FDA Moving to Upgrade Device Safety Vigilance

BY ALICIA AULT
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The Food and Drug Administration announced on Nov. 9 that it is taking steps to improve its postmarketing surveillance of medical device safety, including moving ahead on a proposal to require electronic reporting of adverse events.

The agency said it has created an action plan based on a major review that was completed in 2005. That review looked at how the Center for Radiological Devices and Health (CDRH) handles recalls and enforcement actions against manufacturers that are not in compliance with FDA rules.

"Today's report details a number of action items that we believe will transform the postmarketing safety program," said Dr. Daniel Schultz, director of CDRH, in a briefing with reporters.

The FDA will focus on making improvements in four major areas: collaboration among experts within CDRH, data systems, communications with patients and physicians about risks and benefits, and enforcement.

CDRH leaders will encourage more cross-organizational collaboration so that premarket, postmarket, and enforcement efforts are better coordinated, Dr. Schultz said.

Some of the biggest changes will come in data collection and analysis. The agency hopes to integrate its passive adverse events reporting system (Manufacturer and User Facility Device Experience Database, also known as MAUDE) and its active system, the Medical Product Safety Device Network (MedSun), Dr. Schultz said. Currently, 350 hospitals have been trained to report device problems on MedSun. One goal is to recruit more facilities and find a way to upgrade reporting so it is closer to real time.

The agency also hopes to require manufacturers and others to electronically report

adverse events. Currently, the FDA receives about 200,000 reports to MAUDE each year, and the majority are on paper, which delays entry into the system and analysis for any kind of safety signal, said Dr. Schultz. The FDA has been piloting an electronic reporting program, and is in the process of writing a rule to require electronic reporting, he said.

Once data are being reported and analyzed more quickly, enforcement will be more timely also, he said. It will also let the FDA focus enforcement efforts on the highest-risk products, Dr. Schultz said. "When enforcement is necessary, it needs to be done quickly, accurately, and in a way that's meaningful and corrects problems," he said.

The FDA also aims to improve its communications to health professionals and consumers—whether the communications are notices about unsafe devices or simply background on safety and efficacy of products. CDRH will redesign its Web site to be more consumer-friendly. It will also take a closer look at how best to give out data—and when—on a potentially faulty device.

CDRH is hoping to accomplish most of its planned "action points" without seeking additional funding, at least in the near term, Dr. Schultz said. ■

Emergency Trial Rule Under Scrutiny by FDA

BY ELIZABETH MECHCATIE
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ROCKVILLE, MD. — The Food and Drug Administration is reviewing a decade-old regulation that allows clinical studies of emergency treatments, including automated defibrillator implantation, to be conducted without obtaining informed consent in people with certain life-threatening conditions.

The FDA's reappraisal and proposed revision of the rule were prompted by concerns that current safeguards do not provide enough protection of human subjects, and by comments that the safeguards are too onerous and impede important research.

At present, a narrow exception to the informed consent requirement exists in the case of patients who cannot provide consent because of their conditions and who have no family members available to give consent.

To be exempt from informed consent, an investigation must meet certain criteria, including the following:

► The patient is in a life-threatening situation.

► The available treatments are unproven or not satisfactory.

► Evidence supports the prospect of direct benefit to the individual.

Since the regulation went into effect in October 1996, the FDA has received 56 requests to conduct emergency research under this rule. A total of 21 studies have been conducted, are being conducted, or are about to start enrollment, according to the FDA.

The FDA has issued draft guidance geared toward institutional review boards, clinical investigators, and sponsors developing and conducting emergency research. It also sponsored a public hearing in October on emergency research.

At that hearing, presenters offered examples of emergency research that could not otherwise have been done without the exception.

Although the current rules could be simplified, the exception to informed consent is critical, said Dr. Paul Pepe, professor of surgery, medicine, and public health, and Riggs Family Chair in emergency medicine at the University of Texas Southwestern Medical Center at Dallas.

"Studies of the automated external defibrillator are an example of the tremendous lifesaving potential of emergency treatments," he said. Such studies can also show that treatments that have been widely accepted and appear to be logical may in fact be harmful in some populations, he added. For example, intravenous fluid resuscitation was found to be harmful in certain trauma populations. If these studies had not been done, Dr. Pepe explained, many people would have died.

"Any revisions to current regulations should serve to expand the ability to perform the highest quality emergency research and to enhance patient protections through fairness, openness, and the use of all media that provide explicit detail regarding the research," Dr. Edward P. Sloan and Dr. Charles Cairns said in a statement on behalf of the American College of Emergency Physicians.

The FDA will review written comments on the guidance, as well as comments made at the hearing, to determine whether the rule should be modified. ■