evidence of warnings in the *Physicians' Desk Reference* (PDR) and package inserts to establish the standard of care for use of a particular drug.³ Given practice guidelines, flexibility in treatment may be curtailed in trying new approaches.

In 1957, a brief communication first described 3 cases of neuroleptic-induced TD.⁴ In the following 10 years, some 600 new cases were reported in 37 papers. In the early 1970s, the number of publications and seminars on the subject markedly increased. The number of patients reported for the 1967-1972 period, some 1200, was double that of the previous 10 years. In 1973, the American College of Neuropsychopharmacology and the Food and Drug Administration jointly published a lengthy, detailed statement alerting physicians to the seriousness of the problem. In 1972 and 1973, the package inserts of all antipsychotic drugs, or so-called neuroleptic drugs, were updated to include information on TD.

An ever-increasing number of articles in medical publications warned physicians to use greater caution in the use of these drugs.⁵ The news also reached the general public. An article in 1979 in the *New York Times Sunday Magazine* on the TD side effect was headlined as "The Catch-22 of the Antipsychotic Drugs" and suggested that the cure may be worse than the illness.⁶ It quoted Dr. R. Sovner, psychiatrist at Tufts University School of Medicine: "Tardive dyskinesia is one of the most critical problems that psychiatry must face in the coming decade." One pharmaceutical company in its medical education service stated: "If the therapeutic gains made in the treatment of psycho-

sis are not to be undone, the clinical issues raised by this potentially irreversible drug side effect must be directly faced by the entire mental health community.⁷⁷

In the 1950s, little or no attention was given to TD; it was thought that there was no causal nexus between the drugs and the dyskinesia. There was great enthusiasm at the time as more and more medicated patients were discharged from hospitals. The introduction of neuroleptic drugs in the 1950s had an important role in allowing many patients to live outside the confines of the hospital. In the 1960s, some caution was expressed, but beginning in the 1970s, there was increasing alarm. A psychiatrist in an article in 1984 in a psychiatric publication warned, "The impending flood of tardive dyskinesia litigation has begun. I think that there is an enormous backlog of cases that is going to plague us for years."⁷⁸ The warnings were numerous.⁹ The pendulum swung to the other extreme of linking every dyskinesia to the drugs.

While the knowledge of TD is now more advanced, much remains disputed. The facts are not all in (they never are), but judging from the professional literature, one may conclude that everything on TD is in dispute except its definition. Apart from etymology (*tardive* is related to the word *tardy*, and *dyskinesia* from the Greek root, *kinesi*, meaning *to move*), what is actually known about TD? There is no agreement on its etiopathology, incidence, course, or treatment. In 1979, Dr. Daniel E. Casey, speaking on TD, quoted what Beauteille, the French neurologist, said in 1818 about Huntington's chorea: "Everything is extraordinary in this disease; the name is ridiculous, its symptoms peculiar, its character equivocal, its cause unknown, and the treatment problematical."¹⁰ TD is described in the American Psychiatric Association's 1994 edition of its *Diagnostic and Statistical Manual* as a late-occurring movement disorder that follows prolonged blockade of dopamine receptors in the brain.¹¹

In any event, the advent of the antipsychotic drugs revolutionized the treatment of the mentally ill, dramatically reducing the number of institutionalized mental patients in the country's mental hospitals. The treatment of chronic patients in the community is largely drug-oriented, often without other elements of appropriate psychiatric care. When patients suffer a relapse, the community support is often inadequate to bring the illness under control, and hospitalization is not considered an alternative. Those who are uncooperative because of disordered thinking are likely to be dropped from the rolls, and many end up causing problems in their families or becoming homeless or incarcerated.

Presented here for consideration, in the context of TD, are legal issues involving standard of care in or out of the hospital in view of risk-benefit, informed consent, the right of institutionalized patients to refuse treatment, statute of limitations, and, last but not vital, causal nexus. These legal theories are applied to what is learned from the medi-

cal information on TD. With the increased use today of psychopharmacologic medication, malpractice insurers have reported a marked increase in the cost and frequency of lawsuits alleging inappropriate prescribing.¹²

STANDARD OF CARE

Negligence is based on standard of care, and standard of care is measured by the risk involved in the circumstances. According to reports, high dosages of neuroleptics, prolonged therapy, and the age or sex of the patient increase the risk of TD.¹³ Apparently, the most important variable for determining the reversibility of TD is the length of time TD persists prior to discontinuation of the drugs.¹⁴ The failure to detect early signs of TD or to monitor and intervene in order to prevent further development has been a major area of malpractice litigation.¹⁵ Overdosage and inappropriate or unnecessary medication are also alleged in malpractice litigation.¹⁶ In establishing fault, the doctrine of *res ipsa loquitur* ("the thing speaks for itself") does not apply in TD cases since TD may occur in the absence of negligence.

In addition to the PDR and package inserts, the courts rely on the American Psychiatric Association guidelines for preventing and managing TD as set out by expert testimony.¹⁷ For the prevention and management of TD, a Task Force of the American Psychiatric Association suggested: "Review indications for neuroleptic drugs, and consider alternative treatments when available . . . Establish objective evidence of the benefit from neuroleptics, and review it periodically (at least every 3–6 months) to determine ongoing need and benefit."¹⁸

To the question, Is there a maximum suggested dosage for the antipsychotic drugs? the answer given is that the dosage for any age group should be the lowest possible dose that can sustain the patient at an acceptable level of improvement. That, though, is a platitude. Setting maximum guidelines for even the high-risk groups has been questioned; as is often said: "Dosage determination must be individually tailored to each patient." Concern over malpractice litigation, though, may push the practitioner to low dosage.

In law, the greater the risk of any treatment, the greater the duty to warn or monitor or to seek other alternatives. The risk of TD is high in the case of older patients treated with even low doses of neuroleptics, so the atypicals should be their first-line treatment. Certainly, when there is a relevant cost-benefit study, the accepted practice standard would dictate that the results, if irrefutable, should be followed; but in many cases, there is no relevant cost-benefit study, and in such instances, the better reasoned course is to yield to the collective experience of the medical profession. Otherwise, the evaluation and formulation of medical decisions would be left to the case-by-case intuition of judge or jury while the development of cost-benefit studies is awaited.¹⁹

There is no agreement on the prevalence of TD. Despite the relative ease of making the diagnosis, a large variation exists in the reported incidence of the syndrome, ranging from 0.5% to 50% of the psychiatric hospital population.²⁰ The variation in reported incidence may be the result of differences in the sampling procedure or in the criteria for the diagnosis of the syndrome.²¹ The results of many of the studies may easily have been distorted by the percentage of high-risk patients in the study. Most of the studies on TD have been done in state hospitals involving chronic schizophrenics or patients with organic brain syndrome. The other criticism of the studies is that some of the patients whose movements were held to be positive signs of TD had symptoms that were barely detectable. There is no agreed upon baseline. In some studies, a wiggle is taken as severe TD. In any event, although there are varying data on its incidence, a figure of 10% would be significant. With the new antipsychotic medication developed in the 1990s, called atypical antipsychotic medication, TD seems to be a rare occurrence, but there may be other side effects (such as weight gain and diabetes).

The U.S. Supreme Court, in a decision rendered in 1990 involving a mentally ill state prisoner who filed a civil rights action challenging prison policy that authorized his treatment with antipsychotic drugs against his will without judicial hearing, noted that the parties and *amici* sharply disagreed about the frequency with which TD occurs, its severity, and the medical profession's ability to treat, arrest, or reverse the condition, and it said, "A fair reading of the evidence, however, suggests that the proportion of patients treated with antipsychotic drugs who exhibit the symptoms of tardive dyskinesia ranges from 10% to 25%. According to the American Psychiatric Association, studies of the condition indicate that 60% of TD is mild or minimal in effect, and about 10% may be characterized as severe."²² Nearly a decade later, without noting the development of new medication, the Sixth Circuit Court of Appeals relied on the Supreme Court's citation of statistics on the side effects of antipsychotic medication: "[The Supreme Court] referred to expert testimony stating that 10% to 25% of the patients taking antipsychotic medication develop tardive dyskinesia."²³

From the beginning, some researchers have not regarded TD, reversible or not, as a significant danger of neuroleptic treatment.²⁴ In any event, the new atypical agents in the treatment of schizophrenia and related disorders are reputed to have a broader spectrum of clinical efficacy and a better risk-benefit profile than the classic neuroleptics. The older agents such as haloperidol and fluphenazine, as were involved in the Supreme Court's decision, tended to ameliorate the positive symptoms of schizophrenia while leaving negative symptoms such as apathy and social withdrawal largely untouched. Furthermore, as the term *neuroleptic* (seize the neuron) implies, the older agents showed therapeutic effects at doses essen-

tially inseparable from those that caused extrapyramidal side effects.²⁵

With the appearance of the atypical medications, the neuroleptics have fallen markedly in use. The development of the atypicals was prompted by the occurrence of TD in the use of the neuroleptics. The reduced risk of TD that accompanies the use of the atypicals is rapidly being seen by practitioners as the standard of care for schizophrenia, although the issue has apparently not yet been tested in the courts.²⁶ Expert testimony would likely weigh on the side of the new medication as the standard of care for particular diagnoses. Would a "respectable minority" of the profession justify the use of neuroleptics in view of the new medication? The "respectable minority" doctrine holds that if a minority of respected and qualified physicians approve of and practice a standard of care, that would constitute a sufficient defense to a malpractice claim.

