Enbrel Sales Investigated

The New Jersey Attorney General’s office is now 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 2004. The attorney general allows 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 provide or sell current patient files or promote off-label for any reason,” the spokeswoman said.

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 Department’s testimony by Food and Drug Administration Commissioner Andrew Von Eschenbach on the approval of Ketek (teletiomycin).

“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 request for 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 biologic license application filed by Medicis Pharmaceutical Corp. for Reloxin (injectable botulinum toxin type A), according to Medicis in an FDA filing. Reloxin Approval Delayed

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. 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.

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. Stock 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, where they are, 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 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 part trails for all samples entering and leaving a facility.

Periodic inventories, as well as logging samples in and out, will be far easier with your 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 charting 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 whenever they have to offer a small talk.

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