FDA Aims to Improve Drug Safety, Development

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Officials at the Food and Drug Administration are planning to reorganize its Center for Drug Evaluation and Research in an effort to improve the agency's approach to drug safety and to help improve drug development.

The FDA plans to appoint a new associate director at the Center for Drug Evaluation and Research (CDER) to focus on broad drug safety, policy, and communication issues. Agency officials also plan to consolidate some drug safety–related activities and have that staff report to the new associate director. This would include MedWatch reporting staff and Drug Safety Oversight Board staff.

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The reorganization plans also call for elevating the status of the current Office of Drug Safety, which is primarily responsible for epidemiology and surveillance activities, and its staff will report to the CDER director. The name of the office will also be changed.

"Over the past year, the Center has been the focus of intense internal and external scrutiny regarding drug safety," said Dr. Steven K. Galson, CDER director, in a memo to the center staff. "The current organizational structure perpetuates the misperception that ensuring drug safety is solely the responsibility of the current Office of Drug Safety."

While the Office of Drug Safety is a small unit, about half of CDER's resources are dedicated to drug safety activities, said Deborah Henderson, R.N., director of the Office of Executive Programs at CDER.

But the proposal includes no plans to make the Office of Drug Safety independent from CDER, as some in Congress have proposed. When reviewing drugs, FDA staff members need to balance the effectiveness of the drug against the risks, Ms. Henderson said, so pulling the safety activities out of the center wouldn't be in the best interests of public health.

FDA officials plan to implement the changes over the next 6 months.

The changes will also help to improve regulatory and drug development science through the agency's Critical Path Initiative—a top FDA priority that calls for partnering with industry and academia to improve the drug development process.

Through the Critical Path Initiative, FDA hopes to help industry find better biomarkers and improve clinical trial designs, Ms. Henderson said, which would ultimately lead to better, more targeted drugs.

While a number of CDER staff have been working on the Critical Path Initiative, there has not been a central office within CDER. Under the proposed reorganization, the FDA will create a new office that will report to the CDER director and provide a hub for Critical Path activities.

The FDA also plans to make other changes, including establishing an Office of Counterterrorism and Emergency Operations, which will report to the Office of the Center Director; and realigning the Division of Scientific Investigations from the Office of Medical Policy into the Office of Compliance.

"A reorganization is not designed to achieve instant solutions to the challenges CDER faces, although I believe it will address many of the criticisms and suggestions which have been offered on how to approach our work, including drug safety," Dr. Galson said in his memo to CDER staff.

But real improvements in drug safety need to happen outside the FDA, said Curt D. Furberg, Ph.D., professor in the department of public health sciences at Wake Forest University in Winston-Salem, N.C.

Congress needs to act to give the FDA greater authority to change labels, withdraw drugs, and levy penalties against drug makers who don't live up to their postmarket promises, he said. "FDA can't do that on its own," Dr. Furberg said. "Congress is failing."

The streamlining being proposed by the FDA is a good idea, he said, but it won't address the larger problem. "The issue of safety is much bigger," he said. ■