



# Oncologists and Medical Malpractice

By Patricia Legant, MD, PhD

An experienced oncologist wrote orders for a new salvage regimen that employed higher doses of chemotherapy than usual. Subsequently, the patient developed acute renal failure and required weeks of dialysis, but ultimately recovered, and the tumor responded. To the physician's dismay, he later discovered that he had mistakenly ordered four times the recommended amount of the nephrotoxic drug in the treatment regimen. After careful thought, he decided not to divulge the error to the patient. When tumor progressed 6 months later, the patient obtained a second opinion and learned of the error. He sued, and the case finally settled for \$75,000.

Any physician who has been sued for malpractice is familiar with the unpleasant, visceral reaction generated by a malpractice claim. Whatever the outcome, a claim takes such a financial and emotional toll that the physician hopes never to experience one again. Fortunately, oncologists are much less likely to be sued than physicians in other specialties. Bad outcomes in medicine ordinarily are an invitation for allegation of wrongdoing. The nature of the specialty brings plenty of bad outcomes; however, oncologists are perhaps protected from allegation of wrongdoing by the fact that most of these are not unexpected. Whatever the reason, medical oncologists enjoy relatively low malpractice premiums, and are lumped with nonprocedural internists for risk classification. Indeed, the national organization of physician-run malpractice insurers does not sort cases of medical oncologists separately from those of internists (personal communication, Physicians Insurance Association of America, February 2006).

Though low, the claims rate for oncologists is still significant, and a suit is a devastating episode in the life of an oncologist. It is therefore wise that we be aware of our medicolegal vulnerabilities, avoid exposure to allegations of negligence, and, should a suit occur, have taken steps beforehand to prevent a loss. Described here are several common types of litigation in medical oncology, followed by suggested ways to avoid litigation and, if sued, to win. Although the concerns of

other oncology specialists are not specifically addressed here, many of the topics apply equally to them.

## Potential Areas of Litigation

### 1. Delay in Diagnosis of Cancer

Delay in diagnosis of breast cancer is the leading cause of all malpractice suits against physicians, and delays in diagnosis of lung and colorectal cancer are among the most expensive in terms of indemnity payment (personal communication, Physicians Insurance Association of America, February 2006). Alleged errors in cases of delay in cancer diagnosis typically involve misreading of pathology slides; breakdown of communication between the diagnostic physician (pathologist or radiologist) and the ordering physician, or between the physician and the patient; or failure to follow a symptom or biopsy a mass after initially negative tests. These claims mostly affect primary care and diagnosing physicians such as radiologists and pathologists, rather than oncologists. Nevertheless, oncologists often become entangled in the cases too, either as part of the usual litigation sweep to involve all physicians providing care, or as expert witnesses.

The role of expert witness is alien to most medical oncologists, who are accustomed to quoting evidence from studies, but who may instead be asked to comment on questions for which data are incomplete or nonexistent. For example, cases alleging delay in diagnosis often hinge upon retrospective estimates of survival based on different times of diagnosis and treatment. Scientific concepts like lead-time bias, relative versus absolute risk, and statistical versus clinical significance may be difficult to convey to a lay audience. Attorneys may try to elicit absolute percentages of survival or tumor doubling times, rather than the sort of speculative, qualified estimates with which oncologists are more comfortable.

Oncologists are potentially vulnerable to claims of delay in diagnosis if they miss second malignancies in cancer survivors, who are at increased risk for such cancers due both to genetic predisposition and to late side effects of treatment. Evidence-

based guidelines for follow-up of such survivors are just beginning to appear, and the future may bring advice, but also responsibility, regarding standardized surveillance schedules for detection of these malignancies.

## 2. Chemotherapy Dosing

Particular to the practice of oncology is the use of chemotherapy drugs, which have a lower therapeutic index than drugs used in other specialties, and for which a small dose miscalculation or misplacement of a decimal point in a dose can be fatal. A potential Achilles heel for oncologists then, would be errors in chemotherapy prescribing, mixing, and administration. Every day we write multiple orders for complicated regimens involving several calculations (body surface area, creatinine clearance, area under the curve, etc), consideration of organ function and patient age (renal function with cisplatin, heart disease with anthracyclines), previous drug exposure (cumulative anthracycline or bleomycin doses, heavy pretreatment), toxicities (prior taxane neuropathy), and specific patient characteristics (allergy, pre-existing respiratory failure, pleural effusion, and now certain genetic markers for drug tolerance, as for irinotecan). We must also remember numerous critical supportive drugs and procedures, including steroids, intravenous hydration, antiemetics, allopurinol, growth factors, and drugs to protect against toxicities of specific agents (leucovorin rescue for methotrexate, mesna for ifosfamide, anticoagulant for thalidomide, and prophylactic antibiotics for certain high-dose regimens).

