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H. Richard Beresford
Cornell Law School

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H. Richard Beresford

Department of Neurology, North Shore University Hospital, Manhasset, and Department of Neurology, Cornell University Medical College, New York, New York, U.S.A.

Summary: Physicians who care for patients with epilepsy may function as agents or targets of social control. As agents, they may assist in the identification and control of epileptic drivers, may provide information that enables fair and appropriate job placements for epileptic persons, and give testimony that helps the legal system resolve issues relating to the liability of epileptic persons for harm attributed to seizures or interictal behavioral disturbances. As targets, they may be charged with negligent failure to diagnose, treat, or inform about epilepsy or its associated problems, with failure to exercise due care in protecting persons harmed by their patients, or with failure to preserve confidentiality of medical information. Although legislation and judicial decisions have defined some of the physician's legal duties with reasonable clarity, areas of uncertainty remain, particularly regarding the issue of violating medical confidentiality for the benefit of persons other than the patient. **Key Words:** Epilepsy—Automobile driving—Confidentiality.

Epilepsy has dimensions that generate a variety of legal problems. Because a person may experience sudden and abrupt loss of consciousness, there is a risk of harm both to the person and others affected by his or her loss of control (Spudis et al., 1986; Gastaut and Zifkin, 1987). Ictal events or interictal disturbances may disrupt cognitive or affective processes in more subtle ways than frank unconsciousness and some resulting behaviors may be antisocial (Stevens, 1975; Waxman and Geschwind, 1975; Ashford et al., 1980; Pritchard et al., 1980). Treatment itself may compromise neurological functions in ways that lead to injury to patients or others, or cause damage to extraneural or fetal tissues (Rosenbaum, 1982; Dalessio, 1985). Stigmatizing persons with epilepsy may lead to discrimination and other unjust social responses. Thus, physicians who care for persons with epilepsy can expect to interact with the legal system in one context or another.

One view of law is that it is a system of social control designed to protect interests of both individuals and the larger community. In this framework, a physician may be either an agent or a target of social control. As an agent, the physician protects patients from harm, protects others from risks posed by patients, and contributes expertise that helps the legal system resolve disputes that involve medical questions. A physician becomes a target when aggrieved persons claim that he or she wrongfully harmed or failed to protect them, or when state agencies assert violations of particular laws or regulations (such as those relating to the care of persons with epilepsy or other disorders marked by paroxysmal impairment of neurologic functions). This paper will consider selected aspects of the physician's role as agent or target of social control, emphasizing particular cases that illustrate how the legal system attempts to define, balance, and protect interests of epileptics, their physicians, and other members of society. No effort will be made to survey the gamut of legal problems persons with epilepsy may encounter or to catalogue the large body of state and federal law that pertains to epilepsy.

Address correspondence and reprint requests to Dr. H. R. Beresford at Department of Neurology, North Shore University Hospital, Community Drive, Manhasset, NY 11030, U.S.A.

PHYSICIAN AS AGENT OF SOCIAL CONTROL

The epileptic driver

Driving as an antisocial act

In *People v Decina* (1956), New York's highest court upheld a charge of criminal negligence against a defendant who had a seizure while driving, lost

control of his car, and struck and killed four children. The defendant had had seizures for 9 years, probably the result of a brain abscess that had been surgically removed several years before the onset of epilepsy. At the time of the accident, he was taking antiepileptic drugs and had had no seizures for 9 months. In upholding the validity of the criminal indictment, the court reasoned that his conduct in operating an automobile knowing he might unexpectedly lose consciousness constituted culpable indifference to the rights of others. The court ordered a new trial, however, ruling that the trial judge had erred in allowing testimony by a resident physician who had evaluated the defendant after the accident and had obtained the history of his previous seizures. The court viewed this as confidential information that could not be disclosed without the consent of the patient since it was obtained while the defendant was receiving medical care. In other words, the court recognized that an individual's interest in medical privacy is sufficiently strong to restrict nonconsensual disclosures about his condition in a legal proceeding. Three dissenting judges would have dismissed the case entirely on the ground that a person who is unconscious because of a seizure cannot be said to act with criminal intent.

