Manage Liability Risk When Referring for CAM

BY DOUG BRUNK
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LA JOLLA, CALIF. — When you refer a patient to a provider of complementary and alternative medicine, keep in mind five liability management strategies, David M. Eisenberg, M.D., advised at a meeting on natural supplements in evidence-based practice sponsored by the Scripps Clinic.

The strategies, which he developed in collaboration with Michael H. Cohen, J.D. (Ann. Intern. Med. 2002;136:596-603), include the following:

1 Determine the clinical risk level. Decide whether to:

- ▶ Recommend yet continue to monitor the therapy.
- ▶ Tolerate, provide caution, and closely monitor safety.
- ▶ Avoid and/or actively discourage the therapy.

2 Document the literature supporting the therapeutic choice.

"It's very important to put this in the chart," said Dr. Eisenberg, an internist who directs the division for research and education in complementary and integrative medical therapies at the Osher Institute, Harvard Medical School, Boston. "By the way, that is also true when we're using a novel or experimental drug with an inpatient. This is the same approach."

If treatment with a certain herb is recommended, "document the choice of herb, any recommendation regarding product or brand, and any discussion regarding therapeutic dose, and associated uncertainties regarding use of the herb," he said.

He also makes it a practice to keep a backup file of articles supporting the discussion or recommendation. "You could say this is a bit too conservative, like have suspenders and a belt," he said at the meeting, cosponsored by the University of California, San Diego. "But I think this is the best advice."

'From a conservative legal standpoint, referring to somebody who does not own a license to treat a patient is risky business. Don't do it.'

3 Continue conventional monitoring. "A lot of times we recommend something or accept that a patient is going to do something, and then we don't monitor or follow up," Dr. Eisenberg said. "Undue reliance on CAM may lead to a charge that the patient was dissuaded from necessary conventional medical care."

He added that maintaining conventional treatment "helps demonstrate that the physician has followed the standard of care, even if CAM is included."

4 Provide adequate informed consent. Describe the risks and benefits of using the CAM therapy and of delaying or deferring the conventional therapy, and spell out potential adverse interactions. That is a lot to consider, but such information would be helpful "in the eyes of the law if something went wrong," he said. "You have to ask yourself, could I really defend this action or recommendation?"

Also, clear communication with the patient has been shown to reduce the risk of being sued for malpractice. "Inadequate informed consent is also a theory for malpractice liability in and of itself," Dr. Eisenberg said.

5 Familiarize yourself with providers to whom you refer. Ask yourself, would I refer a friend to this person? "If the answer is 'I'm not sure,' then get some help in making the correct referral," he advised.

Understand any regulations regarding the use of CAM therapies by your relevant state regulatory board.

"You have to check the regulations and scope of practice," he said. "From a conservative legal standpoint, referring to somebody who does not own a license to treat a patient is risky business. Don't do it."

He pointed out that, in general, a physician is not liable merely for making a referral to a specialist. But he cited three exceptions to the general rule:

- ▶ The referral led to delay or deferral of necessary medical treatment. "Do your day job first," he said.
- ▶ The referring provider knew or should have known that the referred-to provider was incompetent.
- ▶ The referred-to provider is considered to be the physician's agent, either because state law requires supervision or an extended form of consultation, or there is a "joint treatment" agreement between the physician and the CAM provider.

Dr. Eisenberg also discussed the notion of a "legal catch-22" when referring a patient for CAM.

For example, if a physician seeks a distant, independent contractor type of relationship with a CAM provider, "there is probably less shared liability risk, but there is probably more risk of harm to the patient because you're referring to a stranger," he noted. "Conversely, there is higher risk of shared liability if you refer to CAM providers you know or have an ongoing professional relationship with, but there's probably less chance of harm [to the patient] because you're involved." ■

Brand Power: Medication Is More Than Just Chemistry

BY CARL SHERMAN
Contributing Writer

NEW YORK — The branding of pharmaceuticals—the creation and manipulation of product identity through such media as direct-to-consumer advertising—exerts a potent influence on the way patients think and feel about their medication and their illness, Nathan Greenslit said at a meeting sponsored by the American Psychoanalytic Association.

"The marketers I've interviewed routinely think that compliance needs to be reframed as a problem of brand loyalty," said Mr. Greenslit, a cultural anthropologist and doctoral candidate in the program in science, technology, and society at Massachusetts Institute of Technology, Cambridge.

