Dr. Mark McClellan, the current administrator of the Centers for Medicare & Medicaid Services (CMS) and former director of the Food and Drug Administration (FDA), has proposed an electronic database that would automatically monitor the safety and efficacy of drugs used under Medicare Part D of the Medicare Modernization Act (MMA). The database will offer the CMS an unprecedented amount of data on drug utilization.

Now that the Medicare Prescription Drug Plan (PDP) benefit has gone live (on January 1, 2006), these data could be used to revamp the FDA’s safety protocols and drug-approval procedures. Because it is predicted that about 40% of total prescriptions in the U.S. will be filled under Part D, the data should provide important insights into outcomes and the overall cost of care related to prescription medications.

The proposed plan would create a database that would help CMS identify the most cost-effective prescription choices. Pharmacy billing information would be linked with Medicare claims data in order to obtain a clear, cross-referenced picture of utilization. The database would also allow CMS to evaluate the off-label uses for which many medications are being prescribed.

These utilization data, as well as patient- and physician-reported outcomes, would then be incorporated into a new adverse events–reporting system (AERS) for the FDA’s use. Ultimately, the data would be combined with other data on drug use and health outcomes as part of the federal government’s plan to implement new health care communications technology to allow all the parts of the health care system to communicate with one another.

This initiative, which Department of Health and Human Services Secretary Mike Leavitt announced in June 2005, would create a public–private partnership known as the “American Health Information Community.” This partnership would create an all-inclusive electronic medical record (EMR) within the next decade.

The FDA is receptive to the CMS’s database plan and has publicly announced its support. It is acknowledged that the AERS that is currently in place needs to be revamped, especially in the light of the COX-2 (rofecoxib, Vioxx, Merck) situation. The current system is useful for detecting rare, easily diagnosed events—such as the association of valdecoxib (Bextra, Pfizer) with Stevens–Johnson syndrome—but it is ill-equipped to pick up problems such as adverse coronary events, because of the high background rate of these events. It is estimated that as many as 90% of serious adverse events remain unreported in the current voluntary AERS. The proposed CMS database could be part of the solution because it would be specifically configured to collect the type of longitudinal data that the FDA needs to track these kinds of events.

The potential benefit of this plan rests with the dissemination of the data to institutions and researchers. A faster, more effective AERS, perhaps with the near real-time release of information to interested parties, would greatly improve medication safety rates and catch potential adverse events before they occur. The database would be invaluable for outcomes research purposes as well as for identifying which drugs are the most efficacious and cost-effective. Public access to these data would shape the way in which purchasing and formulary decisions would be made in the future.

Although the future of Dr. McClellan’s plan looks bright, critics have noted that the high cost of implementing it and the current state of technology are barriers that need to be surmounted. David Graham, a member of the FDA’s Office of Drug Safety, noted that the current databases used by Medicare are not up to the challenge of this kind of system and must be overhauled before they can be used for research purposes.

Another concern is privacy issues, although Dr. McClellan has stated that all information collected would meet the HIPAA privacy standards. Others have cited the pharmaceutical industry as a potential threat, because a database of prescription data for 41 million patients would be a valuable resource to any pharmaceutical company.

Dr. McClellan’s plan is ambitious; the outcome of the plan and the MMA warrant close observation.

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As always, I am interested in your views. My e-mail address is david.nash@jefferson.edu.