

Disclosure

Case Study: Implementation of Eli Lilly's physician payment disclosure initiative

*Eli Lilly was the first pharmaceutical company to announce plans to begin voluntarily disclosing payments to physicians. The late **Mike Bigelow**, Lilly's Assistant General Counsel, was charged with implementing that program. Last month, he traveled to Washington, D.C. to share his experience with his colleagues at the First National Disclosure Summit in Washington, D.C. Sadly, Mike recently lost his battle with pancreatic cancer. A note about his passing is included on p. 7.*

According to Bigelow, Lilly encountered a number of challenges as it started to implement its physician payment disclosure initiative. The most significant challenge, he said, has been explaining to healthcare practitioners who serve as consultants why the disclosures are being made in the first place.

Here is a rundown of some of the key factors that Bigelow said companies should consider when establishing a physician payment disclosure initiative:

Why are you disclosing? The first thing to understand, said Bigelow, is why the company is making the disclosure. The industry is currently subject to a variety of forces in this regard, he pointed out. Some companies are initiating disclosures voluntarily (such as GlaxoSmithKline and Merck), while others are doing so subject to a corporate integrity agreement (such as Cephalon) or a deferred prosecution agreement.

Meanwhile, the entire pharmaceutical industry—and increasingly the medical device sector—is subject to myriad state disclosure requirements and the looming federal Physician Payments Sunshine Act.

What is the impetus that is causing you to disclose? In Lilly's case, the company initiated a voluntary disclosure initiative for payments to physicians shortly before a CIA mandated that activity as part of its state Zyprexa settlement.

This meant that discussions with physicians about the voluntary nature of the initiative were soon followed by conversations about the new mandate, he explained.

WHERE TO BEGIN?

Here are several questions, Bigelow said, companies should consider at the outset:

What are you going to disclose? In terms of implementation, the first thing companies need to consider, regardless of their motive for disclosure, said Bigelow, is precisely what they plan to disclose in terms of payments, expenses, gifts to physicians, and other information. Numerous questions will arise, he said.

For example:

- Are you going to limit the disclosure to payments made to physicians, at least at the outset? Or will it apply to all healthcare practitioners?
- Will it apply to clinical work? Speaking? Consulting? Or all of the above?
- Are you going to disclose expenses in the event that a physician is reimbursed for expenses they incur when making a presentation?
- Are you going to disclose gifts made to *all* physicians? How are you going to do that?
- What sort of caps are you going to put in place for doing that?
- If you have nurse practitioners or diabetes educators, will they be part of the registry?
- Will this be for clinical work, clinical trial-related work, as well as work that is done in a marketing, post-approval context?

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“Those are the laundry list of items that you need to work through,” said Bigelow.

Do you have the right to disclose? Whether companies have the right to disclose payments is a question that frequently arises, said Bigelow. In fact, many physicians sought counsel with their attorneys and argued that Lilly was not allowed to disclose the information, he reported.

According to Bigelow, none of the financial privacy laws appear to preclude disclosure. “HIPAA certainly would not preclude it,” he said.

To address this issue, however, Lilly now includes a provision in its contracts with physician that both sides have the right to make disclosures, he said.

While there appears to be no legal reason that prevents disclosure, companies should, nevertheless, expect some “pushback,” he warned.

Is everybody on board (internally)? Bigelow said companies must ensure that everybody is on board internally before any sort of announcement regarding the disclosure is made. For example, he said, brand teams will likely be heavily involved, because they will get a lot of pushback from the speakers they use. Researchers will also be involved if the company plans to disclose payments that are made to the advisers they use, he added.

“Make certain you have thought of everybody within your company that deals with these physicians,” he said, “and that they have this information.”

Do not expect that your speakers/consultants will understand why. Bigelow said companies must ensure that speakers and consultants understand why the disclosures are being made. “This is probably one of the most important considerations,” he said, because physicians often do not fully appreciate why companies are disclosing the information.