To illustrate the impact of branding, Mr. Greenslit considered the case of Sarafem, a formulation of fluoxetine first marketed by Eli Lilly to women for premenstrual dysphoric disorder (PMDD). The rights to Sarafem have since been sold to another pharmaceutical company, Warner Chilcott Inc.

When Lilly was still marketing the drug, the "physician information" section of its Web site for Sarafem said that "fluoxetine was initially developed and marketed as an antidepressant (Prozac, fluoxetine hydrochloride)," while patients were told, in their section of the Web site, that "Sarafem contains fluoxetine hydrochloride, the same active ingredient found in Prozac."

While both statements are technically true, "socially they produce very different meanings," Mr. Greenslit said. Physicians were informed that Sarafem and Prozac were the same drug with different packages, while the message to patients was that "they are different drugs with the same ingredient."

A contrast in appearance—Prozac is a green and white capsule, while Sarafem is pink and lavender—emphasized the distinction, he said.

The separate branding was justified by Lilly as a response to consumer demand, Mr. Greenslit said, citing a Lilly marketing associate who noted that women don't look at their PMDD symptoms as depression, that Prozac is closely associated with depression, and that "women told us they wanted a treatment with its own identity."

The branding phenomenon underlines the idea that a person's relationship to a drug is more complex than his or her body's relationship to a chemical compound "whose only clinical relevance is its pharmaceutical activity," he said.

A close look at direct-to-consumer advertising suggests the extent of pharmaceutical companies' concern with "the social—that is, precisely *not* the chemical— effects of these drugs," he said. The companies manipulate the symbolic meanings of their products by "mobilizing images and texts," and take great care to avoid mistakes that would increase stigma surrounding the drug and condition for which it is prescribed (e.g., a pink Viagra).

Mitchell D. Wilson, M.D., who discussed Mr. Greenslit's presentation, suggested that "drugs as brands take on the character of objects of fantasy, with a quality of aliveness … they are personified."

As in interpersonal relationships, processes like identification and projection can occur, said Dr. Wilson of the San Francisco Psychoanalytic Institute and Society.

He contrasted the effect of branding to "its pale, poor step cousin, the generic drug: no name, no distinctive shape or color—a nothing in the symbolic world." If the brand name drug is a fantasy object, "the generic drug is truth—not a rich soil for projection."

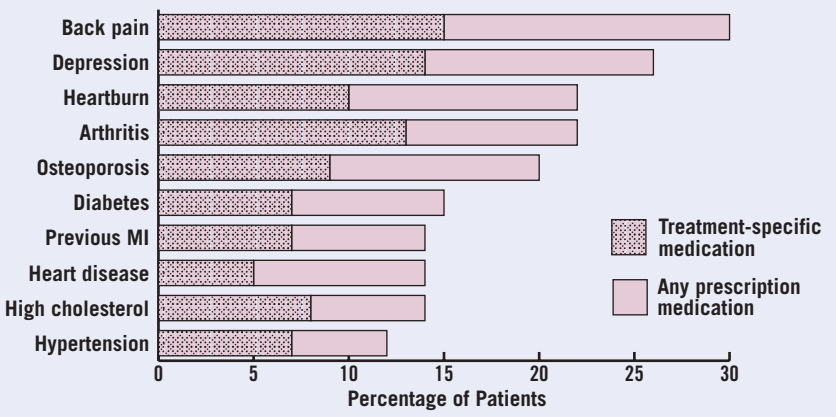
Mr. Greenslit noted that clinical trials are conducted with the generic version of a compound before it has been branded, and thus do not take into account the role that branding might play in the patient's experience of the drug. A closer look might provide insight into connections between marketing and the placebo effect, he suggested.

A member of the audience cautioned against simplistically reducing branding issues to a variant of the argument that drugs are overused or misused; he suggested that the phenomenon might well be considered more generally, extending even to patients' feelings about psychoanalysis.

"We're beneficiaries of brand loyalty, too," he said. ■

DATA WATCH

High Costs Cause Chronically Ill Patients to Skip Medication at Least Once per Month



Note: Based on a nationally representative survey of 4,055 adults aged 50 years and older.
Source: Am. J. Public Health 2004;94:1782-7

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