This troubling case underscores the social control function of law in its emphasis on preventing conduct that endangers society, such as risking loss of control of a vehicle. The physician who cares for a patient with epilepsy serves this function by prescribing appropriate antiepileptic drugs, counseling about the risks of driving, and meeting formal reporting requirements aimed at identifying potentially dangerous drivers. The case also highlights the medical ethical principle that the confidentiality of communications between physician and patient should be protected unless the patient consents to disclosure, and the court's reasoning is consistent with the recent Massachusetts decision in *Alberts v Devine* (1985) that affirms the legal duty of physicians to protect confidentiality of communications from patients. As will be seen, this tension between duty to society and duty to patient may disturb the relationship between physicians and epileptic patients who drive (Masland, 1978; Gregory, 1980).

Reporting laws

All states seek to regulate driving by persons with epilepsy (Epilepsy Foundation of America, 1985*a*,*c*). Restrictions on licensure vary widely. Some states require seizure-free intervals for specified periods before driving is lawful, while others permit driving based on a physician's statement that a patient's epilepsy will not prevent safe operation of a vehicle. In either situation, medical evaluations are required before driving is permitted *provided that* the licensing agency learns that an applicant has epilepsy. The agency may obtain this information from the applicant, the applicant's physician, or from a police or other official report disclosing the possibility of a seizure disorder. Most states impose a duty on applicants to disclose medical conditions relevant to driving, including epilepsy, and do not require physicians to report their epileptic patients to the licensing agency. Laws of a few states mandate reports by physicians but differ in what they require and what penalties they impose for failure to report. These laws generally immunize physicians against liability for reporting that complies with formal regulatory requirements (Gregory, 1980; Epilepsy Foundation of America, 1985*c*).

The regulatory approaches of two states, Connecticut and New York, illustrate the contrasting strategies of mandatory reporting by persons with epilepsy and physician-initiated reporting.

New York requires the applicant who "has ever suffered loss of consciousness" to submit "proof of fitness" to drive. This may take the form of a physician's statement that the applicant has had no loss of consciousness during the previous 12 months, that any loss of consciousness was due only to an adjustment of medications, or that the applicant is capable of "safe operation" of a motor vehicle. If the applicant provides such a statement and a medical consultant to the motor vehicle agency concurs, the agency may license the applicant. If no "proof of fitness" is provided, licensure may be denied or suspended after a hearing in which the applicant may present evidence that he can safely operate a motor vehicle (New York Code of Rules and Regulations, 1987). This approach provides flexibility because it permits driving by persons who may have had seizures in the year preceding the license application if their physicians believe it is safe for them to drive. It also affords applicants the opportunity for a hearing to demonstrate their suitability for licensure. Once granted, a license may be suspended any time a person poses an "immediate hazard." Evidence of such a hazard may include a physician's opinion or evidence from other sources (e.g., police report) that a particular motor vehicle accident resulted from a seizure. While laws of several other states also require that applicants for licensure disclose seizures or other impairments of consciousness and relieve physicians from primary responsibility for reporting a diagnosis of epilepsy to a licensing agency, many impose requirements of specified seizure-free intervals as a condition of licensure and do not permit licensing of applicants

only on the basis of a physician's opinion that it is safe for them to drive.

Connecticut statutes (1979) require a physician to report "immediately" to the state health department the identity of a person "known to him to be subject to recurrent attacks of epilepsy . . . or to recurrent periods of unconsciousness uncontrolled by medical treatment." The health department then must transmit this information to the motor vehicle agency if the person is 16 years of age or older. The agency must protect the confidentiality of the information and use it only to determine eligibility for licensure. A medical advisory board assists the agency in its licensing decisions. No data provided by physicians can be used as evidence at a trial without the person's consent, and physicians who report as prescribed by law are provided immunity from liability for reporting that is in "good faith, nonnegligent, and non-malicious." A few other states require reporting by physicians, including California, Illinois, New Jersey, and Pennsylvania, and provide immunity to those who report (Gregory, 1980; Epilepsy Foundation of America, 1985*c*). Modest fines are provided for failure to report, but Pennsylvania law would expressly permit a finding of negligence against a physician who fails to report an epileptic driver who later has a motor vehicle accident (Epilepsy Foundation of America, 1985*c*).