The primary concern on the part of the public and the media, said Bigelow, is whether physicians are making prescribing decisions based solely on the patient’s best interest. “I think this is what the public wants to see come out of these registries.”

In short, the public wants to know what physicians are receiving (if anything) in connection with the medicines they are prescribing. “That is the sort of dialog they want to have with their physicians,” he said, “and physicians need to be

prepared to have that conversation.”

Companies must also consider the issue from the point of view of Medicare and Medicaid, he added. “The government is paying the bill,” he explained. “You have to get the physicians to understand why it is that the government wants to do this in the first place.”

Explain states and federal mandates to physicians

Bigelow said companies may wish to discuss the nature of state and federal legislation with physicians. He said that physicians need to understand the choice that companies face in this area is not an “all or nothing” proposition. “It is not like somebody woke up on the wrong side of the bed one morning and decided they were all of a sudden going to start posting all of these payments to physicians,” he said.

Physicians need to understand “the decision tree” that currently exists, said Bigelow. Doctors are under investigation along with drug companies, he pointed out. “This is serious business,” said Bigelow, adding that it can be instructive to show physicians recent reports in *The New York Times*, and elsewhere, that point to doctors under

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investigation. “That is something new that you can point to, which says this is as much of an issue for you as it is for drug companies,” he explained.

“It is a huge media issue,” he added. “I have a file with tens, if not hundreds, of articles that have been written on this subject. You cannot avoid it.”

“You may think it is a no-brainer that physicians are going to understand where we are coming from,” said Bigelow, “but I do not think there is necessarily an appreciation on the part of all healthcare professionals about how big an issue it is for them—and for us.”

What to do about it?

The solution to this challenge, said Bigelow, is for companies to take the necessary time to educate

speakers and consultants about these issues. Shortly after Lilly announced it was going to begin its voluntary disclosure initiative, he said, the company held teleconferences with its speakers and consultants and sent them Q&As and backgrounders on the subject.

The objective, he said, was to fully brief them and prepare them to talk to their patients. Subsequently, he said, the company sent letters to its speakers and consultants, explaining what the company is bound to disclose under its CIA. The company also addressed the subject during live speaker training, he added.

Bigelow said he tried to emphasize the value and importance of the products in question when speaking with physicians. It is important for them to know that if they are comfortable speaking about a product that they feel is the best product that they should also feel comfortable explaining their role as a thought leader for that drug, he said.

“I cannot tell you how many one-on-one calls that I have taken from our speakers and consultants who want to have further dialog on this issue,” said Bigelow. “I have even had calls from their attorneys wanting to have conversations about this issue.”

Finally, he said, companies may wish to address the issue more broadly through a Letter to the Editor in a major newspaper under the name of the company CEO, which Lilly has done.

Concerns of speakers/consultants

According to Bigelow, the primary concern expressed by speakers and consultants is that payments represent a difficult and time-consuming issue to explain to patients. “Frankly, they just do not have the time to engage in that dialog,” he said.

When a patient goes to a website and sees that a physician was paid \$10,000 a year for speaking or consulting, they will not immediately understand why the payment was made, he warned. Moreover, physicians often do not understand how “real” the public concerns can be. That makes it important to provide physicians with the tools they will require, he said.

Bigelow said one concern physicians voiced is that the disclosure amounts posted are the same as those they reported to their employers, to the extent they are required to do so. “That is a big deal for them because they have made representations,” he said. “Reputations are at stake.”

Remembering Mike Bigelow

Mike Bigelow, Assistant General Counsel at Eli Lilly, passed away earlier this month of complications from pancreatic cancer. He was not quite 42 years old.

It was early last month that Mike traveled to Washington, D.C. to deliver a presentation at a conference co-sponsored by this newsletter. At the time, it was hard to look at Mike and not be reminded of Randy Pausch, the well-known author of *The Last Lecture*, who fell victim to the very same illness last year. Both were vibrant and industrious young men with three children, suddenly confronted by an illness that offers no reprieve.

