Policy & Practice

Enbrel Sales Investigated

The New Jersey Attorney General's office is investigating Amgen for allegedly promoting Enbrel for off-label uses and for violating privacy laws to get access to potential new patients. On Jan. 14, Attorney General Anne Milgram subpoenaed Amgen for all documents relating to the marketing, sale, and prescription of Enbrel (etanercept) since July 2002. The inquiry follows a lawsuit by two former sales representatives who alleged that the company encouraged them to search physicians' records for patients with mild psoriasis who might be potential candidates for Enbrel therapy. The former employees also claimed to have directly contacted insurers to facilitate reimbursement to physicians for the cost of the biologic. An Amgen spokeswoman said that the company will cooperate fully with the investigation and that the employees' claims "are completely without merit." The company expects salespeople to follow the Code of Conduct. "Amgen does not instruct sales representatives to proactively review patient files or promote off-label for any reason," said the spokeswoman.

HHS Resists Ketek Subpoena

The Department of Health and Human Services has refused to comply with a House Energy and Commerce Committee subpoena of documents related to the March 2007 testimony by Food and Drug Administration Commissioner Andrew von Eschenbach on the approval of Ketek (telithromycin). "There appears to be a continued effort to keep secret the documents we have requested," said Rep. Bart Stupak (D-Mich.), chairman of the committee's oversight and investigation subcommittee. Rep. Stupak spoke at a February subcommittee hearing looking into a Ketek safety study by manufacturer Sanofi-Aventis U.S. LLC and a subsequent FDA inquiry into fraud allegations surrounding that trial. Subcommittee members heard testimony from Senate Finance Committee Chairman Chuck Grassley (R-Iowa) and from FDA and independent investigators that agency officials and Sanofi-Aventis executives ignored warnings that the safety study was riddled with fraud. Both the House panel and the Senate Finance Committee want to determine what the FDA and Sanofi-Aventis knew about the alleged fraud and when. Energy and Commerce Chairman John Dingell (D-Mich.) said he would compel HHS to furnish the documents. An FDA spokeswoman said the agency has given the committee "more than 80,000 pages of information on Ketek," and that the agency has "made every effort to be responsive to the committee's requests."

Reloxin Approval Delayed

FDA has refused to accept the biologics license application filed by Medicis Pharmaceutical Corp. for Reloxin (injectable botulinum toxin type A), according to a Securities and Exchange Commission filing by the company. According to the filing, the application was deemed incomplete because it did not "address how Medicis would fulfill its responsibilities as the manufacturer of the product." The company said the agency cited only administrative, not substantive, problems with the application for approval. Medicis, which licensed Reloxin from the Ipsen Group for commercialization in the United States, Canada, and Japan, "intends to promptly work with the FDA and coordinate its activities with Ipsen to address these administrative issues," according to the filing.

Eyelash Lengthener Sales Halted

Jan Marini Skin Research Inc. has stopped selling its Age Intervention Eyelash Conditioner and Age Intervention Masses of Lashes Performance Mascara in the United States. The company cited its involvement in ongoing patent litigation with Allergan Inc. as one reason for ceasing sales. In a statement, CEO Jan Marini said the company had confidence in the products' safety profile. An older, discontinued product, Age Intervention Eyelash, was the subject of an FDA seizure last November. The agency seized $2 million worth of Age Intervention Eyelash, saying that it was misbranded because it contained bimatoprost, an active ingredient in an FDA-approved drug to treat elevated intraocular pressure. However, Jan Marini had discontinued making or selling Age Intervention Eyelash in 2006. Allergan markets bimatoprost under the trade name Lumigan.

