Generic Drug Industry Threatens FDA With Lawsuit Over Drug Labeling Proposal

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By Alexander Gaffney, RAC (/SearchRegFocus.aspx?name=Alexander Gaffney)

The generic pharmaceutical industry's most prominent trade body, the Generic Pharmaceutical Association (GPhA), is threatening to sue the US Food and Drug Administration (FDA) if the agency finalizes a change in its labeling regulations that would make it easier for generic drug companies to update their product's labels in response to adverse events.

Background

Under the *Federal Food, Drug and Cosmetic Act (FD&C Act)*, generic drug products must—with minor exceptions—adhere exactly to the FDA-approved labeling borne by the drug it references in its 505(j) application, otherwise known as an abbreviated new drug application (ANDA).

In theory and practice, this is to ensure that generic drug manufacturers don't seek to take shortcuts in the drug approval process, or downplay safety risks associated with a drug. But it has also meant that some generic drug manufacturers, aware of rare safety risks not currently reflected in the labeling, have been unable to update their own labeling, putting patients at risk.

To remedy this, FDA proposed a new rule (http://www.raps.org/focus-online/news/news-article-view/article/4285/) in November 2013 allowing generic companies to propose tentative updates to generic drug labels using the "Changes Being Effected" (CBE) zero-day process (CBE-0). FDA would then review the application, and any changes would affect both the generic drug label(s) *and* the reference listed drug (RLD)—the drug to which the ANDA is "generic."

[For an extensive background explainer on this issue, please see Focus' April 2014 article, Understanding the Regulation of Generic Drug Labels (http://www.raps.org/regulatoryDetail.aspx?id=18464).]

Legal Troubles

But since the release of the rule, some have cast serious doubts as to whether FDA actually possesses the legal authority to promulgate the rule. As *Focus* explained in November 2013 (http://www.raps.org/regulatoryDetail.aspx?id=9655), several legal experts took aim at the "sameness" provisions of the *Hatch-Waxman Act*, the law which effectively created the generic drug industry. In short, the law requires generic drug labels to be *exactly* the same as the RLD.

"Hatch/Waxman … does not confer any right upon an ANDA applicant to submit any generic drug with labels that differ/are-not-the-same in ways that affect the safety and effectiveness of that drug," James Beck of the law firm Reed Smith wrote at the time. "[The law] prohibits revisions that seek to change 'warnings' - which is precisely what the CBE provisions involved in the current proposal purport to do," he added.

"Several maxims of statutory construction would seem to preclude the FDA from doing what it seeks to do here," he concluded.

Bob Pollack (http://www.lachmanconsultants.com/robert-pollock.asp), former acting deputy director of FDA's Office of Generic Drugs, made similar observations at the time, wondering aloud (http://www.lachmanconsultants.com/emergency-emergency-everyone-to-get-from-street.asp) how FDA could "propose to ignore the statutory requirement for sameness of labeling?"

For its part, FDA has vigorously pushed back against critics (http://www.raps.org/regulatoryDetail.aspx?id=18310), saying its authority to promulgate the rule comes from its authority to regulate the labeling of drugs under 21 USC 301. Further authority given to it also allows the agency to remove a product from the market if it is considered misleading (i.e. if it fails to have adequate warnings)

"In addition, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) authorizes FDA to issue regulations for the efficient enforcement of the FD&C Act," FDA's Janet Woodcock, director of the Center for Drug Evaluation and Research (CDER), said in sworn testimony (http://www.fda.gov/NewsEvents/Testimony/ucm389606.htm) before the House Energy and Commerce Committee. "FDA's regulations relating to CBE-0 supplements are supported by this provision."

Lawsuit at the Ready

Now the merits of the agency's arguments might soon be tested in court.

In an interview with *Regulatory Focus*, GPhA President Ralph Neas said his organization is preparing a lawsuit to challenge the legality of FDA's generic drug labeling rule if and when it is finalized.

While citing the rule's "draconian impact" and upset of "decades of legal precedence," Neas claimed the rule contradicts "clear statutory language" as interpreted by both *Hatch-Waxman* and the courts.

"This proposed rule exceeds FDA's statutory authority," and if finalized would cause GPhA to challenge its legality in court, Neas said.

FDA has already extended the comment period (http://www.raps.org/focus-online/news/news-article-view/article/4431/) on the proposed labeling rule once, and it is not clear when—or if—the agency plans to

release either a final rule or a re-drafted proposed rule.

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As for resources, ASQ is a good one.

As for salary range, it is somewhat wide in view of the size of an organization and industry's rate. I can provide further input off-line.

Giv...

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Hi Ron,
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RE: Promotional Material Submission (http://connect.raps.org/communities/viewdiscussions/message/?MID=6464)

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