Yet, despite the seeming unfairness of their fate, the word “victim” seems wholly out of place in both cases. Mike was a very decent man who faced his gravest challenge with an uncommon degree of dignity. It was impossible to watch him actively engaged in the conference and not be impressed by his endurance as well as his manner. And it was equally impossible to miss the fact that he was, as I had already gathered from previous encounters, a genuinely nice guy.

Few people have the opportunity to memorialize their lives—and their struggles—in the fashion that Randy Pausch did. But to those who knew Mike, his experience was every bit as poignant. And, by all accounts, his life appears to be every bit as well-lived.

His trip to D.C. last month, like his life, was an impressive performance. His devotion to his profession was unmistakable and can rightly be a source of pride for everybody doing the same good work.

He was, in the end, what he was all along—a good man. We can all be a little better for having known him.

Memorial contributions

Mike had requested that memorial contributions be made to his children’s college education account. Please make any memorial checks payable to: CollegeChoice Advisor 529 Plan. They can be sent to: 12368 Sanderling Trace, Fishers, IN 46037.

Are expenses included?

Expenses have surfaced as a significant issue, said Bigelow. “There is some question as to whether or not we are going to post expense reimbursement,” he said. “At the end of the day, that is not really a gift or a payment to the doctor.”

Then again, he added, the patients may not understand the value of the services provided and why it is they get paid to perform certain services.

Lessons learned

The central lesson of Lilly’s experience in this area, said Bigelow, is that companies must take the requisite time to brief speakers and consultants on why they are disclosing the information. “It is really important to get them on board,” he says. “Physicians, speakers, and consultants need to understand the benefits to them as well as the benefits to the company.”

Second, he said, companies must make certain that physicians who are speaking or consulting have the tools they need in order to feel equipped to have

appropriate conversations with their patients. “Help the physicians to explain the issues,” he said. “There is nothing magical about these materials, but they can be time-consuming.

Third, he said, companies must ensure there is appropriate internal alignment on the issue and that everyone is on board.

Finally, Bigelow warned that companies must be prepared to lose some faculty. While the number of such incidents may not be

as frequent as some people were initially projecting, he said, some faculty are going to decide it is just not worth it. “We have seen that,” he concluded, “but it hasn’t been as bad as some people predicted.” ■

Bigelow warned that companies must be prepared to lose some faculty, but likely fewer than they might expect.

Academic detailing

Congress reintroduces academic detailing bill

On April 1, Senate Special Committee on Aging Chairman Herb Kohl (D-WI) and House Committee on Energy and Commerce Chairman Henry A. Waxman (D-CA) were joined by numerous House and Senate colleagues in introducing a bill in both chambers to provide doctors with “unbiased information” on prescription drugs. The bill’s authors say the federal academic detailing program would provide physicians and other prescribers with “an objective source of information on all prescription drugs, based on independent, scientific research.” Traditional pharmaceutical detailing “seems to be fraught with conflicts of interest,” said Kohl.

Congressional supporters say the academic detailing legislation is part of a larger effort to change the way the pharmaceutical industry interacts with doctors. State activists are also aggressively pushing academic detailing as an alternative—and some hope an eventual substitute—to traditional pharmaceutical detailing.

The notion of “objective information” regarding prescription drugs was a familiar theme voiced by the bill’s co-sponsors. “For far too long, most of the information physicians receive to make prescribing decisions has come from the drug companies marketing reps, not independent experts,” said Waxman.

Some of the legislation’s co-sponsors went a step further. House Ways and Means Health Subcommittee Chairman Pete Stark (D-CA) said the legislation “will test ways to help doctors and patients make medication decisions based on facts, not manufacturer propaganda.”

What the bill would do

The Independent Drug Education and Outreach Act of 2009 would provide grants to produce educational materials for doctors on the safety, efficacy, and cost of prescription drugs, including generic and over-the-counter drugs. A second set of up to ten grants would be made available in order to dispatch trained