More Action Needed on MRSA

U.S. health care facilities are not doing enough to protect patients from methicillin-resistant *Staphylococcus aureus* (MRSA) infections, according to an online poll conducted by the Association for Professionals in Infection Control. A majority of infection control professionals (59%) responded that their health care facilities have stepped up efforts to curb MRSA in the past 6 months. But half said their facilities were "not doing as much as [they] could or should" to stop the transmission of MRSA. "MRSA could be beaten if the leadership at hospitals moved more aggressively to adopt strategies proven to protect patients from these virulent infections," said Lisa McGiffert, director of Consumers Union's Stop Hospital Infections campaign. "We need to require hospitals to report their infection rates so the public can see if they are achieving results." Consumers Union has worked to help pass laws in 20 states requiring hospitals to report their patient infection rates, and it supports a federal infection reporting law. The Centers for Disease Control and Prevention estimates that nearly 95,000 patients developed MRSA infections in 2005—most of which were acquired in health care facilities—and almost 19,000 people died.

—Alicia Ault

Managing Your Dermatology Practice

Organize Your Samples—and Your Reps

My January column, a collection of possible New Year's resolutions, generated quite a few requests for elaboration on some of the suggestions. Hopefully, the next few columns will fulfill some of those requests.

The column in question, if you missed it, can be found in the Archive Collection at www.skinandallergynews.com; or drop me a note and I'll be happy to send you a copy.

The suggestion on organizing samples triggered the most feedback. Everybody, it seems, thinks they have too many samples, but you really don't. What you have is too much packaging.

BY JOSEPH S. EASTERN, M.D.

If you doubt this, take a good look at the next set of samples that comes into your office. Each unit will probably consist of a big box or card, and somewhere within its depths, amid all the wasted space, will be a single tablet or 3-g tube.

All that space-wasting packaging is purposeful, of course. Bigger is better, after all, from a promotional standpoint anyway. Bigger packages are more likely to be noticed, and there's more room for advertising.

The marketing people figure that if they use up all of your available sample space, you won't have room for their competition.

As a result, you probably have sample packages taking up two or three closets' worth of expensive square footage—with the samples themselves occupying perhaps 5% of that space or less.

Not only that, but each time you need a particular sample, somebody has to go hunting for it. Sometimes you find it, sometimes you don't. And when you do, there's a fair chance it's expired. It's a waste of time, space, and energy, and it's not necessary.

Courtesy Dr. Joseph S. Eastern

A well-organized sample closet will save time, space, and energy.

Here's what you do: Create a "parts-bin system" for your samples.

Have a carpenter build you shelving in a central area of the office. Stock those shelves with cardboard or plastic parts bins, which are available in a variety of lengths, widths, shapes, and colors from many different sources.

Three online examples are www.anytimeproducts.com, www.papermart.com, and www.lkgoodwin.com. (As always, I have no financial interest in any product or service mentioned in this column.)

As samples come in, ask the representative who brings them to strip off all the space-wasting packaging, leaving only the tablet bubble-pack cards or the 3-g tubes. You'll be amazed at how much less space they take up. Store them in the bins, and arrange the bins on your shelving by whatever organizational system you fancy. We do it alphabetically.

You'll always know what samples you have, what you're out of, and what's close to its expiration date. You and your staff will waste far less time searching for the samples you want, and you can use all that freed-up sample space for something far more likely to generate revenue for your office.

A parts-bin system could be an even bigger boon to your office if the Food and Drug Administration ever makes good on its recurrent promise to require written paper trails for all samples entering and leaving a facility.

Periodic inventories, as well as logging samples in and out, will be far easier with my system.

While you're organizing your samples, consider organizing your pharmaceutical reps too.

Many offices allow representatives to come and go as they please, and too many physicians, physician assistants, and nurse practitioners are all too willing to stop and chat with them, which disrupts efficient office flow. And if multiple reps show up in a single day, the chaos just multiplies.

Have your reps make appointments, just as your patients do. We allow only one rep appointment per day—during the lunch break, 10 minutes before the start of afternoon hours. That prevents disruption of the schedule, and it prevents me from chatting too long (which I have a tendency to do).

We also encourage reps not to make appointments at all unless they have something of significance to communicate. I'm happy to speak with reps, but not when all they have to offer is small talk. ■

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