LAW & MEDICINE

Informed Consent: Disclosure of Risks

Question: Regarding physician liability arising from medication injuries, which of the following is most accurate?

A. Doctor is liable if drug was prescribed for unapproved off-label use.

B. Doctor is liable for failing to warn of significant risks.

C. Doctor is liable for failing to warn of all complications.

D. Patient did not ask about side effects and therefore was contributorily negligent.

E. Liability will attach to manufacturer for a "defective product."

BY S.Y. TAN, M.D., J.D.

Answer: B. The informed consent doctrine requires that physicians discuss all material risks, including rare but serious risks. Choice A is incorrect because prescribing a drug for an "off-label" use may be an acceptable practice. However, it is prudent for the doctor to document in the records the reason for using the drug. Choice C is overly broad. A warning is required for all material risks (i.e., those that significantly affect the patient's decision to accept or reject the recommended treatment), but a warning is not necessary for all risks.

Patients are assumed to have little or no knowledge of medications, and they have no legal duty to inquire about side effects. The doctor, on the other hand, has an affirmative duty to warn of these side effects. In a malpractice case alleging lack of informed consent due to failure to warn, the defense cannot plead contributory negligence, so choice D is incorrect. Finally, E is also incorrect. The "learned intermediary" doctrine stipulates that the doctor, not the pharmaceutical company, is liable for medication-related injuries as he/she is a learned professional who directly communicates with the patient and who does the actual prescribing. This puts the doctor in the hot seat for an adverse drug reaction, unless the drug company has been negligent in identifying and/or communicating the risk.

Disclosure of Material Risks

In order for patients to meaningfully give their consent to treatment, they should have sufficient information regarding the doctor's treatment plans. The consent must also be given voluntarily. The notion of patient autonomy is so entrenched that the law imposes upon the practitioner the duty to disclose three fundamental aspects of treatment, easily remembered by the mnemonic PAR (P = procedure [or medication/device], A = alternatives, R = risks).

What constitutes a material risk is at the heart of the controversy surrounding the informed consent doctrine. Generally, the patient should be informed of all serious risks, even if unusual or rare. However, in one court case, a 1% risk of hearing loss required disclosure (*Scott v. Wilson,* 396 S.W.2d 532 [Tex. Civ. App. 1965]), whereas in another, the court appeared to say that a 1.5% chance of visual loss did not (*Yeats v. Harms,* 393 P.2d 982 [Kan. 1964]). The California Supreme Court has stated that "material information is that which the physician knows or should know would be regarded as significant by a reasonable person in the patient's position when deciding to accept or reject the recommended medical procedure," that "a (material) fact must also be one which is not commonly appreciated," and that the scope of disclosure may be expanded in patients with "unique concerns or lack of familiarity with medical procedures" (*Truman v. Thomas,* 27 Cal.3d 285 [1980]). There is, however, no legal requirement to deliver a "mini-course in medical science" (*Cobbs v. Grant,* 8 Cal.3d 229 [1972]).

Warren v. Schecter is one of the most dramatic cases to confront the material risk issue. The plaintiff won a $9.6 million judgment against the doctor for his failure to disclose risk of osteoporosis (*Warren v. Schecter,* 67 Cal.Rptr.2d 573 [Cal. 1997]). Dr. Schecter had performed gastric surgery on Janet Warren for peptic ulcer disease, and had warned the patient of the risks of bowel obstruction, dumping syndrome, and anesthetic death. He did not believe osteoporosis, osteomalacia, and bone pain were risks of surgery, and so did not discuss those risks with her. The plaintiff testified at trial that had Dr. Schecter warned of the risk of metabolic bone disease, she would not have consented to surgery. A second operation was undertaken because she developed postoperative dumping syndrome and alkaline reflux gastritis, and the surgeon again failed to advise her of the risk of metabolic bone disease. She again asserted that she would not have consented to the second surgery had she been duly advised.

The plaintiff subsequently developed severe osteoporotic fractures, and filed a malpractice lawsuit alleging that Dr. Schecter was liable under an informed consent theory for performing surgery without advising her of the risk of bone

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Inaccurate Methods Often Used for Physician Cost Profiling

BY MARY ANN MOON

Current methods for profiling individual physicians as to whether they provide low-cost or high-cost care are often inaccurate and produce misleading results, according to a report.

Health plans use cost profiling to limit how many physicians get in-network contracts and to allot bonuses to the physicians whose "resource use" is lower than average. In each case, there must be a method for determining physicians' costs, yet the accuracy of these methods has never been proved, according to John L. Adams, Ph.D., of RAND Corp., and his associates.

"To our knowledge, the reliability of physician cost profiling has not been previously addressed," they noted.