In order to address all these variables carefully and accurately, we need a moment to collect our thoughts. Instead, we are bombarded by phone calls, insurance issues, regulatory demands, and the pressures of declining reimbursement. In the face of these increasing distractions, it is remarkable that so few mistakes are made.

Three recent changes in chemotherapy services increase risk of error and, hence, liability: transfer of chemotherapy preparation and administration (due to financial pressure) out of physician offices to other sites; provision of chemotherapy by entities other than physician offices (e.g., “brown-bagging”); and oral chemotherapy.

Until recently, oncologists would write and then communicate orders to office-based pharmacists and nurses, who would subsequently prepare and administer the drugs under their direct supervision. With recent changes in insurance reimbursement, however, drug preparation and administration are moving outside the office and into hospital outpatient departments. Risk of error accompanies any transfer of orders,<sup>1</sup> and the situation is worsened by relatively less experience with chemotherapy administration among hospital, relative to oncology office, personnel.

In the brown-bagging scenario, insurers seeking to cut costs of chemotherapy drugs promote or even mandate drug purchase

and/or preparation by designated “specialty pharmacies.” In this arrangement, the chain of safe preparation and delivery is disrupted, and oncologists lose control over quality of the source of drug and supervision over its preparation yet remain a focus of liability for any errors on the part of the drug supplier.

New developments in oral cancer therapy may bring additional risk. Birner et al<sup>2</sup> have shown that the shift from parenteral to oral chemotherapy may produce poor patient compliance in taking medicines as instructed. Also, the proliferation of mail-order pharmacy programs may give rise to dose confusion, as patients, eager to achieve greater cost savings, fill several months of drug at a time and then misunderstand later dose changes or discontinuation of the drug. Both under- and overdosing of drugs have potential undesirable consequences. With the former, drug efficacy is needlessly compromised, while with the latter, drug toxicity may be dangerously increased or even fatal.

Pearl Moore, RN, cofounder of the Oncology Nursing Society, comments on another less obvious result of the movement of chemotherapy administration out of oncology offices. Nurses now have much less of an opportunity to educate patients about therapies and their adverse effects, at a time when patients, due to their increased responsibility in self-administering drugs, need this instruction more than ever.<sup>3</sup>

## 3. Pain Control

Judging from two recent cases in California, another potential medicolegal pitfall is undertreatment of pain. In 2001, a physician was convicted of elder abuse and assessed \$1.5 million for suboptimal pain management for a dying patient (*Bergman v Clin*), with similar results in a second case (*Tomlinson v Bayberry Care Center*), in 2003. In contrast to many primary physicians, oncologists are usually well versed in pain management. Fortunately also, national guidelines exist, and physicians are usually protected against allegations of negligence if they operate within these. Guidelines for pain management are available from the American Pain Society and others ([www.guideline.gov](http://www.guideline.gov)). Hospitals have focused greater attention on pain management since both the Joint Commission on Accreditation of Healthcare Organizations and the National Committee on Quality Assurance have begun measuring adherence to such standards.<sup>4</sup>

Narcotic prescribing still constitutes a double-edged sword legally, as physicians and their staff also face liability for overprescribing, as opposed to underprescribing, narcotic analgesics, especially if this then results in patient death. There has been recent concern about excessive regulatory oversight of narcotic prescribing,<sup>5</sup> in the context of the role of the Drug Enforcement Agency (DEA) in overseeing end-of-life care that employs opioids or barbiturates. Somewhat assuaging such worry is the recent US Supreme Court

decision overruling a federal attempt to derail the Oregon Death with Dignity Act by using DEA licensing to regulate medical decision making (*Gonzales v Oregon*, 126 S. Ct 904, 2006; Congress<sup>6</sup>).

#### 4. Informed Consent

To succeed in a claim of negligence for informed consent, the patient must show that the physician failed to inform the patient adequately of significant risks of serious harm associated with the proposed treatment as well as alternatives; that the patient, due to this failure, agreed to therapy that a reasonable patient would otherwise have refused; and that the patient suffered injury due to that therapy accordingly received. These elements may seem obvious, but the actual details of obtaining informed consent are less apparent. Consent for surgical procedures is clearly an area fraught with medicolegal risk, and protection against claims usually requires written consent that is as thorough as possible. For consent for chemotherapy or radiation administration, however, the criteria are less well defined, and practices vary across the country. While a formal written consent form is not required, legal protection (and good medical practice) does mandate a thorough explanation of risks and benefits before beginning treatment, as well as documentation of that explanation in the medical record. It is no longer enough to note, "Informed consent obtained." Instead, the details of that discussion should be explicitly described. Without this record, even a signed consent is not sufficient to protect the physician against suit.