Despite universality of laws requiring some sort of reporting to state agencies, the degree of compliance by either persons with epilepsy or their physicians is uncertain. Anecdotal reports of noncompliance are common, and it seems safe to assume that state agencies license persons whom the agencies don't know have epilepsy, or that, if they know of the epilepsy, are not informed about seizures that might evoke restrictions on licensure. A study of 50 adult males with epilepsy supports this assumption (Quaglieri, 1977). Thirty-five lived in states that require disclosure by persons with epilepsy to licensing agencies. In this group, 86% did not report even though 74% knew that the law required them to report, and 58% denied they had been told by their physicians that they had any duty to report. Fourteen percent told their physicians they had had one or more seizures while driving. Whether this striking degree of noncompliance is prevalent is unclear, but it suggests that many persons who know they have epilepsy, and whose physicians know they have epilepsy, operate motor vehicles without formal restrictions on licensure. Some legal risks of failing to report are self-evident: loss of licensure, fines, criminal prosecution, claims for property damage, or injury. Less evident are the risks to those who do not have a statutory or other mandated duty to report. As to physicians, these risks will be considered later in this report.

Epilepsy and employment

Epilepsy as a disqualifying condition

For the majority of persons with epilepsy whose seizures are well controlled and who are neurologically unimpaired, no rational basis exists for restricting vocational opportunities. Yet employers continue to fire or refuse to hire epileptic persons without regard to clinical facts, and laws designed to deter such actions have met with only limited success (Epilepsy Foundation of America, 1985*b*). Nevertheless, with improved public education about epilepsy and advances in pharmacotherapy, the lot of persons with epilepsy in the workplace may be improving, despite suboptimal implementation of antidiscrimination laws. Aside from providing effective treatment of seizures, physicians may be especially helpful to epileptic workers by counseling them about appropriate vocations and, with the consent of the workers, by informing employers about the workers' suitability for particular types of employment or about what types of restrictions should be imposed. Where employers engage in discriminatory practices, physicians may play a central role in establishing that an epileptic person is qualified for a particular job and help lay a foundation for a legal action to enforce a right to fair employment.

Antidiscrimination laws

Federal and state statutes declare it unlawful for employers to discriminate against handicapped persons (Epilepsy Foundation of America, 1985*b*). Epilepsy generally qualifies as a handicapping condition under these laws, even if the epileptic is seizure-free and has a normal neurological examination. Moreover, under the federal rehabilitation act (1973) that applies to employers who receive various forms of federal support, mere belief by the employer that a person is handicapped counts as a handicap for purposes of triggering the enforcement sections of the law. These forbid employers from firing or refusing to hire handicapped persons who are "otherwise qualified" for a particular job solely on the basis of the perceived handicap. Although the federal law is a potentially powerful weapon against discrimination, it may not be a simple matter to prove its application. A claimant must not only establish that he or she is both handicapped and qualified, but also must show that the employer's decision not to hire or to fire rested only on the existence of the particular handicap (e.g., epilepsy).

In the *Arline* case (1987), the U.S. Supreme Court considered the application of the federal antidiscrimination law to a person who was classified by her employer as unqualified because of the employer's arguably unfounded fears that she posed a risk to others. The Epilepsy Foundation of America filed an amicus brief because of its interest in assuring that epileptic persons not be denied employment because of unfounded fears about their condition. In *Arline,* a public school teacher with a past history of recurrent tuberculosis was fired solely because the school board feared she might be contagious. In her suit against the school board for discriminatory firing, she asserted that, while her history of tuberculosis constituted a handicap, she was currently qualified to teach, and that the board's denying her a teaching position was based solely on her handicap. The school board justified the firing by arguing that her potential contagiousness made her unqualified to teach. The U.S. solicitor general intervened on behalf of the school board arguing that, since federal law or regulations did not expressly define handicap to include a contagious disease, the teacher was not entitled to claim under the antidiscrimination law. The Supreme Court concluded that her tuberculosis could be viewed as a handicap, expressly rejecting the notion that infectious illnesses were excluded from the coverage of the law, and declared that the law forbade her firing solely on the basis of her handicap. It emphasized that one purpose of the law was to prevent discrimination based on prejudice or ignorance, and remanded the case back to the federal district court for a particularized determination, based on "reasonable medical judgments," as to whether her potential for transmitting tuberculosis was such as to affect her qualifications to teach in a classroom.