There are reasons against the atypicals becoming the standard of care. Both types of medication—the new and the old—should be available in the armamentarium of treatments. For therapeutic reasons, an estimated 25% of patients are being treated with both the old and new medications. There may be no reason to turn entirely to new medication when old medication has proved therapeutic without serious side effects. The new medication is not without its side effects. Patients for one reason or another might prefer the old medication, but more likely than not, a patient who continues a long time on neuroleptics will develop TD, and the patient should be warned about it. Arguably, in the case of lengthy treatment, the psychiatrist should try to convince the patient to change medication and not leave it up to the patient. Under the concept of "informed refusal," the physician is obliged to inform the patient of the significant risks of inaction.²⁷ Cost considerations, however, may be a factor in the choice of medication. The old medications cost considerably less than the new, and lesser cost may be reason for the use of older agents. For reasons of economy, either in the state hospital system or outside, the new medications may be unavailable. Managed care companies may have only the old medications in their formularies (for failure to provide appropriate treatment lawsuits are mounting against health maintenance organizations [HMOs] on the ground of breach of fiduciary duty).²⁸ Then, too, in the case of forced medication, the use of new medications may be precluded because they are unavailable in injectable form.²⁹

An accurate diagnosis of TD, distinguishing it from other movement disorders, is a measurement of quality of care. The neuroleptic drugs may cause various movement disorders, including dystonia, akathisia, and pseudoparkinsonism as well as tardive dyskinesia, and the medical intervention required in each case is distinct. However, individuals with TD are not infrequently treated for parkinsonism, a commonly observed movement disorder, making TD worse and possibly decreasing the chances for

eventual remission.³⁰ These other neuroleptic-induced movement disorders, unlike TD, usually appear within the first 70 days of neuroleptic treatment, and they respond favorably to the appropriate drug therapy.

Early detection is said to be the key factor in the probability of eventual remission of all movement disorders. It has often been suggested that if drug treatment has extended for 3 months or more, the patient should be periodically examined to determine the presence of early signs, which include fine vermicular movements of the tongue, abnormal mouthing or chewing movements, and tics in the facial area, particularly blinking.³¹ (Some physicians sardonically label the mouth movement as the Wrigley or chewing-gum syndrome.) Since the physician will be afforded the opportunity to observe the patient only on an intermittent basis, prudence would require that he or she share with the patient's family this description of early warning signs to assure that these signs will not develop unnoticed. Moreover, thus posted, the patient or family would be hard put to challenge informed consent.³²

But it is known that early detection of tardive dyskinesia cannot always be made by simple examination. One of the most unusual characteristics of TD is that the onset and appearance of symptoms usually are not simultaneous. Paradoxically, for the majority of patients, TD may have already begun its course toward irreversibility before any reason for caution is apparent. Abnormal movements may be observed only when there is a decrease in dosage or discontinuation of medication. However, in some cases warning signs may appear though steady medication is maintained; the dyskinesia sometimes breaks through the mask of medication. TD may occur during the administration as well as after the cessation of medication. So it is no remedy to try to hide the dyskinesia forever by high dosage. Indeed, it is a dangerous course of action to try to suppress the symptom by continued or higher dosage. Such action may make irreversible what was a reversible form of the disability.³³

Does standard of care call for periodic drug-free trials or "drug holidays"? Interruption of neuroleptic treatment in patients receiving long-term therapy is widely recommended for two reasons: (1) it may unmask latent dyskinesia and thus help in an early detection of the syndrome, and (2) it may afford some protection for the long-term hazards of these agents.³⁴ According to these studies, drug holidays help assess whether the individual patient should be retained on these drugs while sustaining the patient. Occasional studies, however, report that those who get drugs on an interrupted program seem to do no better or even worse than those who get drugs regularly.³⁵ Yet, only a drug holiday may make it possible to detect or unmask the dyskinesia. But a holiday long enough to unmask the dyskinesia may result in a relapse and rehospitalization. Some patients are dependent on medication and are afraid of remission into a psychotic state; they often do not want

a drug holiday. And is detection an exercise in futility? What will the physician accomplish by clarifying the dilemma? TD or no, they say, it is still necessary to deal with the psychosis.

The potential development of TD, however, calls for a determination as to whether the patient can get along without drugs or on a lower dosage. There have been many cases of reported overdosage. Some guides on the frequency of drug-free intervals have been issued. A weekend drug-free schedule is a popular recommendation. Actually, cessation of medication 1 or 2 days a week is not really a drug holiday; it is the equivalent of a lower dosage.

Pharmaceutical reference guides, package inserts, and the regulations of the U.S. Food and Drug Administration (FDA) are important sources in malpractice litigation. These or other guidelines may be evidence in litigation in establishing standard of care. In a lawsuit, the guidelines may be the physician's best friend (when they have been followed) or his worst enemy (when they have not).³⁶ The innovative practitioner may be penalized even though his individualized approach may be in the best interests of the patient.³⁷ After much vacillation, the FDA denied that any use unapproved by it could be prima facie evidence of malpractice if untoward results occurred. However, the fact remains that any physician prescribing drugs in any manner discordant with approved methodology actually does so at his peril.

Time and again it is said that the benefits of antipsychotic medication outweigh its known risks. It is generally accepted that pharmacotherapy is the single most beneficial aspect of the modern treatment of psychosis and, as such, necessary for most psychotic patients.³⁸ It may be noted, however, that the common combined use of tricyclic antidepressants and neuroleptics in the treatment of depressed patients when tricyclics alone are adequate has been a questionable practice. This practice has been encouraged by the availability of fixed combination preparations of antidepressants and neuroleptics. Some practitioners argued that better treatment would be facilitated by their removal from the market. The combined compound resulted in giving a drug that was not needed or in a ratio not fitted to the needs of the patient. The lawyer could argue strict liability under products liability law in an action against the pharmaceutical company on the ground that it is a defective product.

There is, of course, no completely innocuous drug entity. For every drug benefit, there is a panorama of side effects. One may get a headache from pills taken for indigestion. Indeed, everything imaginable has a certain risk—it is a matter of what is gained compared with what is at risk. In most cases of drug therapy, undesirable responses are tolerated in view of the benefits, but what has been disturbing about the neuroleptic medications has been the apparent irreversibility of TD.

INFORMED CONSENT

The doctrine of informed consent—the “Miranda” warning of medical care—has achieved a status in the law on medical care unmatched in speed of growth and bulk of commentary and has caused increasing concern among physicians. To enforce this right of informed consent, two routes are available to the patient under tort law—one under a battery theory, another under negligence (malpractice). Under a battery theory, the skill with which the treatment is performed is irrelevant, since all that need be shown is that the treatment was performed without consent. Except in an emergency, there must be a consent to treatment—more particularly, an informed consent—otherwise the law considers that there is an invasion of one’s dignitary interest; it is this interest that is protected under the tort law of battery.

Under traditional law, as a defense to a claim of battery, the physician only needed to relate what he proposed to do and obtain the patient’s consent thereto. However, simultaneously with the growth of product liability and consumer law generally, the courts began to require that the physician also relate sufficient information to allow the patient to decide whether such a procedure is acceptable in light of its risks and benefits and the available alternatives. The risks of no treatment must be spelled out as well as the risks of treatment. That duty of full disclosure gave rise to the phrase “informed consent.” Uninformed consent is the equivalent of no consent. The law on informed consent is known as therapeutic jurisprudence: obtaining informed consent may bring about clinical gains by making the patient an active participant in treatment and enhances the therapeutic alliance.

