Physicians Seek Greater Control of Drug Talks

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 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 November issue of the journal Epilepsy & Behavior (Epilepsy Behav. 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 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 makes physicians less likely to want to give the talks, 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, 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. 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.

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.

"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. ■

Feds Want Public Disclosure, Justification of Insurance Costs

BY NASEEM S. MILLER

In an effort to control rising health insurance rates and to bring transparency to the market, the federal government has proposed rules requiring insurers to publicly disclose and justify large rate increases.

Starting in 2011, proposed rate increases of 10% or higher will be publicly disclosed and reviewed to determine if the rate increase is reasonable, according to proposed regulations announced by Health and Human Services Secretary Kathleen Sebelius in December.The effort will be conducted in collaboration with the states.

The initial threshold for review is set at 10% in 2011, Ms. Sebelius said; however, starting in 2012, the states will set their own thresholds based on data and trends they gather. If a state is unable to do so, the proposed rule allows the HHS to do so.

Beginning in 2014, states will be able to exclude from the new health insurance exchanges any health plans that show a pattern of excessive or unjustified premium increases.

Ms. Sebelius said that the states will have the responsibility to keep insurance rates in check, and that the federal government is "not going to be sitting on state commissioners' shoulders and question what it is that they're doing."

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MS. SEBELIUS

Over the past decade, the average health insurance premiums for family coverage have risen 131%, according to the HHS. Some states such as Connecticut and Rhode Island already have the power to review and reject excessive rate increases but not all do and some lack the legal authority or resources to do so.

"The proposed rate review policy will empower consumers, promote competition, encourage insurers to do more to control health care costs and discourage insurers from charging premiums which are unjustified," Jay Angoff, director of the HHS Office of Consumer Information and Insurance Oversight, said in a statement.

The Affordable Care Act makes $250 million available to states to take action against insurers seeking unreasonable rate hikes, and so far $46 million has been awarded to 45 states and the District of Columbia for improving oversight of health insurance rate increases, according to the HHS. The proposed regulations also will work in conjunction with medical loss ratio regulations, which were released in November.

In a statement, Karen Ignani, president and CEO of the insurance trade group America's Health Insurance Plans, said, "While the proposed rule gives consideration to the impact of rising medical costs, it also establishes a threshold for review that is incomplete because it does not adequately factor in all of the components that determine premiums, including the cost of new benefit mandates and the impact of younger and healthier people dropping coverage. Premium review must consider the unique circumstances of small employers that are struggling to afford coverage for their employees, and of the individual market in which people move in and out of coverage depending on whether they anticipate needing medical services."

She added, "It is also important to remember that the new federal law already caps health plans' administrative costs and profits. We welcome the opportunity to submit comments on this proposed rule."

The proposed rule was published in the Federal Register on Dec. 23 and is open for public comment until Feb. 22. Comments can be filed at www.regulations.gov. A final rule could be issued in 6 months.

For more information, visit www.hhs.gov/ociio/initiative/index.html. ■