This decision affirms the principle that employers offend against antidiscrimination laws when they invoke concerns unrelated to a handicapped person's ability to do a given job as a reason for denying access to that job. It also highlights the great importance of medical data for individualized determinations of a handicapped person's capabilities or potential dangerousness. As to persons with epilepsy, relevant factors include the nature of seizures, degree of control of seizures with antiepileptic drugs, compliance with prescribed therapy, adverse reactions to antiepileptics, and extent of any neurological impairment. Findings relating to these factors will indicate what employment is appropriate, and will provide a basis for evaluating whether an employer's decision to fire or refuse to hire was related to the person's qualifications or solely to his or her epilepsy. Even if a handicap such as epilepsy disqualifies a person from a particular job, an employer also has a duty to make a reasonable accommodation to the handicap, such as offering a position for which the person is qualified. For example, in the recent *Smith* case (1987), a federal court decided that a public transportation company was not required to allow an epileptic employee to operate a trolley car, even if antiepileptics were prescribed, and that it made a reasonable accommodation by offering the employee a clerical position. It is thus evident that physicians can both assist their epileptic patients in asserting a right to nondiscriminatory employment and assist employers in making appropriate job placements.

The "epilepsy defense"

Treiman (1986) has recently reviewed the issue of ictal violence, noting an apparent rise in cases where persons charged with crimes have claimed their alleged misconduct derived from epilepsy and not from criminal intent. Defendants invoke this so-called "epilepsy defense" to undercut the prosecution's assertion that they knowingly and willingly committed a criminal act. Because the prosecution must ordinarily prove all elements of a crime beyond a reasonable doubt, including intent to commit a crime, evidence that a defendant acted involuntarily or with less than full awareness may lead a jury to conclude that the defendant lacked criminal intent (or mens rea).

Recent litigation in New York exemplifies a defendant's successful use of the "epilepsy defense." *Matter of Torsney* (1979) involved a policeman who, without apparent provocation, shot and killed a 15-year-old boy. He pleaded a defense of "mental illness" to a charge of murder. At his trial, a defense psychiatrist testified that the shooting either occurred during a psychomotor seizure or as part of a "psychosis associated with epilepsy." Despite lack of a previous history of epilepsy and the opinions of neurologists that he did not have epilepsy, a jury found him not guilty. The court then committed him to a mental hospital, but there neither the examining psychiatrists or neurologists found evidence of mental illness or epilepsy. After a hearing in which further medical evidence was presented that he had neither epilepsy nor diagnosable mental illness, New York's highest court ordered his release. It reasoned that because there was no proof of mental illness, no justification existed for confining him under a statute that requires proof of both mental illness and dangerousness as conditions of involuntary detention. A vigorous dissent argued

that the combination of an "explosive" personality and the specific violent act justified continuing involuntary hospitalization.

The *Torsney* case underscores the question of whether violence directed at a particular person can be interpreted as an ictal event. If it can, invoking epilepsy as a basis for limiting or avoiding criminal liability seems an appropriate legal strategy, especially if a defendant has epilepsy and a particular violent act was paroxysmal and incompatible with his usual behavior. However, despite studies indicating an increased prevalence of epilepsy among criminal populations and anecdotes of ictal violence (Mark and Ervin, 1970; Ashford et al., 1980; Pincus, 1981), it is uncertain if directed ictal violence ever occurs. Delgado-Escueta et al. (1981) recently evaluated 19 subjects with a history of suspected ictal violence by closed circuit television and constant monitoring of EEG. During the study, 13 exhibited aggression during documented seizures, including shouting, spitting, kicking, screaming, assaultive posturing, and destruction of property. None exhibited moderate or severe directed violence, and only one was aggressive towards a particular person. All subjects were amnesic for the aggressive episodes, and the episodes themselves were typically sudden, stereotyped, unsustained, and never embodied a "consecutive series of purposeful movements." From these data, the investigators suggested five criteria for determining if a violent act was an ictal event: diagnosis of epilepsy by a competent specialist, documentation of automatisms by closed-circuit television and biotelemetry, verification of aggressive conduct during documented seizure, history that observed violence was characteristic of a person's previous seizures, and judgment by a competent specialist that the act was in fact part of a seizure.