Around 1960, the failure to obtain an informed consent began to be considered as a breach of the physician’s professional duty, and hence as a matter of negligence (malpractice) requiring expert testimony. The considerable majority, if not all of the cases, now proceed on that basis. The Texas legislature, at the behest of medical groups, enacted a statute requiring all suits alleging failure to inform, or to inform adequately, be based on negligence rather than the intentional tort of battery.³⁹

The vacillation in the various states on the applicable theory represented a shifting adjustment in favoring the aggrieved patient or the defending doctor. The informed consent doctrine as developed under battery was a form of legal first-aid for a complaining patient, as it made the patient’s suit less complicated. The application of the negligence theory has removed some vexatious suits (under a negligence theory other physicians may be called to testify on the merit of giving information) and has made insurance coverage more certain, since some policies do not provide coverage against suits for intentional wrongs like battery. A negligence action may be submitted to a medical liability mediation panel as well.

Under negligence, liability is based on the theory of “failure to use due care.” Due care requires the physician to advise the patient of the risks of therapy; of course, there may be failure to use due care apart from the matter of information. Prescription of neuroleptics or other medication for a patient whose condition does not justify the risks of the medication is negligence, even with consent. Consent does not provide a shield against liability. When there is an untoward result, it may be found that there was negligence in treatment or that there was no warning about a risk. The best safeguard is liability insurance.

The information that must be given to the patient need not include any and all risks of treatment or no treatment; it must cover the “material” risks. There is no duty to discuss “relatively minor risks when it is common knowledge that such risks are inherent in the procedure and are of very low incidence.”⁴⁰ A physician must tell a patient of consequences that he knows will ensue, such as that the patient will have a stiff knee after an arthrodesis of the knee joint, but surely where there is only a remote possibility of complications—as when the complications are “very unusual,” “extremely uncommon,” “could not have been expected by any stretch of the imagination”—there is no duty to mention it. The physician should be consistent in what is told patients; inconsistency may work against the physician in a malpractice suit.

The question is thus again raised: Is TD a material risk? It is the crucial question. The more dangerous the treatment, the higher the standard of informing. While the incidence of TD is rated in the low percentiles, this disorder may be seriously disabling when it does occur. A person affected with TD is given to grotesque involuntary movements of the face or extremities or sometimes the whole body. Needless to say, such nonpurposeful movements can be a social and professional handicap. Informing the patient about this possible side effect is important because even the most cautious approach to antipsychotic medication may not guarantee that the disorder will not appear. Failure to inform the patient of the risk of TD has been a frequent basis of litigation.⁴¹

When should disclosure about TD be made? The acutely psychotic patient needs rapid treatment and is in an extremely stressful situation. Frequently, the individual is frightened by medication or is disoriented and is beyond communication. The emergent nature of the situation or therapeutic privilege may justify the use of antipsychotic medication without disclosure of risks, and, when the patient has been calmed down, he or she can then be informed of the risks of further treatment. A period of time is necessary, as a practical matter, for the individual to realize the value of the medication in reversing a psychotic episode. A discussion of the risks of medication may prevent early intervention by frightening the patient away from medication and resulting in greater deterioration. Moreover, when a relationship with the physician has developed, patients are

usually willing to sign just about anything that is put before them.

Dr. R. Sovner and colleagues have suggested obtaining informed consent at the initiation of treatment: "We believe that this extrapyramidal syndrome alters the risk-benefit ratio of neuroleptic drug therapy for certain patients to the degree that informed consent in writing should be obtained from them prior to the initiation of treatment."⁴² But unlike in the case of other therapies, is it necessary to inform at the commencement of neuroleptic therapy? Dr. Jerrold G. Bernstein advised in his widely used book on drug therapy, "Since tardive dyskinesia does not occur early in the course of antipsychotic treatment, it is probably not appropriate to discuss this complication at the outset of treatment; discussion of this potential complication can be reserved until later in the treatment, after the patient recovers from the acute manifestations of psychosis, and the physician has decided on a course of treatment which may involve a more prolonged period of administration of the neuroleptic."⁴³ Likewise, Dr. Frank J. Ayd advised that in the initial stages of neuroleptic therapy, especially when it is reasonable to assume that neuroleptic administration will be of short duration, the risk of TD need not be stressed because all the available data (with the exception of one report) on the time of onset substantiate that it rarely appears until after 3 months of neuroleptic therapy, the risk increasing steadily thereafter. Thus, as they suggest, physicians need not stress the risk of TD at the outset of neuroleptic therapy, particularly anticipated short-term therapy, because the risk is so minimal under 3 months.⁴⁴ Since patients may change physicians, it is important however to have the patient's neuroleptic drug history. In determining causation, the law is interested more in the straw that broke the camel's back than in all the straws already piled on its back.

The type of warning must also bear relationship to the risk. How should disclosure about TD be made? Does its incidence warrant disclosure only in passing, or, on the other hand, does it warrant disclosure by video presentation? One will not find an answer in the law books, and one will not find it in medical treatises. In medicine, it is a matter of what information for which patient at what time. The art of medicine is the ability of physicians to know what psychological approach would be best for each of their patients; to lay down rules runs counter to individual care.⁴⁵ Various clinics and hospitals use the same consent form irrespective of the type of antipsychotic medication that is prescribed, though the risks are different, but in any event, patients when filling a prescription are given information about the medication, and they may be puzzled when the information is different from that provided by the physician.

Informed consent does not afford absolute protection from liability, but obtaining it (in writing) does indicate that the physician has attempted to advise the patient of

the possible consequences of therapy. Written consent is the best evidence, and in some jurisdictions, a writing is required. Not having a written consent can work against the physician, but having it is usually no shield against liability.

Fearing litigation, physicians in recent years as a matter of course have been obtaining a written consent for all types of treatment. Under the consent doctrine, it is not what is done, but how it is done that is crucial. In effect, it is a type of gamesmanship or, some say, salesmanship. A consent, oral or written, may be vitiated by incompetency or undue influence, but be that as it may, the custom of the day is the written consent form. This custom has led to a lot of paper passing between physicians and patients. In this connection, it may be well to remember an old legal saying: "If parties write at all they must write it all because the law presumes they wrote it all if and when they write at all." Some attorneys believe that a tape recording of the transaction is the most dramatic and effective evidence to defeat a claim of uninformed consent.⁴⁶

In the event of doubt as to the patient's competency, it is advisable to obtain the signed consent from both the patient and a proxy. The argument that a patient voluntarily agreed to assume the risk of TD cannot be successfully invoked against a patient who was incompetent or marginally competent to understand the risks and benefits of the treatment. Proxy consent is usually obtained from the patient's next of kin or the closest possible family member. Guardian or consent by a close relative may be legally adequate when arising out of traditional circumstances. (Quite often, however, it may be difficult to reach a guardian or close relative, so the situation might be described as an emergency, which is an exception to the need of an informed consent.) Proxy consent by a close relative is allowed as a practical matter because, if a guardian were appointed who would have legal authority, it would be the relative who would be named as guardian.⁴⁷ Quite often, a nursing home operator who is named guardian beseeches the physician to prescribe medication on the heavy side so as to render management of the patient easier.

In obtaining an informed consent, no pat formula can be stated on how much information must be given. In practice, the physician, pressed for time, either speaks too rapidly or gives the patient some printed material; sometimes the patient is referred to the library. Actually, one obliged to furnish information must steer between the Scylla of insufficient detail and the Charybdis of an excess of information. Either may result in a lack of informed consent. Like a kind of "Gresham's Law of Information," too much trivial information drowns out the vital.⁴⁸

In theory, competency is an independent variable that determines whether the patient's decision about participating in treatment will be honored, but competency is actually dependent on the interplay of the risk-benefit ratio of treatment and the consent of the patient. The more favor-

able the risk-benefit ratio, the more likely it is that a patient refusing that treatment will be judged incompetent and the more rigorous will be the test that is used to evaluate the patient's competence. Judgments on competency and consent are linked to economic and social facts.⁴⁹

There are several exceptions to the informed consent doctrine: (1) emergency; (2) therapeutic privilege; (3) waiver; and possibly (4) care of the involuntarily committed patient. In the case of an "emergency," the rationale for the exception is that the patient's consent is "implied," inasmuch as a reasonable person would consent to treatment in an emergency if able to do so. The term *emergency*, however, is not self-defining. The therapeutic privilege is justified when disclosure would complicate or hinder treatment or pose psychological harm to the patient. Few cases turn on its application. The waiver exception comes into play when the patient specifically requests not to be informed about the risks but wants only the physician's final judgment.

