

# Manufacturers and Hospitals Spar Over Drug Shortage Reporting

## FDA Proposal Seeks to Improve Early Warning System

Stephen Barlas



*Mr. Barlas is a freelance writer in Washington, D.C., who covers issues inside the Beltway. Send ideas for topics and your comments to sbarlas@verizon.net.*

There is no shortage of controversy over the Food and Drug Administration's proposed new reporting requirements for drug manufacturers who face imminent production problems leading to potential product shortages. In a proposed rule published in November 2013,<sup>1</sup> the FDA came up with some fairly broad terms as yardsticks for when pharmaceutical companies would have to provide indications of what appear to be upcoming shortages, and how quickly companies have to communicate with the FDA about them. Drugs that are reported would appear on the FDA shortage list.

But drug companies think the proposed language will lead to overreporting, meaning alerts on prospective shortages that don't occur because of circumstances that arise after a premature report to the FDA. Hospitals, on the other hand, think that some of the terms the FDA wants to use are ill defined, and that allowing drug manufacturers up to five days to report a shortage after one appears to be imminent gives the companies too much leeway.

This debate has suddenly taken on additional significance because medications that qualify for the shortage list will be eligible for compounding based on a provision in Section 102 of the newly passed Drug Quality and Security Act.<sup>2</sup> So manufacturers want tight restrictions on which drugs can get onto the shortage list that the FDA has kept for a number of years. The FDA's broad definition of products covered by the rule "may allow drug compounders to begin manufacturing a specific drug before it is actually necessary, at the possible peril of public

health," states Sarah Spurgeon, Assistant General Counsel, Pharmaceutical Research and Manufacturers of America (PhRMA). "PhRMA strongly believes widespread compounding is not a sensible public health approach to dealing with drug shortages, as the practice exposes patients to unapproved products made in facilities that have not been subject to a pre-approval inspection."<sup>3</sup>

A couple of long, technical sentences lie at the heart of the FDA's proposed rule, which is required by the Food and Drug Administration Safety and Innovation Act (FDASIA) signed by President Obama in July 2012.<sup>4</sup> Prior to passage of the FDASIA, the FDA imposed an interim final rule (IFR) giving it additional tools to address drug shortages, using as authority an executive order President Obama issued in 2011. The executive order grew out of a governmentwide concern, stoked by hospitals and physicians, that the number of drug shortages had spiked from about 61 in 2005 to more than 250 in 2011. The measures in the IFR helped the FDA significantly decrease drug shortages in 2012 to 117, in part by preventing them. The agency says it averted just under 200 drug and biological product shortages in 2011 and more than 280 such shortages in 2012.<sup>5</sup>

But Congress decided the FDA needed additional tools beyond what the IFR allowed, and provided those in the FDASIA. The heart of the bill is a two-part "trigger." The first part says drug companies must notify the FDA electronically of "a permanent discontinuance or an interruption in manufacturing of the product that is likely to lead to a meaningful disruption in supply (for drugs and biological products other than blood or blood components) or a significant disruption in supply (for blood or blood components) of the product in the United States." But notification is only required for a prescription drug or biological product "that is life-supporting, life-sustaining, or intended for use in the prevention or treatment

of a debilitating disease or condition ..." Notification would have to be made at least six months prior to the date of the permanent discontinuance or interruption in manufacturing, or, if six months' advance notice is not possible, as soon as practicable thereafter, but in no case later than five business days after the permanent discontinuance or interruption in manufacturing occurs.

Both drug companies and hospitals believe that language leaves a lot of room for interpretation, and diametrically different results. "We are concerned that the phrase 'life-supporting, life-sustaining, or intended for use in the prevention of a debilitating disease or condition' is unclear," states Stephen L. Moore, MD, Senior Vice President and Chief Medical Officer, Catholic Health Initiatives. "Similarly, where is the line drawn between nondebilitating disease and debilitating disease?"<sup>6</sup>

Carol Haley, PhD, Director, U.S. Regulatory Policy and Global Intelligence, Pfizer, Inc., states, "The proposed definitions of 'life-supporting or life-sustaining' and 'intended for use in the prevention or treatment of a debilitating disease or condition,' if broadly interpreted, could result in overnotification, as most marketed prescription medicines could be included in these categories."

She also wants more clarity on what the FDA means by "an interruption in manufacturing that is likely to lead to a meaningful disruption in supply of the product in the United States." That definition has a direct impact on the five-day reporting limit. She says the notification clock should start ticking at the point when the manufacturer becomes aware that a meaningful disruption is likely to occur, which may be after an initial potential interruption is identified.

Moore says that instead of using unclear phrasing as the tripwire for reporting, the FDA should create a list of drugs and biologicals that fall into the categories the FDA is proposing to



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define. Moore also believes a five-day reporting lag will significantly weaken the regulation. “We believe that for an unforeseen disruption or discontinuation, FDA should require immediate notification,” he explains.

### REFERENCES

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