If these criteria are rigidly applied, it seems likely that few, if any, episodes of directed violence would be classified as ictal events. While those testifying on behalf of a defendant who has pleaded the "epilepsy defense" may advance less rigorous criteria, data from this study provide a useful framework for courts to apply in evaluating an assertion that a specific violent act derived from epilepsy. However, convincing as these data are on the general question of ictal violence, they can never be conclusive on the issue of whether a particular act by a particular defendant was or was not related to epilepsy. This is an issue that must finally be resolved by a court, taking into account the evidence offered by the medical witnesses of the opposing parties (Beresford, 1980).

PHYSICIAN AS TARGET OF SOCIAL CONTROL

Malpractice liability

Physicians caring for epileptic patients may become defendants in malpractice litigation by various routes. As indicated in the *Duvall* (1984) and *Freese* (1973) cases, these include allegedly negligent failure to diagnose or treat epilepsy or failure to provide appropriate information concerning particular therapeutic decisions. The legal rules that govern malpractice proceedings are straightforward: a claimant must show that it was more probable than not that the physician–defendant failed to observe reasonable or accepted standards of medical practice *and* that this failure caused quantifiable harm to the claimant. Application of the rules is not so straightforward, however. There may be conflicting testimony from medical "experts" on whether a defendant acted reasonably, and it may be exceedingly difficult to decide whether it was the allegedly unreasonable conduct or the disorder itself that produced a particular harm. Moreover, once negligent causation of harm is established, it may be difficult to ascertain what is the proper measure of recoverable damages. For these reasons and because some malpractice claims are in themselves tenuous or baseless, claimants in the aggregate are more likely to lose than win a malpractice suit (Danzon, 1984).

Harbeson v Parke Davis (1983) illustrates the pivotal impact of expert testimony in a malpractice case and how a court may determine damages in the context of its own social vision. The suit involved a claim by a woman with epilepsy that her physicians negligently failed to warn her of the risks of taking Dilantin during pregnancy. When she asked her physicians about these risks, they mentioned cleft palate and hirsutism but not the so-called "fetal hydantoin syndrome." She later bore two children that her medical expert testified had this syndrome. He also testified that this syndrome was a known risk of Dilantin that should have been disclosed to a pregnant woman taking the drug. The Washington supreme court concluded that it was malpractice to omit this disclosure, and upheld liability for both "wrongful birth" and "wrongful life." In calculating damages for "wrongful life," it decided that the children were entitled to recover amounts sufficient to meet the lifetime costs of care attributable to their affliction. However, it rejected an allowance for "pain and suffering," in part because of the problem of quantifying an award based on comparing a miserable life with no life at all. It justified its overall

finding of liability by the need to encourage proper genetic counseling and provide a "comprehensive and consistent deterrent to malpractice."

This case offers several lessons. One is obvious: the dialogue between epileptics and their physicians about the risks of anticonvulsant therapy has profound legal implications. It must not be perfunctory and must address the particular situation of the patient. Another is that in the rush to condemn lawyers for their role in malpractice litigation, physicians should not overlook the fact that no claimant prevails unless a medical professional ventures an opinion that the physician–defendant was negligent and that this negligence caused harm. Moreover, this opinion must be so persuasive that, despite contrary testimony by a defendant's medical witnesses, a court will accept it as the most reasonable assessment of a disputed event. Thus, loss of a malpractice suit implies that both some professional peers and a court have found negligence. However, perhaps the most consequential lesson is the court's perception that awards of damages not only compensate injured persons but encourage better practice. The notion that the threat of later financial loss deters physicians and others from socially unacceptable conduct lies at the heart of expanding formulations of tort liability and the general sharp rise in costs of liability insurance.