INSTITUTIONALIZED PATIENTS

The extent to which treatment may be imposed on a patient who has been involuntarily committed to a hospital for care and treatment has been and remains controversial. The popular phrase is "right to refuse treatment." The hospital physician may find himself in the dilemma of having the responsibility to treat an individual committed by the court for "care and treatment," and finding the individual refusing the very treatment that may ameliorate the condition for which he is committed. At the same time, the physician or institution may be threatened with a "false imprisonment" or "right to treatment" suit because the patient is not receiving treatment.

The right or competency to refuse treatment has a lengthy litigation history and continues to be hotly debated.⁵⁰ Some courts have drawn a line between "intrusive" and "nonintrusive" therapies, the former requiring court approval. In 1976, the Minnesota Supreme Court rated drug therapy as more intrusive than milieu therapy and psychoanalysis, but less intrusive than aversion therapy, electroshock, and psychosurgery.⁵¹ Subsequently, a Minnesota trial court ruled that the use of fluphenazine does not qualify as an "intrusive form of psychiatric treatment" calling for court approval.⁵² The Massachusetts and Washington Supreme Courts have equated the intrusiveness of psychotropic drugs with electroconvulsive therapy (ECT) or psychosurgery, and therefore psychotropic drugs should be treated "in the same manner we would treat psychosurgery or electroconvulsive therapy."⁵³

Statutes have been enacted in regard to forced medication. They are designed to safeguard a patient's right to be free of forced medication unless the prescribed medication is necessary to effectively treat the patient, unless the medication is the least restrictive form of intervention avail-

able for the patient's treatment, and unless the benefits of the medication outweigh its known risks to the patient.⁵⁴ Under the doctrine of "least restrictive alternative" or "least intrusive alternative," when a drug is not available in injectable form (as in the case of the atypical antipsychotic medication) and the patient refuses to take it orally, then the medication that may be regarded as more intrusive because of its side effects (the neuroleptics) may be forced upon the patient.⁵⁵ Nowadays, in many jurisdictions, at the time of commitment a treatment order is usually issued along with the order of commitment to obviate the need of court approval for forced treatment, just as in an earlier time when a competency hearing was routinely part of the commitment process.

Should new findings on TD result in a reordering of the classification of intrusiveness of antipsychotic medication? In the past, before the advent of the atypical antipsychotics, some observers claimed that knowing more about how psychotropic drugs worked might cause us to consider them more intrusive, because of their side effects, than ECT. The advent of the atypicals may bring about a different view of intrusiveness.⁵⁶

Sometimes patients who refuse medication are willing to accept another medication but it is not made available. In an instance where that was contested at law, a patient in the Texas hospital system some years ago complained of lack of equal access to clozapine. The petitioner claimed a denial of equal protection of the law under the 14th Amendment. Finding that it could not afford to provide the medication for all patients who might benefit from it, the State of Texas decided to provide it to no one; it has since changed its policy, finding that it was penny-wise but pound-foolish. In a case in Kansas,⁵⁷ a female patient, diagnosed as schizophrenic and long-time haloperidol user suffering from TD, got an injunction prohibiting the State Department of Social and Rehabilitative Services from refusing to provide coverage for clozapine. The refusal to cover clozapine in this instance was unlawful because it arbitrarily reduced coverage given to an individual solely on the basis of her illness.⁵⁸ The patient needed clozapine because the more usual drugs prescribed for her schizophrenia aggravated her TD. The State of Michigan, among other states, provides clozapine to all patients who might benefit from it.

The various issues that have arisen in the treatment of patients in mental hospitals have also arisen in regard to the treatment of prisoners in correctional facilities. The most widespread form of treatment in correctional facilities is psychotropic medication, and this finding has raised issues as to whether the medications are prescribed on the basis of a bona fide clinical diagnosis and not for punishment or control; whether medications are administered by qualified nurses, with periodic monitoring for effectiveness, side effects, and polypharmacy; whether appropriate laboratory tests are done and recorded; and whether the

formulary provides for access to the full range of medications that are safe and effective for the treatment of mental illness, including the newer generation of medications.⁵⁹

The U.S. Supreme Court has upheld the state's authority to forcibly administer antipsychotic medication for the treatment of a prisoner or to protect the safety of other prisoners and prison staff. The Court said that a convicted prisoner's refusal of antipsychotic medication, which it recognized to be a liberty interest protected by the due process clause of the 14th Amendment, was "adequately protected, and perhaps better served, by allowing the decision to medicate to be made by medical professionals rather than a judge." After acknowledging the fallibility of medical and psychiatric diagnosis, the Court stated that the shortcoming of medical specialists cannot necessarily be avoided by shifting decision-making authority from trained specialists to an untrained judge or administrative hearing officer. The Washington State policy had procedural components: the inmate had to be told the tentative diagnosis, the factual basis of that diagnosis, and why medication was necessary; a hearing had to be held with the right to cross-examine witnesses and the assistance of a lay advisor; and, finally, periodic review of the inmate's need for medication was mandatory. The Court found that the requirements of both state law and the due process clause of the 14th Amendment were met by Washington State's policy.⁶⁰ On another occasion, the Court asked whether the "treatment with antipsychotic medication was medically appropriate and, considering less intrusive alternatives, essential for the sake of [the individual's] own safety or the safety of others."⁶¹ Various state laws require court approval for forced antipsychotic medication.⁶²

Much has been written about the marked transformation of correctional institutions over the past decade or so. With the closing of mental hospitals, jails and prisons have become "America's new mental hospitals."⁶³ There has been an explosive growth in the population of seriously mentally ill inmates in correctional facilities not only because of the closing of state mental hospitals but also mainly because of the emphasis now on incarceration of criminal offenders. Since 1970, the prison population has increased from 260,000 to 1.8 million people in 1997 (nearly a 600% increase).⁶⁴

The Supreme Court has said that these institutions are constitutionally required to develop a capacity to provide adequate mental health services for inmates in their custody.⁶⁵ More precisely, they cannot be "deliberately indifferent" to "serious medical needs" of inmates, including the need for mental health treatment.⁶⁶ Though many psychiatrists who used to work in the now-abandoned state hospitals now work in correctional facilities, the most commonly found problems in correctional mental health programs are the use of medication without adequate professional involvement and monitoring; the failure to provide for involuntary administration of antipsychotic medi-

cation when clinically indicated; the lack of access to mental health professionals in a crisis, or in sufficient numbers to provide treatment to the treatable inmates with serious mental disorders; the failure to have an adequate program of suicide prevention; and prolonged delays in access to treatment, during which the inmate's condition substantially deteriorates or the inmate experiences needless suffering.⁶⁷ Because of the expense of treatment and in view of the obligation of the institution to provide treatment, inmates are sometimes discharged from prison rather than provided treatment (e.g., as in the case of a prisoner with AIDS).

STATUTE OF LIMITATIONS

Another issue: When does the statute of limitations' "clock" begin to run in a malpractice case involving TD? Statutes of limitations on malpractice usually provide that suit must begin within 2 years from the time the claim accrues. Does the claim accrue at the time of last treatment or from the time of appearance of the dyskinesia? As the name "tardive dyskinesia" suggests, it is a "late-appearing movement disorder" evolving as imperceptibly as the unfolding of a flower.⁶⁸ As reported, it does not develop until after a person has been taking the drugs for many months, and it often appears for the first time after the person stops taking the drug. It then blossoms out, for, strangely enough, the drug often masks the disorder it causes.

