PATIENT SAFETY BLOG

PATRICK MALONE & ASSOCIATES, P.C.
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Toll Free: 888.625.6635
(888.MaloneLaw)
Local: 202.742.1500

Efforts Ramp Up to Reduce Drug Shortages

December 28, 2011 by Patrick A. Malone

Last month we wrote about an executive order that renewed attention to the problem of drug shortages and the FDA's inability to fix them. This month, both the Government Accountability Office (GAO) and a U.S. Senate Committee provided more ammunition for granting greater authority for the FDA to address the problem. There's no real news, but there are more and louder authoritative voices to prompt positive change.

As recounted on FDA Law Blog, Marcia Crosse, GAO Director of Health, told the Senate Committee on Health, Education, Labor and Pensions that the FDA is "constrained in its ability to protect the public health from the impact of [drug] shortages."

Bills in both the Senate and House of Representatives, and an FDA interim rule to enable the agency to improve its collection and distribution of drug shortage information to physician and patient organizations and to work with manufacturers to respond to potential drug shortages speak to the government's interest in solving the problem.

And, the pharmaceutical industry is beginning to step up. The Generic Pharmaceutical Association (GPhA) announced its own Accelerated Recovery Initiative to "reverse current drug shortages and prevent further ones. . . ."

Patrick A. Malone
Patrick Malone & Associates, P.C.
1331 H Street N.W.
Suite 902
Washington, DC 20005

pmalone@patrickmalonelaw.com
www.patrickmalonelaw.com
202-742-1500
202-742-1515 (fax)

Specifically, the industry initiative calls for:

- an independent third party to gather current and future supply information from stakeholders for products identified as meeting the critical criteria;
- that information to be used to determine current and potential supply gaps, with a focus on those products where a shortage is expected to last longer than 90 days; and
- a high-level SWAT team to be formed within FDA with the ability to quickly respond to critical shortages and work with the current Drug Shortage staff expanded through the president's drug shortage initiative.

The GAO confirmed much of what everybody already knew or suspected. Between 2006 and 2011:

- Drug shortages have increased by 200 percent.
- The average duration of a drug shortage has been approximately nine months.

The GAO analyzed the causes of 15 drug shortages that had a significant impact on public health. Twelve out of the 15 shortages were caused primarily by manufacturing problems. Other factors contributed, such as having to make lengthy improvements to aging facilities and disruptions in the supply of certain drug ingredients.

Also, some drugs are produced by only a few manufacturers, so if one experiences manufacturing problems or supply-chain issues, there aren't a lot of options to boost production elsewhere.

As noted, these issues aren't news, nor the fact that even if the FDA knows in advance about drug shortages, it can't resolve problems unless it has the muscle—the statutory authority—to require manufacturers to do what's necessary to prevent, mitigate or end shortages.

As FDA Law Blog summarizes, the interim rule may significantly increase the instances in which sole manufacturers are required to notify FDA of an impending production disturbance. But without action by Congress, the FDA can't expand the shortage reporting requirements, and will remain, as the GAO indicates, "constrained" with regard to drug shortages.

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