Liability to third parties

While physicians can readily appreciate that their epileptic patients will risk harm to themselves by noncompliance with recommended treatments or other self-defeating behaviors, it is less easy to envision the risks of these behaviors to third parties. The most evident of these latter risks is driving in the face of uncontrolled or uncontrollable seizures. As previously noted, state laws generally seek to assure that epileptic persons or their physicians report to drivers' licensing agencies so that the agencies can impose appropriate restrictions on driving. If such reporting is complete and accurate, it would seem that physicians should be free from any responsibility for whatever harms their patients cause while driving. But suppose state law requires that the patient report, that in fact no report is made, and that the patient drives in the face of continuing seizures. Is there a situation in which the physician might be held legally responsible for injuries to third parties resulting from a seizure the patient experiences while driving?

One such scenario might arise where the physician fails to prescribe appropriate antiepileptic drugs or fails to advise the patient of the risks of driving until it is known that seizures are controllable. In the *Duvall* case (1984), persons injured in an accident caused by an epileptic person's seizure brought suit against his physician. They alleged that the physician had failed to provide treatment and had failed to warn of the risks of driving without taking medications, and that these omissions violated a duty the physician owed to them as members of the general public. The trial judge dismissed the suit, but the appeals court reversed this ruling. It concluded that the doctor–patient relationship imposed a duty on the physician to take reasonable steps to control the dangerous conduct of his patient, and that if the physician should have foreseen that failing to treat his patient's epilepsy or warning him not to drive risked harm to other drivers, he could be found liable to the injured claimants. The court did not find the physician liable; it simply concluded that the theory of liability was valid. Accordingly, the case was sent back to the trial court for further proceedings. Whatever the final disposition in this case, it shows that under some circumstances, law will impose on physicians a duty to protect persons whose interests are threatened by their patients.

The implications of creating such a duty were explored in the now famous *Tarasoff* case (1976). The court clearly recognized the potential conflict with a physician's duty to protect medical privacy or confidentiality, but concluded that a physician's duty to warn a particular person whom he knew to be endangered outweighed his duty to respect confidentiality. Scholarly criticism of the result in *Tarasoff* emphasized that requiring physicians to act in this way will only dissuade potentially dangerous patients from seeking or cooperating in medical care and will ultimately increase the risks to society (Stone, 1976). This critique seems especially relevant to the situation of the epileptic driver, effective management of whom depends heavily on a willingness to seek and follow medical advice (Masland, 1978). Although the *Tarasoff* doctrine has not been widely adopted, the Michigan court accepted its rationale in the *Duvall* case (1984) by creating a duty running from an epileptic's physician to third parties. Thus, even if state law requires reporting by epileptic persons and not by their physicians, the physician who knows that an epileptic patient is driving, despite uncontrolled seizures and despite the physician's warnings not to do so, and who fails to take reasonable steps to prevent public harm may be vulnerable under the *Tarasoff* doctrine. One reasonable step for a physician to take is to notify the state licensing agency or local police department

and leave to that agency the matter of enforcing restrictions on driving.

Nonconsensual reporting of this nature is a clear breach of medical confidentiality, and questions emerge about the potential liability of the physician who acts in this way. One threat is that the patient might sue for invasion of privacy. Another is that disclosure may violate state laws or regulations that protect communications between patients and physicians. As indicated in *Tarasoff* and the accompanying debate, however, the legal system will tolerate violations of confidentiality that entail good faith efforts to protect the public and are proportionate to the degree of risk involved. Nevertheless, any nonconsensual disclosure of confidential information should rest on competent legal advice.

A less complicated but still significant risk to the physician of an epileptic driver relates to the adverse effects of antiepileptic drugs. It is general knowledge that many of these drugs are potentially intoxicating, and it is foreseeable that they may adversely affect the capabilities to operate motor vehicles. Thus, if a patient has a motor vehicle accident because of antiepileptic drug-induced intoxication, both the patient and third parties may have a sustainable claim against the prescribing physician for injuries incurred in the accident if they can prove that an inappropriate drug or dosage of drug was prescribed, or that the physician failed to advise of the risk of sedation or failed to monitor treatment appropriately. The prospect of liability would be much diminished if the patient had been informed of the risks of sedation and the physician had monitored blood levels of antiepileptic drugs in an appropriate fashion.