As a consequence, this delay in appearance of symptoms may find the opposing sides in litigation arguing whether the cause of action begins at the start or end of medication or at the time when the harm was first realized by the patient. The majority of jurisdictions hold that in such cases a cause of action accrues and the prescriptive period begins to run on the date the claimant discovered, or with reasonable diligence should have discovered, the alleged harm.⁶⁹ Some courts have ruled that the statute begins to run only when the patient is aware not only of his disability but also of the linkage of the treatment to his disorder. Under this line of jurisprudence, the claim begins to accrue only when the patient becomes aware that his disability was caused by the physician's treatment.⁷⁰

CAUSATION

To establish tort liability in battery or negligence, a causal nexus must be established between act and injury. This linkage is fundamental and logically ought to be considered before all other matters of proof. It is necessary to pinpoint the aggrieving agent or ministrations.⁷¹ The judge instructs the jury at the time of their deliberations: "The legal cause of an injury is a cause which, in natural and continuous sequence, produces the injury, and without which the injury would not have occurred." Thus the patient must establish that the harm of which he complains

occurred as a result of the ministrations of the physician who is blamed. The question of negligence, discussed above under standard of care, is not to be confused with that of the causal connection between the negligence and the injury. They are 2 different elements of a tort case that must be established. The patient must offer proof that the TD occurred more probably than not as the result of the physician's prescription. The DSM states, "Although [movement disorders] are labeled 'medication induced,' it is often difficult to establish the causal relationship between medication exposure and the development of the movement disorder, especially because some of these movement disorders also occur in the absence of medication exposure."⁷²

Even before the advent of the neuroleptics, there was the occurrence of TD. Schizophrenia is a neurologic disease that has a motor component. Without any exposure to neuroleptics, patients may develop spontaneous neurologic disorder associated with schizophrenia, and at a lower rate with other disorders. On the other hand, with exposure to neuroleptics, there is a greater risk of developing TD in the case of mood disorders. In the case of patients with disorders other than schizophrenia, the emergence of a movement disorder is almost always the result of neuroleptics.

In the case of a particular patient with schizophrenia, it is not possible to determine whether the involuntary movement was due to the schizophrenia and not neuroleptic induced. So, in either case, the courts tend to rule that the appearance of an involuntary movement is the result of medication.⁷³ The courts have grappled with the subject of epidemiology and what it means to establish causation. The burden of proof in civil cases is typically "preponderance of the evidence" (i.e., "more likely than not"). In a case where radiation was alleged to be the cause of cancer for various citizens in Utah, the Court provided an analysis of statistical significance in establishing causation:

In a case where a plaintiff tries to establish a factual connection between a particular "cause" and a delayed, nonspecific effect such as cancer or leukemia, the strongest evidence of relationship is likely to be statistical in form. Where the injuries are causally indistinguishable, and where experts cannot determine whether an individual injury arises from culpable human cause or non-culpable natural causes, evidence that there is an increased incidence of the injury in a population following exposure to defendant's risk-creating conduct may justify an inference of "causal linkage" between defendant's conduct and plaintiff's injuries.⁷⁴

Sometimes the proximate cause of the patient's developing TD can be attributed to the patient (or the family). Thus, in one case summary, judgment was granted in favor of the psychiatrist because the patient had failed to inform him of side effects she was experiencing until it was too late for him to effectively treat them. The court noted that, as under traditional law, the plaintiff has a duty to exercise

ordinary care for her own protection by keeping her physician informed of problems she might be having with the prescribed treatment.⁷⁵

The physician coming on the scene late in the treatment of the patient may be held to have caused a disability although his prescribed dosage was on the low side. Legal, or proximate, cause is illustrated by the story of the camel whose back was broken by a straw added onto the load already on the camel's back. A similar result is reached when pollution of a stream results from conduct that might otherwise have been harmless but for the prior history. To be sure, one or more of the polluters may be held responsible for the harm done. Quite frequently, the psychotic patient has a history of medication, hence it is important to have the patient's drug history.⁷⁶

There are apparently no direct reports of TD occurring as a result of therapy with the tricyclic antidepressant drugs alone. There are a few instances reported of TD that have occurred in patients who were taking tricyclic antidepressants and antipsychotic medication concurrently. In most of these reports, the antipsychotic drugs used were the phenothiazines. However, the medications associated with the development of TD are not limited to the neuroleptics.⁷⁷ TD can be caused or influenced by other pharmacologic agents, or it may occur spontaneously.⁷⁸ Several drugs have been identified that exacerbate TD.

A study by the research department of the Carrier Foundation reported a significant prevalence of TD among elderly residents of nursing homes who have never received neuroleptics. This study strongly suggested that aging either alone or in combination with senile brain disease may produce a syndrome that may be called "spontaneous dyskinesia," and that neuroleptics cannot be held solely responsible for dyskinesia.⁷⁹ What seemed to be TD, by description, was noted already by Kraepelin in the 1890s in elderly (chronic) patients diagnosed with dementia praecox—this long before the pharmacologic revolution.

DRUG MANUFACTURER'S LIABILITY

The liability of a drug manufacturer under products liability law is another specific ground of liability. Drug manufacturers are subject to strict liability, rather than simple negligence, for failure to warn of known or knowable risks of their product.⁸⁰ Manufacturing defect, design defect, and failure to warn are distinguishable causes of action. The Restatement of Torts⁸¹ provides that those drugs that are incapable of being made safe in design for their intended uses are not deemed defective if "properly prepared and accompanied by proper directions and warning."

A product has a manufacturing defect when, as produced, it does not conform to the manufacturer's own design. In contrast to a manufacturing defect, which usually occurs in only a small portion of any particular mass-produced product, a design defect is one that occurs in an

entire product line. Much of the controversy surrounding design defect liability involves the difficulty of making risk-benefit assessment. The Restatement of Torts and much of the case law refer to drugs as “unavoidably unsafe” and decline to impose liability on the pharmaceutical company or distributor for harm that results after an adequate warning of the risks is given.

A prescription drug is deemed defective in design if it is not reasonably safe “at the time of sale or other distribution.” It is not reasonably safe when the foreseeable risks of harm are so great in relation to foreseeable therapeutic benefits that a reasonable health care provider who knows of the feared risks and hoped-for benefits would not prescribe the drug for *any* class of patients. The any-class-of-patients provision means that if the drug has net benefits for any class of people it is not a design-defective drug, even though its overall harm far exceeds its overall benefit. Otherwise stated, once a drug is shown to have net benefit for any group, the manufacturer’s or distributor’s liability is limited to manufacturing defects or to failure to provide appropriate warnings or instructions.⁸¹ FDA approval assures the pharmaceutical company against liability on the ground of defective design, unless there is fraud in regard to significant information provided the FDA.

The duty of the pharmaceutical company is to provide information to the physician so that the physician can make an informed decision on risk-benefit. The theory is that the physician is a “learned intermediary” who is in the best position to make a risk-benefit assessment. There is no duty on the pharmaceutical company to warn the consumer directly, and that remains the law notwithstanding the massive increase of medication advertising directed at consumers (e.g., sildenafil). The FDA only requires advertisements to mention the most common side effects, ignoring uncommon, but often troubling and serious side effects.⁸²

CONCLUSION

At one time no movement disorder was called TD; now, in some circles, every movement disorder is given that label. TD is not a myth, but it is also not an epidemic, especially today with developments in medication. Every drug—being a chemical—is bound to have some untoward side effect. Is the use of antipsychotic medication a necessary trade-off between psychosis and TD? What are the options? The “risk-benefit” or “cost-benefit” ratio speaks to the use of antipsychotic medication, yet at the same time, says little. What is the measuring stick? Can we measure it in dollars? To be sure, the issue cannot be evaluated in numbers; it is a way of thinking. Although it appears that the benefits of the drug outweigh the risks, the crucial question is really whether or not TD is avoidable. If not avoidable, then a consent that is informed about the risks is essential. If avoidable, then consent is no safeguard against liability.

Drug names: amantadine (Symmetrel and others), benzotropine (Cogentin and others), carbamazepine (Tegretol and others), chlorpromazine (Thorazine and others), clozapine (Clozaril and others), diphenhydramine (Benadryl and others), divalproex sodium (Depakote), haloperidol (Haldol and others), loxapine (Loxitane and others), nortriptyline (Pamelor and others), perphenazine (Trilafon and others), procyclidine (Kemadrin), risperidone (Risperdal), sildenafil (Viagra), thioridazine (Mellaril and others), thiothixene (Navane), trifluoperazine (Stelazine), trihexyphenidyl (Artane and others).

