Physicians Seek Greater Control of Drug Talks

Fear of lawsuits about off-label promotion has led drug companies to increasingly muzzle physicians.

BY MARY ELLEN SCHNEIDER

With lawsuits and regulatory scrutiny increasing, pharmaceutical companies are tightening the reins on their promotional programs. But now physicians are pushing back, asserting their right to go off the script even when they're being paid by the drug companies.

"No respectable speaker wants to recite a company's [slide] deck," said Dr. Selim R. Benbadis, director of the comprehensive epilepsy program at the University of South Florida and Tampa General Hospital, who also does promotional speaking for drug companies at so-called dinner talks.

For Dr. Benbadis, getting the drug companies to give back some of the control over these promotional talks has become a "crusade" of sorts. He has reached out to many notable physicians in the epilepsy community and to the drug companies themselves in an effort to find some common ground.

Last fall, he and five other academic epilepsy specialists penned an open letter to the pharmaceutical industry, telling them in no uncertain terms that they would not simply present a company's slide deck.

"No expertise is needed to recite the company's slides, and this can be easily done by pharmaceutical representatives ('drug reps')," they wrote. "We want to educate physicians more broadly, and believe it can be done ethically and legally while still delivering a useful message for both sides." The letter was published in the journal Epilepsy & Behavior (2010;19:544-5).

Although most drug companies have long maintained an official policy that their slides be presented without editing, the common practice of speakers has been to add some of their own slides to try to craft a talk that was broader and more informative than a presentation on a single drug.

"The companies never liked this, but they had what I call a 'don't ask, don't tell' policy," Dr. Benbadis said.

But in the last couple of years, largely because of lawsuits about off-label promotion, the pharmaceutical companies have begun to enforce their existing policies. That shift has been frustrating for many physicians who give these types of promotional talks, Dr. Benbadis said. The lack of freedom to add their own slides makes physicians less likely to want to give the presentations, he said, but it also makes the talks much less interesting for attendees.

The Pharmaceutical Research and Manufacturers of America (PhRMA), which represents the drug and biotechnology industry, said that companies provide physician speakers with materials to ensure that the content of these talks complies with language approved by the Food and Drug Administration.

"While companies take great pains to ensure that the physicians they engage to speak on their behalf are experts in their field, the companies themselves remain responsible for the content of the program," Diane Bieri, PhRMA executive vice president and general counsel, said in a statement. "At the end of the day, [the FDA] expects and demands compliance, and rightly so."

The open letter published in Epilepsy & Behavior offered a few suggestions for new ways to approach these talks. The preferred option, the authors wrote, would be for drug companies to give unrestricted educational grants to CME-granting institutions for educational programs for physicians. Short of that, the companies could make the faculty responsible for the content of the talk. For example, pharmaceutical companies could ask their faculty speakers to sign a waiver exonerating the company of liability for any claims they make.

Another possibility would be to create a new type of educational event that would be not quite CME but not quite a promotional program.

Finally, the authors suggested that companies could allow a two-part program with a promotional portion and an educational portion.

Since the letter was published, there has been some progress, Dr. Benbadis said. In general, representatives from the drug companies agree that some type of accommodation needs to be made, he said, although some are more willing than others to do this. A couple of the companies are working with their speakers to create a large set of company-approved slides that include not only promotional material on the drug, but also disease-state slides. That would allow speakers to put together a talk from a larger and more diverse pool of company-approved materials.

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Meanwhile, other companies have signaled their willingness to allow speakers to create different talks, and have approved those talks on an individual basis. But because the process is time consuming, Dr. Benbadis said those companies aren't advertising the availability of that option.

A shift back toward greater flexibility is critical if these talks are going to survive, Dr. Benbadis said. "These talks serve a purpose, I think, for the companies and for us and for the community."

But other physicians see CME talks as a better alternative for physician education.

Dr. Jacqueline A. French, a professor of neurology at New York University and the president of the Epilepsy Study Consortium, said that the restrictions currently in place regarding the dinner talks make it very difficult to provide open and unbiased information.

Promotional talks do help to fill a gap in education. Dr. French, who does not give promotional talks, said that a cessation of the dinner talks would make it harder for physicians in private practice to get practical information about drug treatments. Generally, physicians in private practice don't attend grand rounds–type lectures, which are usually focused on the science behind a disease rather than on therapeutics. But restrictions on what physicians can say about off-label prescribing severely limit what can be discussed at a dinner talk, she said, making such talks a less-viable option.

The situation highlights the gap that exists in medical education, she said. Educators need to start thinking of creative ways to get information out to physicians so they can stay up to date on new therapeutics, Dr. French said.

Susan Chimonas, Ph.D., codirector of research at the Institute on Medicine as a Profession at Columbia University, New York, agrees that providing medical education under the umbrella of CME is a better option. Although the authors of the open letter are well intentioned, Dr. Chimonas said, there are many proposals for better ways to organize medical education, and physicians would be better served by working toward that goal rather than trying to figure out how to tweak the industry talks so that they are "less offensive."

Promotional talks are useful for the drug companies, but they tend to undermine public trust in the medical profession and put physicians into the uncomfortable position of being drug marketers, she said.

"I suspect that this practice is sticking around because it works for industry and it works for the people who participate in it," Dr. Chimonas said. "If you take it away, industry will move on and figure out other ways to influence and physicians will find other ways, that are probably better, to stay up to date," she said. ■

Medicare's Physician Compare Web Site Goes Live

BY MARY ELLEN SCHNEIDER

FROM THE CENTERS FOR MEDICARE AND MEDICAID SERVICES

Medicare officials on Dec. 30 launched a new online tool that allows consumers to locate physicians in their communities and get information about their specialties, degrees, and other training.

The new tool, called Physician Compare, is available online at www.medicare.gov/find-a-doctor. The tool is modeled after the Hospital Compare Web site (www.hospitalcompare.hhs.gov), which allows consumers to compare hospitals based on quality data and patient evaluations.

Currently, the Physician Compare Web site contains mostly practice information. However, it does let consumers know whether the practice reported quality data to the Centers for Medicare and Medicaid Services under the Physician Quality Reporting System. The PQRI is a voluntary program "that rewards physicians and other eligible healthcare professionals for reporting data on quality measures related to services furnished to Medicare beneficiaries," according to the press release announcing the launch of Physician Compare. More than 200,000 physicians and other health care providers reported data to the CMS under the voluntary system in 2009.

The new tool 'helps to pave the way for consumers' to have information about physicians as they do for nursing homes, home health agencies, and health plans.

"The new Physician Compare tool begins to fill an important gap in our online tools by providing more information about physicians and other health care workers," Dr. Donald Berwick, CMS administrator, said in a statement. "This helps to pave the way for consumers" to have information about physicians as they do for nursing homes, home health agencies, and health and drug plans, Dr. Berwick noted.

Later this year, officials at the CMS plan to add information to Physician Compare about whether doctors are participating in the voluntary electronic prescribing program. Under the Affordable Care Act, the CMS is required to expand the Web site to include information on quality of care and patient experience data by 2013. ■