Exact legal standards for disclosure vary by state. In some states, disclosure should encompass what a reasonable physician would supply, whereas other states require what a reasonable patient would want to know, and still others use a hybrid of both viewpoints. These different approaches then influence the relevance of expert testimony about local physician custom, as opposed to assumptions about local patient expectation. Under any of the three standards of disclosure, certain kinds of information should be documented in the medical record. These include "diagnosis, nature of the proposed treatment, consequences of that treatment, alternatives to the proposed treatment, and the prognosis, with and without the treatment."<sup>7</sup> Physicians should also disclose potential conflicts of interest.

While physicians are not expected, nor would they be able, to disclose every possible risk, they "should always err on the side of greater disclosure rather than too little," and should also make an effort to mention major, though less likely, possible events such as infertility, death, and late second malignancies. How to impart all this information to patients succinctly, yet clearly, and without frightening them into refusing treatment, is a major challenge. Moreover, speaking candidly to the patient about his prognosis, however essential for informed decision making, so soon after he learns his

diagnosis and then meets the oncologist for the first time, can be emotionally traumatic for all concerned.

These questions become even more complex when dealing with mentally impaired or incompetent patients or, in pediatric oncology, with children and parents.<sup>8</sup> Finally, consent for clinical trial participation is possibly even more involved, as highlighted by recent cases concerning bone marrow transplantation trials brought against the Fred Hutchinson Cancer Research Center in Seattle. Informed consent in oncology research poses certain unique dilemmas, as desperate patients may confuse research and treatment and have unrealistic expectations about benefits.<sup>9</sup> ASCO offers guidance in its policy statement on oversight of clinical research.<sup>10</sup>

#### 5. Protection of Privacy

Since the advent of the Health Insurance Portability and Accountability Act (HIPAA) in 1996, effective in 2003, it would be hard to be unaware of the extreme importance of maintaining confidentiality of medical information and records. Most oncologists understand that, under the legal doctrine of *respondeat superior*, responsibility for lapses in confidentiality by their office staff is ascribed to their physician employer, thus necessitating careful staff training in these matters. Oncologists and their staff also know how difficult it is to deny immediate access to information to patients' family members until patient consent can be obtained. Particularly risky is communicating HIV or genetic testing results, especially considering competing ethical obligations to protect patient privacy but also warn sexual partners, in the case of HIV-positive patients, or family members, in the case of familial diseases. Some recommend getting a specific release for HIV information in addition to a general release if a medical record contains mention of HIV status.<sup>11</sup> State law varies on this point and also on other permissible circumstances allowing release of HIV information.

Another potential minefield is electronic information. In the midst of pressure to move toward both telemedicine and electronic messaging, liability for breaks in confidentiality is not yet well defined.<sup>12</sup> Any release of information should comply with the "minimum necessary" standard of choosing which information to release. One important exception to HIPAA regulations to bear in mind is the case of a mentally incompetent patient, for whom information may be released in the patient's interest, though the circumstances of such incompetence must be documented.

#### 6. Genetic Counseling

With growing availability of tests for genetic predisposition to malignancy, patients are turning increasingly to their oncologists for advice on whether to test and what to do with test results. One could conceivably be held liable for omitting indicated testing or neglecting to maintain surveillance for an

associated cancer. It is difficult for busy oncologists to stay abreast of advancing advice in this field, though ASCO regularly offers education and even a whole curriculum on the subject.<sup>13</sup> As in all oncology care, if uncertain, one should not hesitate to look it up or refer to another physician or genetic counselor who has the requisite expertise.

## 7. Communication Breakdown

For effective supervision of hospital patients, oncologists depend on communication with nurses. During a busy day, or especially in the middle of the night, it is easy to dismiss a nurse's concern as overreaction. Even if their worry is exaggerated, there may be some grounds for the nurse's uneasiness. Should something later go wrong and a claim be filed, the nurse may feel unable to support the physician's version of events. Moreover, perceived lack of respect for the nurse's opinion may discourage his or her calling in the event of future problems.

