FDA Reorganizing in Hopes Of Improving Drug Safety

BY MARY ELLEN SCHNEIDER
Senior Writer

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.

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," CDER Director Steven K. Galson, M.D., said 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, the 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.

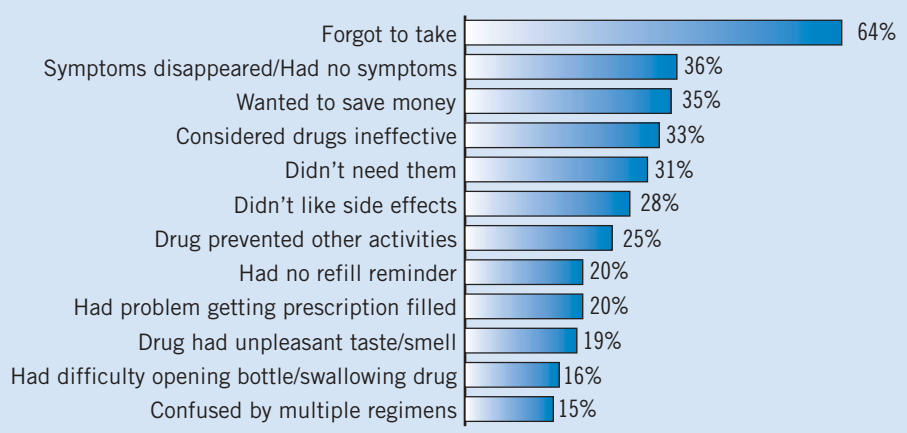
But real improvements in drug safety need to happen outside the FDA, said Curt D. Furberg, M.D., Ph.D., professor, department of public health sciences at Wake Forest University in Winston-Salem, N.C.

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. ■

DATA WATCH

Reasons for Prescription Drug Noncompliance



Note: Based on a nationwide survey of 1,648 adults who had drugs prescribed to them within the last year; the survey was conducted March 16-18, 2005.

Sources: Wall Street Journal Online, Harris Interactive

KEVIN FOLEY, RESEARCH/ANGIE RIES, DESIGN

POLICY & PRACTICE

Competitive Drug Acquisition

Starting April 3, 2006, physicians can begin the initial vendor election process as part of Medicare's Competitive Acquisition Program (CAP) for physician-administered drugs covered under Medicare Part B. The voluntary program allows physicians to obtain Part B drugs from vendors who are selected in a competitive bidding process. Vendors would then bill Medicare and collect any applicable deductible and coinsurance from beneficiaries for the drugs. Physicians would continue to be paid for the cost of drug administration. Physicians can obtain drugs through the program starting on July 1, 2006. Officials at the Centers for Medicare and Medicaid Services announced refinements to the CAP process last month, including establishing a process for approved vendors to furnish additional drugs under the program and establishing a framework for vendors to enter into arrangements with CAP physicians for the collection of coinsurance.

Alternative Medicine Centers

The National Center for Complementary and Alternative Medicine (NCCAM) is funding five new research centers to study complementary and alternative approaches to HIV/AIDS, arthritis, asthma, and pain. Three of the new centers will focus on therapies used in traditional Chinese medicine, such as acupuncture and Chinese herbal mixtures. The other centers will study millimeter wave therapy—a type of energy medicine—and botanical therapies used by traditional healers in Africa. For example, NCCAM has awarded $1.2 million in first-year funding to the Center for Arthritis and Traditional Chinese Medicine at the University of Maryland in Baltimore. Researchers there will conduct a clinical trial of an 11-herb Chinese formula known as HLXL for osteoarthritis of the knee; assess acupuncture's effect on inflammatory pain in an animal model; and study the efficacy of HLXL in an animal model of autoimmune arthritis. NCCAM is a component of the National Institutes of Health.

The Research Pipeline

Drug researchers are currently developing 446 medicines aimed at diseases that disproportionately affect women in the United States, according to a report from the Pharmaceutical Research and Manufacturers of America (PhRMA). Seventy-two of the drugs are being developed for arthritis or musculoskeletal disorders. The 41 million women with arthritis in the United States account for 70% of rheumatoid arthritis sufferers and 60% of osteoarthritis sufferers, according to PhRMA. In addition, researchers are working on 47 drugs for autoimmune diseases including lupus, fibromyalgia, psoriasis, and multiple sclerosis. These medicines are either in clinical trials or awaiting approval by the Food and Drug Administration.

Unproven Health Claims

The Food and Drug Administration issued warning letters to 29 companies for making unproven claims that their products treat or prevent disease. The letters were issued to companies that manufacture, market, or distribute products made from cherries and other fruits. The companies made a range of claims about diseases including arthritis, cancer, and heart disease. Under the Federal Food, Drug, and Cosmetic Act, products intended for use in the "diagnosis, cure, mitigation, treatment, or prevention of disease" are considered drugs and must be approved for safety and effectiveness by the FDA.

Cream Skimming Continues

Specialty hospitals are under scrutiny once again. A study found that Arizona heart physicians who partly owned cardiac specialty hospitals were more likely than were physicians with no ownership stake to treat low-acuity, high-profit cases in their own facilities and refer the more complex, lower-profit cases to community hospitals. Jean Mitchell, Ph.D., a professor of public policy at Georgetown University, Washington, analyzed 6 years of inpatient discharge data to compare the practice patterns of physicians who were owners of cardiac specialty hospitals in Phoenix and Tucson with those of physicians who only treated patients in full-service community hospitals with an accredited cardiac care program. She found that physician-owners treated higher percentages of patients with Medicare fee-for-service or commercial PPOs, and lower percentages of patients enrolled in Medicaid and HMOs. The American Medical Association endorses the existence of such hospitals, although the Center for Medicare and Medicaid Services has reinstituted a freeze on the approval of new specialty hospitals until it completes a review next year. The study appeared as a Health Affairs Web-exclusive article.

HHS Considers Investigation

The Department of Health and Human Services' Office of Inspector General is looking into the circumstances surrounding the resignation of former Food and Drug Administration Commissioner Lester M. Crawford, D.V.M., Ph.D., to determine if an investigation should be opened, an OIG spokeswoman said. In a response to a query from Rep. Maurice Hinchey (D-N.Y.), HHS Inspector General Daniel R. Levinson said that the OIG is doing an initial review of the facts, not an investigation in any regulatory sense, according to the spokeswoman. "After reviewing the facts, the OIG will determine if an investigation is formally launched," she said. "Dr. Crawford's departure, a mere 2 months after confirmation to his position, raises significant questions," Rep. Hinchey and several fellow members of Congress wrote in their request.

—Mary Ellen Schneider