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# Meningitis Outbreak Exposes FDA's Oversight Failures

By **Rachel Slajda**

*Law360, New York (October 10, 2012, 8:16 PM ET)* -- As a fatal meningitis outbreak sparks calls for increased federal regulation of compounding pharmacies, industry experts say the real problem is not that the U.S. Food and Drug Administration lacks enforcement authority, but that it has failed to make clear when it will use the considerable power it already has.

The outbreak, which as of Wednesday has killed 12 people, has been traced to a Massachusetts compounding pharmacy, New England Compounding Center, which according to authorities distributed more than 17,000 contaminated doses of a steroid used for pain relief.

The outbreak has led to outrage and calls for Congress to give the FDA more authority over compounders, which, as pharmacies, are largely in the hands of state regulators. Several lawmakers have demanded investigations or said they will introduce legislation aimed at increasing FDA authority.

But industry experts say the FDA already has considerable authority over drug compounders that veer from pharmacy into manufacturing territory. The problem is that the FDA's enforcement policies have often been ambiguous, they say, and it can be hard for a compounder to know whether their activities cross a line.

“No one knows where the line has been drawn between compounding and manufacturing,” said Mark Brown, a partner with King & Spalding LLP who is representing a compounder in an unrelated case concerning FDA's authority. “It's obvious FDA's guidelines are not clear enough. I don't think anybody can argue with a straight face that the rules are clear.”

Compounding pharmacies traditionally make customized drugs at a doctor's request, often in doses or forms not available commercially, when a patient has special needs. That activity is left to state boards of pharmacy to regulate.

But sometimes compounders start acting a lot more like manufacturers. That's a problem, because compounders are not required to meet the safety and efficacy standards that registered manufacturers are held to.

The question for compounding pharmacies is where the line is. The FDA has issued compliance documents that list the activities it considers outside the scope of pharmacy practice, although many in the industry would like to see a more explicit bright-line distinction. The current ambiguity puts too much risk on businesses, they say.

“If you're a compounder, the situation is very unclear and if you're competing with compounders, it's certainly very unclear. ... When there's no policy other than, we'll react to the moment, it's very hard to plan and to make investments,” said Steve Mahinka, chairman of Morgan Lewis & Bockius LLP's life sciences and health care interdisciplinary group.

“You don't know the enforcement selection criteria,” he said. “It's just a whack-a-mole enforcement approach.”

Experts argue the FDA has consciously chosen not to issue formal notice-and-comment rulemaking, in order to give itself maximum flexibility when it comes to enforcement.

The FDA referred Law360 to its compliance guidelines.

The Massachusetts pharmacy appeared to be clearly over the line by making a drug that was already commercially available in FDA-approved form. Compounding drugs that are commercially available or copies of commercial drugs is one of the FDA's red-flag activities.

But some experts say the FDA shot itself in the foot last year, when it announced it would not go after compounding pharmacists who were selling a version of a pregnancy drug marketed by K-V Pharmaceutical Co. as Makena.

K-V won FDA approval of the drug, which had long been made by compounders, in 2011. The company sold Makena at $1,500 a dose, when the compounders had charged around $15 a dose, prompting outcry from Congress. Despite demands by K-V that the FDA stop the compounders, the FDA said it was using its enforcement discretion not to pursue the pharmacies, a decision widely seen as the result of the price difference. K-V has blamed its subsequent bankruptcy on the FDA's actions.

According to Sheldon Bradshaw, a former chief counsel at the FDA, some compounders saw that as a green light to start making commercially available drugs.

“That press release completely emboldened this industry. Under the compliance policy guide, that was one of the few bright lines you couldn't cross. You weren't allowed to manufacture a compounded version of an FDA-approved drug,” said Bradshaw, now a partner at Hunton & Williams LLP. “Now, you have an FDA press release saying you can do that here, [and compounders said], we can now start making knockoffs of FDA-approved drugs.”

He sees the meningitis outbreak as a direct result of the Makena decision.

“I put a lot of blame on that decision,” he said. “If FDA went after that, I don't think we'd have the problem we're having today.”

At the very least, the Makena decision added a layer of ambiguity to the FDA's policies, and may make it harder for the agency to now take a hard stand against compounders making commercially approved drugs, Mahinka said.

“The agency put itself into a terrible policy position,” he said. “To expect the agency to undertake a coherent policy formulation and consistent approach to compounders is unlikely. ... It will be difficult to approach any of these compounding issues on a principled basis.”

For now, the FDA is working with the Centers for Disease Control and Prevention to respond to the outbreak. The agency's oversight committees in Congress have requested bipartisan briefings on the situation, with an eye toward preventing future outbreaks.

--Editing by John Quinn and Lindsay Naylor.