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Discussion

Question: Are there any federal guidelines or regulations that apply to interstate truckers with epilepsy?

Dr. Beresford: Yes, although I'm not familiar with them in detail. They are regulations, not statutes. Most of the original licensure that makes persons eligible to drive is handled on a state-by-state basis, and there are special provisions for chauffeurs', public conveyance, and trucking licenses. I am just not familiar with the details.

Question: Would you comment on a physician's liability should antiepileptic drugs not be prescribed for someone at low risk for seizure recurrence, for example, a single seizure, and such a patient subsequently has a seizure that engenders risk or actual damage to himself or someone else?

Dr. Beresford: The standard in a malpractice suit is that a physician's conduct must be shown to have deviated from reasonable or accepted standards of medical practice. If the balance of the evidence is that it is reasonable or accepted practice not to treat a single seizure, then the physician's risk of liability is small.

The problem with the malpractice suit, however, is that one gets into a battle of experts. In the rush by physicians to condemn lawyers and judges for what has happened in the court liability system, they sometimes forget that physicians are involved there as well, and that it is physicians who come into court and testify. Typically, it is the plaintiff's physician who is going to make or break the case. Because of this, one cannot give a doctrinaire answer. It seems to me, though, that with standards of practice evolving in favor of not treating single seizures under many circumstances, it is a perfectly good defense should the issue come up.

Dr. Pedley: There are a number of questions for Dr. Beresford that I am not going to ask because they relate to very particular circumstances, nor will I ask advice about when this or that patient can drive. I think the answers are so specific to the particular circumstances, and so variable from state to state, that it really would not be appropriate to devote time to this. I refer you to your own attorneys who can advise you in light of what is relevant in your own state.

Question: Based on one of the cases you discussed, do you recommend that physicians use specific terms such as "fetal hydantoin syndrome" when discussing teratogenic risks of antiepileptic drugs?

Dr. Beresford: In a way, it is kind of unfortunate I used that particular case because of the factual question about whether that entity actually exists or is even an appropriate type of diagnosis. It has always seemed to me that the most important thing about informed consent is the quality of the dialogue, and the fact that the dialogue is documented in the medical record. When one lists 99 things that may go wrong but does not list the 100th thing, and it is then the 100th thing that actually happens, it has always struck me as wrong that this then becomes a basis for liability.

In response specifically to your question, it seems to me that if one concludes that there is no such thing as fetal hydantoin syndromes but rather a variety of fetal effects that can occur with a number of antiepileptic drugs (and this seems to be the evolving view), then I do not think it is necessary to disclose it.

Dr. Leppik: From a medical standpoint, I do what our local lawyers have advised me to do. That is, I bring up the issue of possible drug-related teratogenic effects with any woman of childbearing age and potential. I agree that the importance is not that you cover every conceivable complication, but that a discussion is initiated that indicates there are some risks associated with treatment. I also say that I think the risks are outweighed by the benefits of the treatment.

I also make sure that patients have plenty of opportunity to ask questions and open up to me about particular concerns they have, or have been advised about. Finally, I give them a written handout of some material that I prepared that goes over this issue in a general way. I fully agreed with Dr. Beresford that the idea of having to list every possible complication is very counterproductive.

Question: Have recent changes resulting in increased flexibility for epileptic patients' obtaining licensure, for example, Maryland's recent reduction in length of time required for seizure control to 3 months, resulted in any increased number of accidents, injuries, or litigation from seizure-related accidents?

Dr. Beresford: Not that I am aware of.

Question: Are there any legal implications for physicians who prescribe generic brands of antiepileptic drugs as opposed to brand names?

Dr. Beresford: The only implication would be if there is convincing evidence that the generic drug is inferior. This is one of those fact questions. It goes back to the state of the medical evidence.