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

NOTES AND REFERENCES

1. Neugeboren J. Meanwhile, back on the ward.... Am Scholar 1994;63:337. It is not a unique story. See also Wyden P. Conquering Schizophrenia. New York, NY: Knopf; 1998
2. Lince v Monson, 363 Mich 135, 108 NW2d 845 (1961); see Slovenko R. Malpractice in psychotherapy: an overview. Psychiatr Clin North Am 1999;22:1
3. Bowman v Songer, 820 P2d 1110 (Colo 1991); Thompson v Carter, 518 So2d 609 (Miss 1987). In Morlino v Medical Center of Ocean County, 706 A2d 721 (NJ 1998), the court held that the PDR does not alone establish the standard of care, although the jury may consider portions of the PDR, when supported by expert testimony, in determining the standard.
4. Schonecker M. En eigentumliches Syndrom im oralen Bereich bei Megaphen Applikation. Nerventanz 1957;28:35. Noted in: Crane GE. Persistent dyskinesia. Br J Psychiatry 1973;122:395
5. See, eg, Crane GE. The prevention of tardive dyskinesia. Am J Psychiatry 1977;134:756
6. Steinmann M. The catch-22 of antipsychotic drugs. New York Times Sunday Magazine. March 18, 1979:114
7. Tardive Dyskinesia/Diagnosis and Management. East Hanover, NJ: Sandoz; 1978
8. Baker B. Expect a flood of tardive dyskinesia malpractice suits. Clin Psychiatry News. Jan 1984:3
9. See, eg, Appelbaum PS, Schaffner K, Meisel A. Responsibility and compensation for tardive dyskinesia. Am J Psychiatry 1985;142:806. Crane GE. Clinical psychopharmacology in its 20th year. Science 1973;181:124
10. Casey DE. Clinical aspects of tardive dyskinesia. Presented at the Cleveland VA Medical Center; Nov 16, 1979
11. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition. Washington, DC: American Psychiatric Association; 1994:679–680, 747–749
12. Zwillich T. Anxiety builds over jump in liability for prescribing errors. Clin Psychiatry News. Feb 1999:1
13. Crane GE. Tardive dyskinesia in patients treated with major neuroleptics: a review of the literature. Am J Psychiatry 1968;124(suppl):40
14. Kobayaski RM. Drug therapy of tardive dyskinesia. N Engl J Med 1977; 296:257
15. See, eg, Accardo v Cenac, 722 So2d 302 (La App 1998); Rosenbloom v Goldberg, No. 29798, Suffolk Cty Super Ct (Mass 1984); Urbani v Yale University School of Medicine, No. 85-46EBB (D Conn 1986); Hedin v United States, No. 583-3 (D Minn 1984); Snider v Harding Hosp, No. 84-CV-06-3582, Franklin Cir Ct (Md 1980)
16. In Faigenbaum v Oakland Medical Center, 143 Mich App 303, 373 NW2d 161 (1985), aff’d, Hyde v University of Michigan Board of Regents, 426 Mich 223, 393 NW2d 847 (1986), the patient manifested classic tardive dyskinesia (TD) symptoms following neuroleptic medication. Misreading her symptoms, the physician advised the patient to seek medical care for what he thought were signs of Huntington’s chorea, an inherited disease. According to the court, neuroleptic treatment was poorly monitored. In addition, the diagnosis of TD was missed by several psychiatrists and a consulting neurologist, leading to a continuation of neuroleptic treatment amid severe dyskinesic movements. A psychiatrist testified at trial that the patient suffered from “one of the worst cases of TD I’ve ever seen.” The patient was awarded a million dollars, which plus interest amounted to nearly a million and a half. (The attorney for the patient was Geoffrey Fieger, later associated with Dr. Jack Kevorkian.) Subsequently, the mal-

practice claim against the hospital was reversed on the grounds of governmental immunity. The patient's TD symptoms disappeared, but she had her judgment against the physicians.

Another oft-cited case involved Timothy Clites, a mentally retarded individual who was confined in 1963 in a state hospital. By 1970, his behavior had become aggressive, and he was given several neuroleptic medications. By 1975, he was diagnosed as suffering from TD, allegedly caused by the long-term use of neuroleptics. The Iowa Court of Appeals held that the state violated "industry standards" of reasonable care, specifically by using polypharmacy, by failure to obtain consultation, by lack of drug holidays, and by use of neuroleptics to control his behavior. *Clites v Iowa*, 322 NW2d 917 (Iowa App 1982)

