

Easing Information Overload: New FDA Rules Make Package Inserts More Reader-Friendly



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The Food and Drug Administration's (FDA's) new rule regarding changes to the content and format of drug package inserts (patient information sheets) is aimed at reducing medication errors by providing clearer, easier-to-understand information to physicians. However, some critics are complaining that one provision of the rule—that drug companies cannot be sued in state courts if they follow the new federal guidelines to the letter—may in fact encourage drug companies to withhold critical information.

This state law pre-emption provision was one of two headlines resulting from the FDA's publication of the final rule in January. The second headline related to the drug industry's failure to dissuade the FDA from requiring manufacturers to include a *Highlights of Prescribing Information* section in the patient information sheets, which are supplied to physicians for all approved medications. The industry was concerned that these highlights, which are severely condensed snippets of the *Full Prescribing Information* section, would become a magnet for lawsuits filed by trial lawyers alleging that the highlights were incomplete, misleading, or both.

Alan Goldhammer, Associate Vice President of Regulatory Affairs at Pharmaceutical Research and Manufacturers of America (PhRMA), the industry trade association, downplays any unhappiness on the part of the drug industry with the final rule.

"We view the new content and format in a favorable light," he says.

Moreover, he adds, as physicians begin to access package inserts in electronic formats, for example, on their personal digital assistants (PDAs), drug companies will be able to use hyperlinks in the text of the highlights section to automatically connect physicians with the more detailed explanation in the full prescribing information.

That said, drug companies still hope for additional clarity from the FDA on what should be included in the highlights section. At the same time that it published the final rule, the agency published draft guidance on that topic and gave the industry 90 days to comment.

"We're taking a look at that draft guidance," Mr. Goldhammer confirms. "I have no idea what we will say."

The FDA proposed changes to the package insert in 2000, soon after the Institute of Medicine published its ballyhooed report at the end of 1999 on the alarming number of medication errors in hospitals. The new highlights section is supposed to briefly summarize the full prescribing information with "chunks" (the FDA's argot) of succinct information that physicians can quickly grasp and digest. Drug companies were worried about having to summarize complicated issues, and inevitably—because the highlights section is limited to half a page—about having to omit potentially critical information. Those omissions, the drug companies claimed, could provide ammunition for trial lawyers interested in filing medical liability lawsuits.

However, the FDA not only downplayed that concern, it also rebuffed industry requests to specify exactly which information should be included in the highlights. Many companies believed that some sort of standard was necessary, particularly for drugs in the same therapeutic class.

Again, the agency threw cold water on these concerns. Although it acknowl-

edged that "it is critical to ensure accuracy and consistency in the information included in highlights," it then said that "it would not be appropriate, or possible, to specify in the final rule the precise content of highlights. Judgment will continue to be necessary."

Perhaps to assuage the concerns of drug companies about the vagueness of the highlights requirement and the possibility of future liability lawsuits, the FDA tossed in a provision that had not been part of the proposed rule issued in 2000: that if drug companies meet the minimum standards of the package insert rule, they cannot be sued in state courts for failing to disclose important warnings.

That state law pre-emption provision drew strong objections from the Association of Trial Lawyers of America, which has called this provision "a fundamental rollback of drug safety." The organization promises to mount a legal challenge to the new rule.

"We asked for that pre-emption in our comments to the FDA after the proposed rule came out," Mr. Goldhammer confirms. "It will be interesting to see how that plays out."

The final rule applies only to drugs that the FDA has approved in the past five years. The revised package inserts must be available for newer drugs first. For example, drugs that were approved in the year before June 30, 2006, must have a revised package insert by June 30, 2010. For drugs that were approved in the four to five years prior to June 30, 2006, the deadline for the updated package inserts is June 30, 2013.

But with at least one major lawsuit in the works, the final rule's dictate on deadlines, as well as other aspects, could be subject to revision. ■