U.S. FDA: Strengthening Postmarket Program

Elizabeth Patnode

November 22, 2006

"The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health." - FDA mission statement

Under the Department of Health and Human Sciences is the U.S. Food and Drug Administration, which contains eight subdivisions. These offices include the Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), Center for Drug Evaluation and Research (CDER), Center for Food Safety and Applied Nutrition (CFSAN), Center for Veterinary Medicine (CVM), National Center for Toxicological Research (NCTR), Office of the Commissioner (OC), and Office of Regulatory Affairs (ORA). These offices and centers have offices within them as well. The FDA also includes two affiliated organizations which include the Joint Institute for Food Safety and Applied Nutrition and the National Center for Food Safety and Technology.

On November 9, 2006, the U.S. FDA's Center for Devices and Radiological Health's Postmarket Transformation Leadership Team (PTLT) developed a new plan to strengthen its current postmarket testing and monitoring program for medical devices. This center is responsible for ensuring the safety of and regulating over 80,000 devices. The new outlook is intended for medical devices once they have reached the market. With continual medical developments and an increasing number of recalls, CDRH has identified specific flaws amongst its current monitoring system. Once these problems were recognized earlier this year, the Center identified and focused on the areas in need of improvement.

Many weaknesses and problems escalated to finally bring CDRH to a point in which transforming its postmarket program became essential. The PTLT identified an inadequate amount and unsatisfactory success with communication amongst the center and between CDRH and its reporting networks, clinical practitioners, and the community. Concerning precise and prompt data reporting, a slow and outdated Medical Device Reporting system (MDR) has set CDRH behind. Background research and analysis of previous postmarket evaluations lack when medical device issues arise. The Center commonly finds confusion amongst itself, industries, and its analysis network on how and when to report postmarket issues and events. The PTLT has also found a large gap between relaying postmarket information to premarket researchers, businesses, practitioners, and FDA departments. Largely, CDRH also lacks funding and resources for field activity in the postmarket department.

CDRH has outlined four major areas that specifically need improvement and are currently the center's highest priorities in revamping its postmarket program. According to the November CDRH PTLT Report, concerned with strengthening the FDA's postmarket program for medical devices, the areas include creating a culture of collaboration, developing world class data systems, enhancing risk/benefit communication efforts, and collaborating on enforcement strategies and outcomes.

The first area of concern focuses mainly on creating cross-cutting groups to help organize information transfer and to establish a more effective public health promotion and protection network. The system is intended to last permanently and to be practiced daily, as to not only be referred to during crisis situations. Employee recognition is also considered under this area of improvement, based on successful collaborations and a functional working matrix.

The intended improvement of data systems is crucial for the PTLT's updating process. Data input and output with constant updates and analysis, will be strengthened, improved, and created initially and as postmarket issues arise. This process change includes the creation of unique medical device classification electronic device registration, and a search for an alternative method of device reporting. An update of the current center's computer data system, MAUDE, and its reporting system MedSun, has been mandated. MAUDE is a generation-old software program that requires manual entries (requiring more time and money), does not return data in a user-friendly format, does not allow for simple searches or to return usable data to staff or other system users, and has an extremely large backlog of reports (causing an inability to detect problems) due to paper methods and incomplete or erroneous data from the manufacturer. MedSun (Medical Device Surveillance Network) is a network that encourages its 350 enrolled healthcare facilities to report defects faulty equipment, and unexpected events. Volunteers and enrollments are high for the network and the Center is successful in reporting feedback and precautions back to the enrolled facilities. The Center must now concentrate on also sharing its analysis and safety information to healthcare facilities outside of the MedSun network. Seeking outside experts for the update and reporting process is also one of the team's goals. This includes the benefits the Center will gain once access to outside databases is enabled, particularly from healthcare professionals and doctor organizations.

In order to be successful with enhancing the risk/benefit communications, the center has focused on creating a stronger name in the community, and working closer with clinical practitioners. As far as collaboration of enforcement strategies CDRH will be transformed after a stronger relationship between the transformation team, the center, and the FDA (including the Office of Regulatory Affairs and the Office of Chief Counsel) occurs. Inspection preparations will mandate a review of previous postmarket data. The transformation team plans to update enforcement data systems, and to train employees to keep these systems current. The latest enforcement tools shall be utilized by the center as well.

Although device manufacturers pay CDRH a user fee to help continue the postmarket review process, the program expires next year, and finances are already low. Postmarket inspections and updates are critical, but with low finances, and diminishing outside resources, transformations have been difficult and delayed. The PTLT is determined and has outlined goals to change the program though, as the Center continues to aspire to transform the postmarket review program.

http://www.fda.gov/bbs/topics/NEWS/2006/NEW01506.html
http://www.boston.com/business/healthcare/articles/2006/11/10/fda_plans_tougher_review_of_devices/
http://www.nj.com/business/ledger/index.ssf?/base/business-0/1163137545198150.xml&coll=1
http://en.wikipedia.org/wiki/FDA
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