Dr. Adams and his colleagues assessed the reliability of current methods of cost profiling using claims data from four Massachusetts insurance companies concerning 1.1 million adult patients treated during 2004-2005. A total of 12,789 physicians were included in the study. They were predominantly men who were board certified, had been trained in the United States, and had been in practice for more than 10 years.

The physicians worked in 28 specialties, including cardiology, endocrinology, gastroenterology, and obstetrics and gynecology. Family physicians, general physicians, and internal medicine physicians comprised approximately one-third of the sample.

The investigators estimated the reliability of cost profiles on a scale of 0-1, with 0 representing completely unreliable profiles and 1 representing completely reliable profiles. They then estimated the proportion of physicians in each specialty whose cost performance would be calculated inaccurately.

Overall, only 41% of physicians across all specialties had cost profile scores of 0.70 or greater, a commonly used threshold of acceptable accuracy. Only 47% of internists, 30% of cardiologists, 41% of family or general physicians, 57% of ob.gyns., 59% of gastroenterologists, and 22% of endocrinologists received scores of 0.70.

Overall, only 9% of physicians in the study had scores of 0.90 or greater, indicating optimal accuracy.

The proportion of physicians who were classified as "lower cost" but who were not in fact lower cost ranged from 29% to 67%, depending on the specialty. Fully 50% of internists, 40% of cardiologists, 39% of family or general physicians, 36% of ob.gyns., 32% of gastroenterologists, and 50% of endocrinologists were misclassified as "lower-cost" providers when they were not.

Also, 22% of internists were misclassified as "higher cost" when they were not in fact higher cost. This same misclassification occurred for 14% of cardiologists, 16% of family or general physicians, 10% of ob.gyns., 11% of gastroenterologists, and 19% of endocrinologists.

These findings indicate that standard methods of cost profiling are highly unreliable, and that many individuals and groups are basing important decisions on inaccuracies. "Consumers, physicians, and purchasers are all at risk of being misled by the results produced by these tools," the investigators concluded (N. Engl. J. Med. 2010;362:1014-21).

The study findings also suggest that using cost profiles that are based on these unreliable methods will not reduce health care spending, they added. ■

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MY TAKE

Abandon Flawed Evaluation Programs

The RAND Corp. study verifies the American Medical Association's long-standing contention that there are serious flaws in health insurer programs that attempt to rate physicians based on cost of care.

The RAND study shows that physician ratings conducted by insurers can be wrong up to two-thirds of the time for some groups of physicians. Inaccurate information can erode patient confidence and trust in caring physicians, and disrupt patients' relationships with physicians who have cared for them for years.

Patients should always be able to trust that the information they receive on physicians is valid and reliable, especially when the data are used by insurers to influence or restrict patients' choice of physicians.

Given the potential for irreparable damage to the patient-physician relationship, the AMA calls on the health insurance industry to abandon flawed physician evaluation and ranking programs, and join with the AMA to create constructive programs that produce meaningful data for increasing the quality and efficiency of health care.

J. JAMES ROHACK, M.D., *is president of the American Medical Association. He reported having no conflicts of interest.*

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complications. The jury found that Dr. Schecter did not disclose to Ms. Warren all relevant information that would have enabled her to make an informed decision regarding surgery and that a reasonably prudent person in her position would not have consented to surgery if adequately informed of all the significant perils.

Other Aspects of Disclosure

Besides risks associated with surgery or a medication, courts have also looked at other aspects of disclosure in the doctor-patient relationship. Some litigated examples include disclosing the limited experience of a neurosurgeon (*Johnson v. Kokemoor,* 545 N.W.2d 495 [Wis. 1996]), financial incentives amounting to a breach of fiduciary responsibility *(Moore v. The Regents of the University of California, 793* P.2d 479 [Cal. 1990]), and a surgeon's disclosure of his positive HIV status (*Estate of Behringer v. The Medical Center at Princeton,* 192 A.2d 1251 [N.J. Super. 1991]) or alcoholism (*Hidding v. Williams,* 578 So.2d 1192 [La.App. 1991]). However, in *Arato v. Avedon,* the California Supreme Court held that the law did not require physicians to inform their terminally ill patients of their prognosis and life expectancy (*Arato v. Avedon,* 858 P.2d 598 [Cal. 1993]).

An example of statutory law regarding informed consent is found in Hawaii Revised Statutes §671-3. Amended by the 2003 legislature, the statute mandates disclosure of "recognized material risks of serious complications or mortality" but does not define the word "material." This amended language replaced the earlier version's "recognized, serious, possible risks, complications and anticipated benefits," arguably lightening the doctor's duty regarding risk disclosure. In reality, the new language is unlikely to have a significant practical effect. An earlier 1976 version of the law merely required the disclosure of "probable risks and effects." ■

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