Oncologists often receive requests for advice about patients whom they have not actually been asked to see. Such curbside consults carry considerable risk, as they rely on a truncated version of patient history, and an opinion is given off the cuff, without more thoughtful analysis. The oncologist never has an opportunity to see the patient or review the chart data firsthand. The requesting physician nevertheless frequently divulges to the patient the identity of the oncologist who was generous in giving advice. That oncologist then gets named along with the treating physician if a claim arises later. Dealing with such requests for curbside consults is a delicate matter, as one wishes to avoid alienating a referring physician. If the case is straightforward, one might go ahead and give advice but ask that it be anonymous, for medicolegal reasons. If the case is in the least complex, however, one should ask to see the patient officially.

## Ways to Avoid Litigation

### 1. Good Patient-Physician Communication

Frequently listed as a reason why patients sue their physicians is the patients' perception that their viewpoint was ignored. In an era of extreme time pressure and declining reimbursement, one must still try to listen sincerely to one's patients and answer their questions. The office staff is part of the communication system too, and must be well trained in courtesy, safe triage, and privacy safeguards. To improve informed consent, safe prescription of chemotherapy, and timely and effective management of toxicity, verbal education can productively be reinforced by written and online materials. But a moment of precious time and genuine sympathy can go a long way toward preventing litigation.

### 2. Good Medical Records

Many negligence cases are lost due to incomplete, illegible, or missing medical records. Electronic medical records (EMR) may help in the future, but bring their own set of problems.

Maintenance of confidentiality in EMR is one obvious challenge, and one should pay attention that, on template notes, one did examine what one checked, and add narrative explanation when necessary to justify any decisions.<sup>14</sup> Cases are also lost by late corrections of a record. In the absence of a date, signature, and possibly even written explanation for a correction, such amendments are interpreted by the legal system as fraudulent. This assumption especially traps members of groups of multiple doctors, who must resist the temptation to correct each other's records without meticulous annotation of when and why. Corrections should consist of a single line through the erroneous part, rather than obliteration, as with whiteout.

Good medical record keeping also extends to phone calls and laboratory and x-ray reports. Phone messages must clearly document time, date, and purpose of the call, and also problem resolution. These and all laboratory and x-ray reports must reliably be reviewed and initialed by the physician prior to filing in the chart.

### 3. Tracking Systems for Follow-Up

Physicians all know patients who are led to water, but just won't drink. The law seems to believe that they should practically be shoved in. Less metaphorically, physicians may tell patients to get a follow-up mammogram or colonoscopy, or prothrombin time measurement, but find themselves held liable if patients fail to follow through and are not then contacted by the office. Similarly, if patients fail to keep appointments, and there is no record of efforts to contact them to reschedule, they may prevail in a claim for negligence if they later develop some problem.

Oncologists are used to flow sheets and following and charting a wide array of data, including blood counts, coagulation parameters, and liver and kidney function, all during active cancer treatment, and also response measures such as x-rays, scans, and tumor markers. They must also get in the habit of watching, and documenting, newer measures of potential toxicity, such as regular ECGs for patients on herceptin, and creatinines for those on zoledronic acid. As guidelines for follow-up of survivors proliferate, they must in addition chart carcinoembryonic antigen, abdomen and pelvis computed tomography scans, colonoscopies, thyroid examinations, and even cholesterols, at prescribed intervals, and record advice against smoking.

### 4. Cooperative Teamwork Among Physicians, Pharmacists, Nurses, and Staff

Even before publication of the Institute of Medicine report on medical error in 1999,<sup>15</sup> there were calls for a "systems approach" to reducing chemotherapy errors.<sup>16</sup> Suggestions have included multiple levels of order recalculation and verification; dosage limits; bridging of gaps in continuity of care; order simplification and standardization; computerized physician order entry; prohibition of verbal orders; dedicated

oncology units; and patient and family education.<sup>17</sup> For their own and their patients' protection, oncologists should embrace these system improvements where proven effective, but recognize that the tort system still attributes adverse outcomes to individual human error, and also seeks the deepest pocket in assigning legal blame. Thus, one should still be attuned to one's own "human factors."

Communication among all parties caring for cancer patients must be seamless and accurate, especially regarding chemotherapy administration. As in an airplane cockpit, anyone should feel comfortable to express misgivings and request clarification of an order.<sup>18</sup> Ideally, all the time and mental effort devoted to devising a therapy plan would be reimbursed and thus protected. Meanwhile, oncologists should try personally to proofread their own orders at least once, and to encourage the expression of honest disagreement among their coworkers, in the interest of preventing errors. Standardized order sets may be helpful, but any of us who has dealt with computer systems knows that standardized orders, either written or computerized, cannot substitute for a moment of focused concentration on the task at hand.<sup>19</sup> Specifically regarding safe prescribing of oral chemotherapy drugs, Birner et al<sup>2</sup> go so far as to recommend that oncologists "write non-refillable prescriptions only for the amount of medication necessary to complete one cycle of chemotherapy."