17. See Slovenko R. Introduction. In: Simon RI. *Clinical Psychiatry and the Law*. 2nd ed. Washington, DC: American Psychiatric Press; 1992:xxi-xxx
18. *Tardive Dyskinesia: A Task Force Report of the American Psychiatric Association*. Washington, DC: American Psychiatric Association; 1992: 250-251
19. King JH. In search of a standard of care for the medical profession: the "accepted practice" formula. *Vand L Rev* 1975;28:1213
20. "Roughly 40 percent of schizophrenics on drugs for many years develop tardive dyskinesia." Clark M. *Drugs and psychiatry: a new era*. Newsweek. Nov 12, 1979:98
21. Alexopoulos GS. Lack of complaints in schizophrenics with tardive dyskinesia. *J Nerv Ment Dis* 1979;167:125
22. *Washington v Harper*, 494 US 210,230 (1990)
23. *United States v Brandon*, 158 F3d 947,954 (6th Cir 1998)
24. Kline NS. On the rarity of "irreversible" oral dyskinesia following phenothiazines. *Am J Psychiatry* 1968;124:48. Turek IS. Drug induced dyskinesia: reality or myth? *Dis Nerv Syst* 1975;66:397
25. Pies R. Assessing the value of atypical antipsychotics and enhancing their risk/benefit ratio. *Adv Psychiatr Med (suppl to Psychiatr Times)*. Feb 1999: 1-4
26. In the case of *In the Matter of Nancy Reinhold*, 1991 WL 42601 (Minn App 1991), the Minnesota Court of Appeals noted, "Clozaril does not cause or worsen tardive dyskinesia. . . . We encourage the use of this medication as long as it is medically appropriate."
27. *Truman v Thomas*, 27 Cal 3d 285, 611 P2d 902, 165 Cal Rptr 308 (1980)
28. *McEvoy v Group Health Co-op*, 570 NW2d 397 (Wis 1997)
29. In re *Len P*. 1999 WL 42067 (Ill App 1999)
30. Ehrensing RH. Tardive dyskinesia. *Arch Intern Med* 1978;138:1261
31. Ayd FJ. Ethical and legal dilemmas posed by tardive dyskinesia. *Int Drug Ther Newsletter* 1977;12:29
32. Clyne KE, Juhl RP. Tardive dyskinesia. *J Maine Med Assoc* 1976;67:129
33. See Ehrensing RH, note 30.
34. See, eg, Ayd FJ. Prevention of recurrence (maintenance therapy). In: DiMascio A, Shader RI, eds. *Clinical Handbook of Psychopharmacology*. New York, NY: Science House, 1970:297-310. Crane GE. Prevention and management of tardive dyskinesia. *Am J Psychiatry* 1972;129:126
35. Drug-free periods have, paradoxically perhaps, been implicated as a factor that increases the risk for tardive dyskinesia. In: *Tardive Dyskinesia: A Task Force Report of the American Psychiatric Association*. Washington, DC: American Psychiatric Association; 1992. See also Jeste DV, Potkin SG, Sinha S, et al. Tardive dyskinesia: reversible and persistent. *Arch Gen Psychiatry* 1979;36:585
36. West JC. The legal implications of medical practice guidelines. *J Health Hosp Law* 1994;27:97
37. On how strictly the physician must follow the instructions, Dr. James L. Goddard, then Commissioner of the U. S. Food and Drug Administration, said: "In the routine practice of medicine, it is judicious for a physician to follow the labeling directions, which generally provide for individualization of drug dosage. However, as licensed practitioner, he is not precluded from using a commercially available drug in a manner which his knowledge and experience indicate to him is in the best interest of his patient. . . . Physicians are sometimes sued for their use of any drugs on patients, even when the directions have been followed. We would anticipate more difficulty in defending a civil suit, where labeling instructions are not followed. Certainly informed patient consent would be a factor in a nonapproved use, since such use would be investigational." Quoted in Appleton WS. *Legal Problems in Psychiatric Drug Prescription*. *Am J Psychiatry* 1968;124:174
38. Trent CL, Muhl WP. Professional liability insurance and the American psychiatrist. *Am J Psychiatry* 1975;132:1312
39. Texas Revised Civil Statutes, Ann. art 4590i, sec 6.02 (West Supp 1999)
40. *Cobbs v Grant*, 502 P2d 1 (Cal 1972)
41. The Texas Court of Appeals in *Tajchman v Giller*, 938 SW2d 95 (Tex App 1996) and *Galvin v Downey*, 933 SW2d 316 (Tex. App 1996) incorporates the discussion about informed consent from *Barclay v Campbell*, 704 SW2d 8,10 (Tex 1986) (which appears to be the leading TD case on informed consent) to explain what constitutes an inherent risk that is material enough to require disclosure. See also *Headley v Hanneken*, No. ST81-151, Marion Cty Super Ct (Ohio 1984)
42. Sovner R, DiMascio A, Berkowitz D, et al. Tardive dyskinesia and informed consent. *Psychosomatics* 1978;19:172
43. Bernstein JG. *Handbook of Drug Therapy in Psychiatry*. 3rd ed. St. Louis, Mo: Mosby; 1995:28
44. See Ayd FJ, note 32. At least one case, however, has been reported of a patient who developed TD only one month after his first exposure to neuroleptic drug treatment. Chouinard G, Jones BD. Early onset of tardive dyskinesia: case report. *Am J Psychiatry* 1979;136:1323
45. Kornfeld DS. Doctor's dilemma: what truth for which patient at what time? [letter] *New York Times*, May 16, 1978:34. "For the record—and to protect himself—the physician has to recite the worst possibilities. But . . . in some circumstances, an artful ambiguity allows hope; in others, temporary denial is helpful." Lazarus RS, Goleman D. Positive denial: the case for not facing reality. *Psychol Today* Nov 1979:44
46. Alton WG. *Malpractice*. Boston, Mass: Little, Brown; 1977
47. In a Louisiana case, a 62-year-old woman diagnosed as schizophrenic sued the State of Louisiana for failure to obtain informed consent for the administration of neuroleptic medication. She suffered TD. The court noted that a written consent to hospitalization, which was an adequate consent to the use of antipsychotic medication, was signed by the patient. The court found that the patient's daughter provided informed consent to the continued use of the medication. *Frazier v Dept of Health & Human Resources*, 500 So2d 858 (La 1986). Consent from a near relative, when the patient is incompetent, is considered sufficient in the administration of electroshock. *Wilson v Lehman*, 379 SW2d 478 (Ky 1964); *Lester v Aetna Cas & Surety Co*, 240 F2d 676 (5th Cir 1957), cert denied, 354 US 923 (1957) (spousal consent)
48. The hazard of over-information may be illustrated by case law on consumer contracts. In *Jones v Goodyear Tire & Rubber Co*, 442 F Supp 1157 (ED La 1977), the court found "it is practically impossible to read the form from beginning to end without getting lost."
49. Roth LH, Meisel A, Lidz CW. Tests of competency to consent to treatment. *Am J Psychiatry* 1977;134:279. Meisel A. The "exceptions" to the informed consent doctrine: striking a balance between competing values in medical decision-making. *Wis L Rev* 1979:413
50. Two cases—*Rogers v Okin*, 457 US 291 (1982), and *Rennie v Klein*, 462 F Supp 1131 (N.J. 1978), 476 F Supp 1294 (D.N.J. 1979), aff'd in part, 653 F2d 836 (3d Cir 1981), vacated and remanded, 458 US 1119 (1982), on remand, 700 F2d 266 (3d Cir 1983)—were the prototypes for "right to refuse" litigation during the 1970s and 1980s. The trial court in *Rogers* noted that recent studies had "suggest[ed] that tardive dyskinesia is more widespread in mental patients than previously [thought]" and cited psychiatric research estimating that 50% or more of chronic patients, and over 40% of outpatients treated with medications developed TD. The judge characterized antipsychotic medication as "mind-altering" and treatment as "involuntary mind control." 478 F Supp 1342 at 1360, 1367 (D Mass 1979). The trial judge in *Rennie* castigated the hospitals for ignoring TD and for badly mishandling other side effects. 476 F Supp 1294, 1300. Nationwide, in subsequent litigation, most jurisdictions have recognized a nominal right to refuse, but have allowed the hospital director or other hospital officials to override the patient's refusal. That was the outcome in New Jersey, where *Rennie* was litigated. A few other jurisdictions require that hospitals respect a patient refusal absent a judicial adjudication of the patient's incompetence or a judicial assessment of the reasons for and against compelling medication. That was the outcome in Massachusetts, where *Rogers* was litigated. See Appelbaum PS. *Almost a Revolution*. New York, NY: Oxford University Press; 1994. Gelman S. The law and psychiatry wars, 1960-1980. *Calif West L Rev* 1997;34:153
51. The Minnesota Supreme Court in *Price v Shepard*, 239 NW2d 905 (Minn 1976), said: "We cannot draw a clear line between the more intrusive forms of treatment requiring a procedural hearing and those which do not. Certainly this procedure is not intended to apply to the use of mild tranquilizers or those therapies requiring the cooperation of the patient. On the other hand, given current medical practice, this procedure must be followed where psychosurgery or electroshock therapy is proposed."
52. In re *Paul Fussa*, No. 46912 (Minn Prob Ct 1976)
53. In re *Guardianship of Roe*, 383 Mass 415, 421 NE2d 40 (1981); *Harper v*

