The Food and Drug Administration (FDA) is trying to improve the way it assesses drug safety and communicates postmarketing problems by reorganizing the Center for Drug Evaluation and Research (CDER), the largest of the FDA’s five centers. A major aspect of this effort was the creation of a new position, Associate CDER Director of Safety Policy and Communication. Paul Seligman, MD, MPH, an FDA official, was promoted to that position in mid-April. He will provide oversight of drug safety policies and will manage the staff members who disseminate safety information to health care professionals and patients through the FDA’s MedWatch Web site.

Obviously, this project, which has been in the works since last fall and is still unfolding, is a response to the considerable criticism directed at the agency because of its inaction after receiving troubling information about Merck’s rofecoxib (Vioxx) and some antidepressants. In April, the Government Accountability Office (GAO) issued a report reiterating numerous drug-monitoring problems afflicting the agency, many of which had been previously exposed, such as the gaping holes in its postmarketing surveillance system.

The report details efforts by the Office of Drug Safety (ODS) over the past half decade to convince the Office of New Drugs (OND), which has the sole power to approve new medications, that some recently approved medications, such as leflunomide (Arava, Aventis), cerivastatin (Baycol, Bayer), valdecoxib (Bextra, G. D. Searle), and cisapride (Propulsid, Janssen) posed unresolved safety problems.

After reading the GAO report, one is left wondering whether the CDER “reorganization”—moving a bureaucrat up a few notches and giving him a new title—is enough to cure what ails the CDER drug safety surveillance operation. Was this simply a matter of rearranging the deck chairs on the Titanic?

It is clear that the FDA needs more than a reorganization to emerge from the clouds darkening the skies over its offices in Rockville, Maryland. To start with, the ODS needs more resources.

In fiscal year 2005, the ODS spent $26.9 million and employed 106 staff members; by contrast, the OND spent $110.6 million and had a staff of 715. The GAO report portrays a “Keystone Cops” relationship between the two offices. Each office has its own confusing methods of operation, complicated by a revolving door at the top. The ODS has had eight directors in 10 years. The ODS director acknowledged to the GAO that his shop apparently uses the equivalent of a pencil and sheet of paper to keep track of evolving drug problems. He is developing a tracking system, apparently its first organized one, which is now being tested; it is expected to become operational sometime in 2006.

CDER director Steven K. Galson, MD, has said that the reorganization will remove the ODS from the OND, where it suffers from subservience. The name of the ODS will be changed, and it will be placed directly under his name on the organizational chart. However, this has not yet taken place. When that happens, it is not clear how Dr. Seligman will fit in.

Will a new ODS director be appointed? Will Dr. Seligman assume that job? No one knows.

The FDA’s shortcomings will not be cured internally. It will take congressional direction, which has been in precious short supply. Senator Charles Grassley (R-Iowa) introduced an FDA drug safety review reform bill in April 2005 with great fanfare. It contained some good ideas, even though it wasn’t particularly radical or far-reaching. But even that mild bit of legislative remedy has been stuck in the Capitol Hill medicine cabinet. There have been no hearings on that bill, and it has gone nowhere. The House Appropriations Committee did include an amendment in its FDA budget bill for fiscal 2007, passed in mid-May 2006, which gives the agency the authority to require drug companies to complete postmarketing clinical trials.

The GAO report points out that the FDA can do that now only in limited circumstances. But whether that amendment survives in the final FDA appropriations bill is anyone’s guess.

Neither that amendment nor the Grassley bill addresses postmarketing communications with pharmacists. The FDA’s MedWatch system is supposed to update pharmacists with safety alerts and monthly safety labeling changes. Even CDER admits that the program needs to be strengthened. CDER has asked the White House Office of Management and Budget for permission to send a survey to users of MedWatch asking for suggestions on how to improve the communications process.

The GAO recommended several other improvements it would like to see made at CDER. Those recommendations did not include promoting current staffers or creating new offices. Systemic changes are needed, and they have been needed for a long time.

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