## 5. Avoidance of Jousting

One excellent way to generate a claim is to disparage a colleague's care. Current calls for cancer patients always to get a second opinion are often no more than thinly disguised marketing ploys, and also serve to erode patient trust in all their oncologists. In giving a second opinion, one is certainly not obliged to agree with the prior treatment plan, but one should resist the temptation to criticize the previous physician's expertise or judgment, either to the patient or in the written record. Aside from considerations of ethics and courtesy, one should follow this advice even purely for self-interest, as the criticizing physician is likely to be swept into a suit right along with the prior physician.

## 6. Giving a "Safe" Apology

Patients do want to be informed about an error and its apparent cause, and desire an apology and reassurance that steps will be taken to prevent recurrence. Evidence also suggests that such an apology is often effective in averting a claim of malpractice. Physicians' impulse too may be to apologize to the patient.<sup>20</sup> Nevertheless, in most states, such an apology may legally constitute an admission of guilt. A few states have passed laws protecting such expressions of sympathy from legal interpretation as presumption of culpability. Except in Colorado, however, these states do not exempt other portions of such a conversation from admission at trial. Thus, even in states with such "I'm sorry" legislation, the physician may need help in framing the conversation, in

hopes of bringing psychological relief to the patient without compromising the physician's ability to defend himself against a later claim of negligence. Even in Colorado, with the broadest law, the local medical malpractice carrier (COPIC) has a special program that intervenes in timely fashion and rehearses the physician in an effective apology, for greatest benefit to patient and physician.

## Alternate Dispute Resolution

The adversarial nature of the malpractice litigation process has disadvantages both for patient plaintiff and physician defendant. The actual facts of the case may be distorted and obscured, the patient may be over- or undercompensated or not compensated at all, and the system is extremely expensive and time-consuming. Moreover, 60% of the available funds are expended on administrative costs (mostly legal fees), rather than on patient compensation.<sup>21</sup> To address these problems, a number of alternative processes have arisen over the last 10 years.

Some of these have focused on improving quality of evidence and consistency of decision making by involving experts in the adjudication. For example, some states require *certificates of merit* to be signed by a physician before a case can go forward. Others require a *prelitigation screening panel* in which an advisory panel convenes for an abbreviated hearing of the evidence, ostensibly so that nonmeritorious suits will be dismissed. Unfortunately, neither of these techniques has functioned effectively in substantially discouraging frivolous claims.

Other methods have been proposed to speed the process along. For example, "early offer" programs provide incentives to encourage settlement between litigating parties shortly after an adverse event. *Settlement conferences* promote mediation of sorts, and in fact characterize resolution of the vast majority of claims with payment.

Malpractice insurance carriers or health maintenance organizations may encourage physicians to ask their patients to waive their ability to resolve disputes in court, and instead proceed through arbitration. *Arbitration* involves selection of one or several neutral persons by the litigants. These arbitrators then hear the case and render a decision about any award. Arbitration is usually much faster and less expensive than usual litigation, may result in more knowledgeable decision makers, and directs a larger share of any award to the plaintiff. For an arbitration decision to serve as final, all parties to the suit must have agreed in writing beforehand to submit disputes to this process before the alleged act of negligence took place. At this time, a growing number of states have adopted this approach.

*No-fault compensation*, or more specifically, predetermined compensation for avoidable bad outcomes, is derived from the philosophies underlying automobile insurance and

workers compensation. This approach would require a wholesale overhaul of the current tort system, and, not surprisingly, is strongly opposed by the trial bar. Cost concerns are salient as well, in that less than 20% of injured patients currently bring suits, whereas any no-fault program would potentially identify and compensate more of these patients. Other methods are summarized well elsewhere.<sup>22</sup>

## Conclusion

Oncology is at times an emotionally draining specialty. In fact, as implied by studies of burnout among oncologists,<sup>23</sup> we put an enormous amount of our time and heart into our work. We may therefore be particularly vulnerable to feelings of frustration and anger when sued for false allegation, or guilt, embarrassment, or depression when sued for valid cause. Such feelings are common in all physicians who are sued, and can hurt professional and interpersonal relationships. Many malpractice insurers offer confidential psychological help, which oncologists should not hesitate to

use. Quelling the emotions that accompany a malpractice claim may mitigate the professional and personal fallout and even make one a better partner in one's own defense.

Ideally, with caution regarding the hazards discussed, some knowledge about prevention, and just a little luck, one may not have to face a claim very often. Fortunately, most of the methods for avoiding malpractice suits simply amount to providing good patient care.

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