- State of Washington, 110 Wash2d 873, 759 P2d 358 (1988)
54. Herewith a synopsis of some recent decisions. In a North Dakota case, the court noted the patient's reactions to haloperidol and risperidone. About haloperidol the patient said, "It is a vicious drug that makes people want to slide along the floor." About risperidone the patient said, "It seemed to round out that high speed thing I was working on" and it brought "me down to that old business sense." The doctor reported that risperidone "probably has a much less chance of causing tardive dyskinesia." The court concluded that risperidone is least restrictive and haloperidol could be administered only if the patient refuses risperidone. *Shannon J v RAJ*, 554 NW2d 809 (ND 1996)
- In an Illinois case, the appellate court reversed an order allowing involuntarily administered psychotropic drugs. The court classified both haloperidol and risperidone as drugs with serious side effects. The patient argued that there was extensive evidence before the trial court as to the possible serious side effects of both haloperidol and risperidone, and further noted that psychotropic medication is less effective where the recipient of the medication does not agree to accept the medication. The doctor testified, however, that the benefits of the medication would substantially outweigh any possible negative effects of the medication. The appellate court ruled that because the patient offered rational reasons for refusing the medication, the hospital was not permitted to involuntarily administer the drugs. *In re Brad Israel*, 664 NE2d 1032 (Ill App 1996)
- In a Minnesota case, the medical records of the patient indicated that clozapine was the most effective treatment. The patient asked to be given fluphenazine, but because he had shown signs of TD that request was refused. The patient was given haloperidol and intermittent clozapine, but his condition again deteriorated. The hospital wanted to give 900 mg of clozapine and 100 mg of haloperidol. The caregivers testified that clozapine is best for treatment "while avoiding the risks of tardive dyskinesia." The appellate court affirmed the order to administer clozapine, 900 mg, and haloperidol, 100 mg. *In the Matter of Richard Martin*, 527 NW2d 170 (Minn App 1995)
- In a Tennessee case, the court ordered the discharge of an insanity acquittee and established a mandatory outpatient program for him. The individual was committed in 1981, and there was no significant improvement until 1992 when he was put on clozapine treatment, which had become available. The court noted the report of the case managers that "clozapine requires weekly monitoring and blood tests of a patient." *State of Tennessee v Martin*, 1996 WL 687028 (Tenn Crim App 1996)
- In another Minnesota case, the issue was whether the individual who had been committed to a security hospital as mentally ill and dangerous should be treated with the typical neuroleptic loxapine that he was then receiving or with clozapine. Medical opinion on the issue differed. One psychiatrist believed loxapine was a better choice—unlike clozapine, he said, loxapine can be administered by long-acting injections, which might prevent dangerous behavior after his release. In contrast, 2 other medical examiners favored clozapine. They concluded that the individual had TD and believed use of loxapine was therefore not appropriate. The trial court, after hearing the testimony, left the decision to the discretion of the medical professionals, and the order was affirmed on appeal. *In re Stewart*, 1991 WL 126637 (Minn App 1991)
55. In a Minnesota case, the experts testified that clozapine was necessary to treat the patient's illness and that other neuroleptics, including haloperidol, were not effective. The court noted, "If he refuses to take clozapine voluntarily, the only alternative means of administration is by nasogastric tube." *In the Matter of Richard Martin*, 527 NW2d 170 (Minn App 1995). See also *In re Len P.* 1999 WL 42067 (Ill App 1999); *In the Matter of Nancy Reinhold*, 1991WL42601 (Minn App 1991)
56. Pinals DA, Buckley PF. Novel antipsychotic agents and their implications for forensic psychiatry. *J Am Acad Psychiatry Law* 1999;27:7
57. *Viser v Taylor*, 756 F Supp 501 (D Kan 1990)
58. Services covered by a state Medicaid plan must be sufficient in amount, duration, and scope to reasonably achieve its purpose. 42 CFR §440.230(b). A state Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition. 42 CFR §440.230(c)
59. See Metzner JL. An introduction to correctional psychiatry. *J Am Acad Psychiatry Law* 1998;26:107. The American Psychiatric Association has published guidelines for psychiatric services in jails and prisons in *Psychiatric Services in Jails and Prisons*. Washington, DC: American Psychiatric Association; 1989. Task Force Report No. 29.
60. *Washington v Harper*, 494 US 210, 232 (1990)
61. *Riggins v Nevada*, 504 US 127 at 135 (1992). Many other cases dealing with due process and the issue of forcing involuntarily committed mental patients or prisoners to take psychotropic drugs mention TD as the most serious of the side effects of neuroleptic drugs. A list of cases after 1990 in this class includes: *TD v New York State Office of Mental Health*, 650 NYS2d 173 (1996); *Enis v Wisconsin Dept of Health*, 962 F Supp 1192 (WD Wis 1996); *Shannon J v RAJ*, 554 NW2d 809 (ND 1996); *Hightower v Olmsted*, 959 F Supp 1549 (ND Ga 1996); *In Interest of CW*, 552 NW2d 382 (ND 1996); *In re Conservatorship of Foster*, 547 NW2d 81 (Minn 1996); *Guardianship of Boyle*, 674 A2d 912 (Me 1996); *In re Israel*, 664 NE2d 1032 (Ill App 1996); *State v Garcia*, 669 A2d 573 (Conn 1996); *In Matter of Rauenhorst*, 1995 WL 673385 (Minn App 1995); *In re Schapp*, 654 NE2d 1084 (Ill App 1995); *In Interest of SJ*, 528 NW2d 367 (ND 1995); *Matter of Martin*, 527 NW2d 170 (Minn App 1995); *State v Adams*, 888 P2d 1207 (Wash App 1995); *In re CE*, 641 NE2d 345 (Ill 1994); *Sullivan v Flanigan*, 8 F3d 591 (7th Cir 1993); *Woodland v Angus*, 820 F Supp 1497 (D Utah 1993); *Donaldson v District Court for City of Denver*, 847 P2d 632 (Colo 1993); *State v Perry*, 610 So2d 746 (La 1992); *Felce v Fieder*, 974 F2d 1484 (7th Cir 1992); *Guardianship of Roe*, 583 NE2d 1282 (Mass 1992); *Maul v Constan*, 928 F2d 784 (7th Cir 1991); *Williams v Wilzack*, 573 A2d 809 (Md 1990); *Matter of Schauer*, 450 NW2d 194 (Minn App 1990). See Winick BJ. *The Right to Refuse Mental Health Treatment*. Washington, DC: American Psychological Association; 1997
62. Cohen F. *The Mentally Disordered Inmate and the Law*. Kingston, NJ: Civic Research Institute; 1999. California has the most extensive statutory limits on forced treatment of mental patients and mentally ill prisoners. *Cal Penal Code §§2670-2680* (West 1995); *Keyhea v Rushen*, 223 Cal Rptr, 746 (Ct App 1986)
63. See Torrey EF. *Jails and prisons—America's new mental hospitals* [editorial]. *Am J Public Health* 1995;85:1611
64. Egan T. *The war on crack retreats, still taking prisoners*. *New York Times*. Feb 28, 1999:1
65. *Estelle v Gamble*, 429 US 97 (1976)
66. *Farmer v Brennan*, 511 US 825 (1994)
67. See *Madrid v Gomez*, 889 F Supp 1146 (ND Cal 1995); *Casey v Lewis*, 834 F Supp 1477 (D Ariz 1993); *Coleman v Wilson*, 912 F Supp 1282 (ED Cal 1995); *Lightfoot v Walker*, 486 F Supp 504 (SD Ill 1980); see also Cohen F. *Liability for custodial suicide: the information base requirements*. *Jail Suicide Update* 1992;4:1
68. Zander TK. *Prolixin decanoate: a review of the research*. *Mental Disability Law Reporter*. July–Aug 1977:37–42
69. *In Talley v Portland Residence*, 582 NW2d 590 (Minn App 1998), the plaintiff, a disabled, mentally retarded adult, was given the medication that allegedly caused his TD before he had a conservator. Thus, the claim was not barred by statute of limitations.
- In a Texas case, the patient was given neuroleptic drugs between 1980 and 1985 without being informed of possible side effects. The patient developed TD. The psychiatrist relied solely on the statute of limitations as a defense. It was found that the psychiatrist fraudulently concealed the patient's condition even after a neurologist opined to the patient that she may have developed TD. The patient's conversation with the neurologist did not set the statute of limitations running. The court could not fault a psychologically disturbed patient for relying on her psychiatrist over a neurologist seen on merely one occasion. The claim was not barred by the statute of limitations. *Gatling v Perna*, 788 SW2d 44 (Tex App 1990)
70. *In Adkins v Tafel*, 871 SW2d 289 (Tex App 1994), the patient, given haloperidol that allegedly caused TD, sued 2 physicians and a pharmacist; the suit against one of the physicians and the pharmacist was barred by the statute of limitations. The physician who obtained summary judgment had given the patient haloperidol for 13 years but was found not culpable of fraudulent concealment as he believed that the patient's tremors were a result of a car crash and not a drug side effect. The patient's family learned of the connection between haloperidol and TD from the Phil Donahue show. See also *De Witt v United States*, 593 F2d 276 (7th Cir 1979); *Leary v Rupp*, 280 NW2d 466 (Mich App 1979); *Ohler v Tacoma General Hospital*, 598 P2d 1358 (Wash 1979); *Willis v United States*, 879 F Supp 889 (CD Ill 1994); *De Witt v United States*, 593 F2d 276 (7th Cir 1979); *Leary v Rupp*, 280 NW2d 466 (Mich App 1979); *Ohler v Tacoma General Hospital*, 598 P2d 1358 (Wash 1979)
71. "When the injury might, with equal probability, have resulted from the acts of others as well as from the acts of defendant, proof of facts, other than that of injury, from which defendant's negligence can be inferred, must be

made before the questions can be submitted to the jury. Otherwise, the verdict would be founded on mere speculation. . . . An inference of negligence based on an inferred fact of which there is neither evidence nor predominating probability cannot be safely made." Olson v St. Joseph's Hospital, 281 NW2d 704 (Minn 1979)

72. DSM-IV, pp 678-679
73. In *Accardo v Cenac*, 722 So2d 302 (La App 1998), the Louisiana Court of Appeals stated: "The evidence overwhelmingly established that the mental disorder of schizophrenia does not cause any of the symptoms resulting from abnormal movements. The record firmly established that the uncontrollable twisting, writhing, flailing, contorting, contracting, grimacing, etc. displayed by [the patient] are all components of the neurological disease and have nothing to do with her schizophrenia."
74. *Allen v United States*, 588 F Supp 247, 416 (D Utah 1984), reversed on unrelated grounds, 816 F2d 1417 (10th Cir 1987), cert denied, 484 US 1004 (1988)
75. *Tisdale v Johnson*, 177 Ga App 487, 339 SE2d 764 (1986)
76. In *Marzolf v Gilgore*, 933 F Supp 1021 (D Kansas 1996), the patient who was given phenothiazine class drugs for over 14 years was held to have a cause of action against the physician who prescribed the drug for the final 6 months of the long drug-taking period. The early prescription "primed" the patient for the later complications. The final doses, rather than the prior 13½ years, may be deemed the cause-in-law of the patient's TD. Summary judgment for the physician was denied as the facts created a question for the jury.
77. Rosenbaum AH. Tardive dyskinesia: relationship with a primary affective disorder. *Dis Nerv Syst* 1977;38:423
78. Altrocchi PH. Spontaneous oral-facial dyskinesias. *Arch Neurol* 1973;26:506
79. Casey DE. Managing tardive dyskinesia. *J Clin Psychiatry* 1978;39:748
80. *Carlin v Superior Court (Upjohn Co)*, 56 Cal Rptr2d 162 (1996)
81. American Law Institute. Restatement of Torts §402A
82. Terzian TV. Direct-to-consumer prescription drug advertising. *Am J Law Med* 1999;25:149

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