FDA's Steps to Avert Shortages Under Scrutiny

FDA to require manufacturers of some drugs to give early warning of impending supply problems.

BY ALICIA AULT

FROM A HEARING OF THE SENATE HEALTH, EDUCATION, LABOR, AND PENSIONS COMMITTEE

WASHINGTON – As a Senate committee held a hearing Dec. 15 on the continuing drug shortage problem, the Food and Drug Administration announced that it would require some manufacturers to give the agency early warning of an imminent shortage.

The agency issued an interim final rule in response to President Obama's Oct. 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.

The FDA has monitored 220 drug shortages since January 2011 and has prevented 96, said Dr. Sandra Kweder.

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 that Oct. 31 order, among other things, reminding drug makers of their legal duty to report, in some instances, impending supply problems.

"Our efforts are having an effect," said Dr. Kweder. She noted that the agency used to receive about 10 notifications a month of a potential shortage, and that since late October it has 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 on line again, and had also approved Pfizer as a new maker of that chemotherapy drug.

The U.S. General Accounting Office issued a new report at the hearing that urged Congress to require all manufacturers to report potential supply issues to the FDA.

"Because 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 agency has been able to prevent shortages when it knows in advance that there will be a problem, she said.

The GAO found that the agency does not maintain a database on shortages. That means it can't track trends or create effective strategies, said Ms. Crosse. The agency does have 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 due to a lack of competition in the generic injectable industry. Data presented by 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.

PHOTOS: ALICIA AULT/ELSEVIER GLOBAL MEDICAL NEWS

Shortages may result from a lack of competition in generic injectables, said Sen. Richard Blumenthal (D-Conn.).

"The shortages are creating a public health menace," he said, adding that he's considering whether to direct the Department of Justice or the Federal Trade Commission to investigate what he called "astonishing and appalling markups" 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 does have to be approved by the Federal Trade Commission and the Department of Health and Human Services, said Mr. Neas. ■

Proposed Health Exchange Benefits 'Skimpy,' Providers Say

BY MARY ELLEN SCHNEIDER

Physicians who support a single-payer health system are urging the federal government to reject the Institute of Medicine's recommendations for designing the benefits package to be offered in the state-based health insurance exchanges.

Physicians for a National Health Plan (PNHP) is leading the effort to cast off recommendations issued by the Institute of Medicine (IOM) in October, charging the panel was unduly influenced by the insurance industry. The IOM panel called on the Department of Health and Human Services to base the essential benefits package on the benefits typically offered by small employers. It also urged the agency to consider cost when designing the package of required benefits.

In a Dec. 1 letter to HHS Secretary Kathleen Sebelius, more than 2,400 physicians, nurses, and health advocates criticized the IOM recommendations, saying that they would provide "skimpy" coverage.

"The inadequate coverage the IOM recommends would shift costs from corporate and government payers onto families already burdened by illness," according to the PNHP letter. "Yet this strategy will not lower costs. Delaying care often creates even higher costs. Steadily rising copayments and deductibles over the past 2 decades have failed to stem skyrocketing medical inflation."

Dr. Steffie Woolhandler, a cofounder of PNHP and professor of public health at the City University of New York, said that the recommendations from the IOM panel are not what was envisioned by supporters of the Affordable Care Act. Instead, supporters had expected that the essential benefits package would be based on the more generous benefits offered by large employers.

The letter also attacked the IOM panel for including members who have "amassed personal wealth through their involvement with health insurers and other for-profit health care firms."

Dr. Woolhandler, who served as an IOM fellow in 1990-1991, cited the inclusion of Sam Ho, executive vice president of UnitedHealthcare, and Leonard Schaeffer, former chairman and CEO of WellPoint.

Allowing individuals with financial ties to the insurance industry to serve on the IOM panel is contrary to the IOM's own recommendations, issued in 2009, on minimizing conflicts of interest on panels that issue clinical practice guidelines, Dr. Woolhandler added.

Although Mr. Ho and Mr. Schaeffer have knowledge about the insurance business, there are many qualified experts without conflicts who could have been selected for the panel, she said. "A lot of people know about health insurance benefits," she said.

The IOM stood by the panel and its recommendations. "The IOM report speaks for itself and details the solid rationale for each of its recommendations for achieving a balance between coverage and cost," said Christine Stencel, an IOM spokeswoman.

The 18-member panel was chaired by Dr. John R. Ball, former executive vice president of the American Society for Clinical Pathology. The panel also included Dr. Alan Nelson, a health policy expert and retired internist/endocrinologist; Christopher F. Koller, health insurance commissioner for Rhode Island; and several policy experts. ■