FDA issues new rule on drug shortages

Reported by Alicia Ault

The Food and Drug Administration (FDA) has announced that it would require some manufacturers to give the agency early warning of an imminent drug shortage.

The agency made the announcement on December 15, 2011, as a Senate committee held a hearing the continuing drug shortage problem. It issued an interim final rule in response to President Obama's October 31 Executive Order asking the agency to use its existing authority to address the shortage issue. The rule would require manufacturers who are the only suppliers of a product "to report to the FDA all interruptions in manufacturing of products that are life supporting, life sustaining, or intended for use in the prevention of a debilitating disease or condition," according to a press release from the Department of Health and Human Services.

Dr. Sandra Kweder, deputy director of the FDA's Office of New Drugs, said at the Health, Education, Labor and Pensions (HELP) committee hearing that the agency has been busy since the October 31 order, among other things, reminding drug makers of their legal duty to report, in some instances, impending supply problems. She noted that the agency used to receive about 10 notifications a month of a potential shortage, and that between late October and mid-December, it had received 61 notifications. The agency has monitored 220 shortages since January 2011, and has prevented 96, she said.

Dr. Kweder said the agency had averted shortages by helping manufacturers get supplies of critical ingredients, by helping them change manufacturing processes, or by going to competitors and encouraging them to ramp up production of the drug that is in short supply. She noted that the FDA had recently worked with generic drug maker Teva to get its doxorubicin production online again, and had also approved Pfizer as a new maker of that chemotherapy drug.

The General Accounting Office (GAO) issued a new report at the hearing that urged Congress to require all manufacturers to report potential supply issues to the FDA. "Because the FDA usually doesn't know about a shortage until it is well under way, the agency's approach to managing drug shortages is predominately reactive," said Marcia Crosse, director of health care at the GAO.

The GAO found that the agency does not maintain a database on shortages, which means it can't track trends or create effective strategies, said Ms. Crosse. The agency has the power to expedite reviews of generic drug applications, but currently has a backlog of 8,000 applications, said Ms. Crosse. Several Republican members of the Senate HELP committee questioned whether the agency was doing all it could to ease that backlog. Ms. Crosse said that the FDA had expedited hundreds of applications, but that it could not say whether any were completed in time to help resolve any particular shortage.

Sen. Richard Blumenthal (D-Conn.) suggested that some of the shortages might be owing to a lack of competition in the generic injectable industry. Data presented by the market research company IMS Health shows that more than 82% of the products in short supply over the last 5 years were generic injectables. "I will be proposing more aggressive measures that are necessary to crack down on what appear to be anticonsumer practices," said Sen. Blumenthal, a former attorney general of Connecticut. "The shortages are creating a public health menace," he said, adding that he was considering whether to direct the Department of Justice or the Federal Trade Commission to investigate what he called "astonishing and appalling mark-ups" for drugs in short supply.

The generic industry responded with a new initiative, which it announced at the hearing. The Accelerated Recovery Initiative includes manufacturers who represent 80% of the generic injectable market. They are proposing to provide more timely assessments of shortages and "establish practices that allow for potential, voluntary production adjustments to lessen or eliminate the impact of a current shortage," according to testimony by Ralph Neas, president and CEO of the Generic Pharmaceutical Association. The initiative has to be approved by the Federal Trade Commission and the Department of Health and Human Services, said Mr. Neas.

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