LAW & MEDICINE

Complementary and Alternative Medicine

Question: Ms. Holistica purchased Slim-Yu, an over-the-counter (OTC) herbal supplement advertised as a weight-loss agent. She asked her primary care doctor about its effectiveness and safety, and he said that it was "OK." Two months later, Ms. Holistica developed jaundice, abnormal liver function tests, and liver failure. Which of the following is incorrect?:

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A. Her doctor cannot be liable because he did not prescribe the supplement.

B. Her doctor may be liable because he had given his approval for its use.

C. Ms. Holistica should consider suing the drugstore for selling Slim-Yu.

D. Ms. Holistica should consider suing the manufacturer for a defective product.

E. No one is liable unless the plaintiff proves proximate causation.

Answer: A. All choices are true except A. To be sure, the doctor did not prescribe Slim-Yu, but he did give his "OK," and the patient may have relied upon his approval. Just because it's an OTC preparation does not absolve the physician if he was providing medical advice in a professional capacity. Totally unregulated, a few of these OTC supplements can be expected to result in harmful effects. The injured party will naturally consider suing both the manufacturer and the drugstore for putting the item on the market. Ms. Holistica will still have to prove that the weight-loss agent proximately caused the injury, or else all defendants will escape liability.

Lack of informed consent is the usual basis for lawsuits against physicians who practice complementary and alternative medicine (CAM). In *Charell v. Gonzalez*, a cancer patient refused treatment by her oncologist and opted instead for "nutritional therapy" offered by another physician. Her cancer metastasized, leading to blindness and back problems. The patient alleged negligence and failure to warn of risks. The jury found the physician 51% liable for lack of informed consent and departure from standard of care, whereas the plaintiff was found to be 49% at fault for choosing to ignore the recommendations of her oncologists.

In *Moore v. Baker*, a patient attempted to sue her neurologist for failure to offer EDTA chelation therapy as an alternative to surgical treatment. The patient had undergone a carotid endarterectomy and during the recovery period, a blood clot developed, causing brain damage. She alleged that EDTA chelation therapy was as effective as surgery and was less risky. However, her suit failed, the court holding: "The evidence overwhelmingly suggests that the mainstream medical community does not recognize or accept EDTA therapy as an alternative to a carotid endarterectomy … "

CAM is not usually taught as tried and true therapy in medical schools, so the use of such "nontraditional" therapy may be equated with experimental, even substandard, care. One appellate judge has warned: "Currently, the law does not encourage medical doctors to stray from the pack (because) it is well-settled that in medical malpractice actions, the question of negligence must be decided by reference to relevant medical standards of care …"

There are several legal defenses for a physician's integrating, utilizing, or supporting CAM therapies. One possible defense is to assert the "respectable minority" standard of care. Or the treating physician can plead clinical innovation for a difficult or desperate situation. Yet another defense is to assert assumption of risk. In *Schneider v. Revici*, a physician recommended nutritional (selenium and dietary restrictions) and other nonsurgical treatments for breast cancer. The patient had signed a detailed consent form disclosing that the treatments lacked Food and Drug Administration approval and could not be guaranteed and agreed to release the physician from liability. The cancer spread and the patient sued for common law fraud, medical malpractice, and lack of informed consent, but the court of appeals held that assumption of risk is a complete defense. The same court held in another case that a patient's failure to sign a consent form did not preclude the jury from considering the assumption of risk defense, as consent may be written or verbal.

Even if it is the patient's choice, physicians must still exercise due care when implementing CAM. In *Gonzalez v. New York State Department of Health*, Dr. Gonzalez was charged with gross negligence and incompetence after he used unconventional therapies to treat six patients with incurable cancer who had failed or rejected conventional treatment. A hearing committee found that he missed signs of disease progression and failed to perform adequate assessments, testing, and follow-up. The court held that a patient's consent to or even insistence upon a certain treatment does not relieve the physician from the obligation of providing the usual standard of care.

The allopathic physician should stay up to date with therapeutic developments in CAM. For example, a 1997 National Institutes of Health consensus statement supported acupuncture as a legitimate therapy with proven efficacy for adult postoperative- and chemotherapy-induced nausea and vomiting. Many "nontraditional" treatments, such as those for back pain, are gaining acceptance. When discussing alternative therapy with a patient, the physician should first fully inform the patient about conventional treatments and their limitations. Next, the physician should explain why the novel, rather than the recognized conventional therapy is being considered. Finally, whether the physician intends to carry out CAM therapy or refer to another practitioner, the patient must be warned about the potential risks associated with such therapy.

In order to guard against malpractice liability, one might consider the approach recommended by Cohen and Eisenberg: Where safety and or efficacy are not established, physicians should be guarded in offering the treatment. They should discourage patients from pursuing dangerous treatments such as injections of unapproved substances and pay close attention to known herb-drug interactions, for example, St. John's wort interacting with oral contraceptives, chemotherapy agents, and immunosuppressants, and ginkgo biloba affecting anticlotting medications. Physicians must also routinely inquire about herbal and home remedies when obtaining a medication history. If a patient insists on CAM treatments despite warnings, document the discussion carefully, including disclosure of potential dangers and lack of efficacy. ■

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Education Reforms Needed to Implement Medical Home

BY JANE ANDERSON

FROM A HEALTH EDUCATION SUMMIT SPONSORED BY THE CARTER CENTER

Implementing the patient-centered medical home is not enough to improve health care quality – physician education also needs to emphasize team-based approaches to medical care, participants said at a summit to discuss training gaps in primary care, behavioral health care, and health promotion.

The summit, held at the Carter Center in Atlanta, examined whether medical students are being trained appropriately to function efficiently and effectively in the newly reformed health care environment.

"Purchasers are actively choosing to buy different kinds of care" because they can't find the types of health care they need in the current system, said Dr. John Bartlett, senior adviser for the Primary Care Initiative at the Carter Center.

"Private purchasers are getting tired of paying the price of poor-quality medical education," Dr. Bartlett said in a conference call convened to discuss the meeting's conclusions.

Meeting participants identified several key deficits in the U.S. medical education system, according to Dr. Michael Barr, senior vice president for medical practice, professionalism, and quality at the American College of Physicians.

"We train people separately and expect them to work together," Dr. Barr said. "The current education system doesn't seem to value that type of training environment."

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In many programs, physicians-in-training don't meet actual patients until relatively late in their training, and many curricula don't emphasize the types of mental health issues that primary care physicians will need to practice, he added.

Some medical schools have implemented educational programs worth emulating, although implementing those programs on a large-scale basis might require changes in medical school accreditation requirements and regulatory requirements, Dr. Barr said.

For example, the University of Wisconsin, which uses patients as educators, introduces medical students to patients on their first day in class, Dr. Barr said. This helps to sensitize medical students very early in their careers to issues that will arise in primary care.

Dr. Barr pointed out several changes in medical education that could be implemented relatively quickly:

- Providing more training for med students with nonphysician mental health professionals.
- Emphasizing wellness and prevention.
- Developing faculty members who can teach within the patient-centered medical home model of care.

Dr. Bartlett added that medical schools also need to focus on ambulatory mental health issues, such as mild to moderate depression, that primary care physicians are most likely to encounter in practice. ■