Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Postmarket Safety Program – Synopsis and Recommendations

Introduction

Medical devices, ranging from surgical sutures and contact lenses to prosthetic heart valves and diagnostic imaging systems, are critical to the delivery of health care in the U.S. The medical device industry consists of about 15,000 manufacturers, producing nearly 100,000 individual products. After introduction into the marketplace, many devices remain in use for 10-20 years.

The responsibility for ensuring the safety and effectiveness of medical devices rests with the U.S. Food and Drug Administration and specifically in FDA's Center for Devices and Radiological Health (CDRH). This program includes both the review and approval of new devices entering the marketplace and a postmarket program aimed at monitoring the safety of devices already in use and taking remedial action as needed.

This Synopsis provides a brief description of the CDRH postmarket program, summarizes the special challenges in implementing the program, outlines the program's basic goals, and lists a series of recommended action steps CDRH will consider to strengthen its postmarket effectiveness.

The full report, "Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Postmarket Safety Program", provides a comprehensive inventory of the program. It is part of an ongoing effort by CDRH to assess and improve the postmarket tools available to ensure the continuing safety and effectiveness of medical devices after they reach the market.

Along with the recommendations contained in this Synopsis, the full report will also contribute information necessary for the agency to satisfy requirements under the Medical Device User Fee Act of 2002 (MDUFMA). Under section 104 of MDUFMA, FDA must conduct a study to determine: the impact of the user fee program on the FDA's ability to conduct postmarket surveillance, what improvements are needed in the postmarket surveillance program and how much they will cost, the extent to which device companies comply with postmarket surveillance requirements, and recommendations about whether, and in what amounts, user fee funds should be dedicated to postmarket surveillance if MDUFMA is reauthorized.

Components of CDRH's Postmarket Program

CDRH's postmarket program has three key components, Postmarket Problem Identification, Problem Assessment, and Public Health Response.

1. Postmarket Problem Identification

Postmarket problem identification tools are used to identify unanticipated public health hazards and to enhance the quantity and quality of information about potential medical device risks in the marketplace. Key sources of problem identification include mandatory reports from manufacturers under the Medical Device Reporting (MDR) system, reports from hospitals enrolled in the Center's targeted surveillance system (MedSun), and information from inspections of manufacturers carried out by FDA. Information is also utilized from recall notification reports, bio-research monitoring investigations carried out by FDA, user complaints and comments, international vigilance reports, manufacturers' reports of medical device modifications, and the results of studies carried out by manufacturers after their products are approved.

2. Postmarket Problem Assessment

Based on the information derived from the above sources, the potential risk that may be associated with adverse events from medical devices is scientifically evaluated. Teams of FDA staff members, consulting with outside experts, analyze the available data and identify the nature, magnitude and public health significance of the problem. Recommendations are then made for an appropriate Center action to protect the public.

3. Postmarket Public Health Response

Once a postmarket problem is assessed, public health response tools are used to inform the public, the medical device industry, and health care professionals about the risks that have been identified. The primary tools are risk communication (Urgent Alerts, Multimedia Outreach, Publications and Presentations), and enforcement actions (administrative and judicial). These tools can overlap, in that a communication effort is often undertaken to announce and explain an enforcement action.

Risk/Benefit Communication

CDRH staff utilize targeted risk communication tools depending on the urgency of the message, the intended audience, and the risk communication goals. When a postmarket assessment determines that a public health problem is an imminent health hazard, urgent alerts are issued. CDRH also provides information about public health concerns on a constant basis. FDA Patient Safety News, for example, is a monthly video news show distributed to health care practitioners via medical satellite TV networks and the Internet (www.fda.gov/PSN). Other multimedia sources used by the Center include the e-consumer initiative (designed to reach the public), and several websites (www.fda.gov/cdrh)

Enforcement

CDRH is authorized to use both administrative and judicial enforcement actions to resolve safety problems with marketed medical devices. These include product recalls, injunctions and seizures, as well as detentions of imported products. CDRH can also impose Civil Money Penalties when a firm continues to violate FDA regulations and, when a device presents a substantial risk that cannot be corrected, the product can be banned.

Special Challenges in Implementing an Effective Postmarket Program

Several factors make it difficult to effectively monitor and assess the safety of already-marketed medical devices.

- Adverse events related to medical devices are widely under-reported by device users. This makes it possible to miss rare events, and even when a problem is detected, under-reporting makes it difficult to assess the true public health risk.

- Although we receive tens of thousands of adverse event reports each year, a large proportion of them provide only sketchy information, particularly about the way the device was used and what may have caused the problem. This makes it difficult to assess the nature of the problem, and to distinguish between separate problems that may affect the same device.

- When an adverse event occurs, it is often difficult to identify the specific device involved, particularly since health care providers generally do not document device use in patient records. Devices lack unique identifiers, and manufacturers continually produce modified versions of their products. And device firms are often purchased by other companies, which compounds the problem of product identification. As a result, identifying information about the device often does not appear in large databases.

- Devices are often used "off-label," that is, for indications and in patient populations that were not included in the product's premarket testing and approval. This makes it difficult to determine whether an observed problem is inherent in the device, or whether it resulted from inappropriate use.

- There is a gradual shift in the use of medical devices from hospitals and clinics to patients' homes, so that more non-professionals are involved in using these products. This adds another element of uncertainty as we attempt to diagnose the cause of a problem and identify possible solutions.

Goals of an Effective Postmarket Program for Medical Devices

The above challenges notwithstanding, our basic goal for the postmarket program is to access accurate and timely data about adverse events, analyze and assess this information quickly, and alert device users to signals of potential risk. In order to do that, we must:

- Assure that people throughout the Center are working collaboratively to solve postmarket problems. To encourage this collaboration, we must identify all sources of postmarket data and better coordinate the exchange of information throughout the Center.

- Build and manage effective information and knowledge systems so that we can smoothly move information throughout the postmarket process, from data collection to analysis to public health action.

- Take advantage of what we learn about the postmarket performance of devices by cycling this information back into the premarket review process for new devices.

- Through recruitment, training and career development, ensure that the postmarket program can be implemented well into the future, and that it will adapt to changes in medical technologies and information systems.

- Partner with public and private enterprises throughout the medical device community to ensure that we are communicating with them on an ongoing basis and that we leverage our limited resources.

- Communicate risk information clearly and persuasively to a wide variety of device user audiences.

Action Steps

With the above goals in mind, we are taking the following steps to strengthen the CDRH postmarket program:

1. Develop a "Culture of Collaboration" on Postmarket Safety within the Center

We must shift to a culture that places more emphasis on the importance of our postmarket efforts and on collaboration in identifying and solving postmarket problems, both within the Center and with outside constituencies.

To help accomplish this, a senior-level team comprised of Center management and outside consultants experienced in medical device safety and product regulation will guide the transformation process and also oversee implementation of the other recommendations listed here.

Using the description of our present postmarket efforts provided in the postmarket safety program report as a baseline, the senior-level team will determine the factors that enhance or hinder collaboration within the Center, particularly at the interface between premarket and postmarket activities.

The team will also explore areas where external expertise might be applied to postmarket issues. This might include the use of our already-existing advisory panels to provide guidance and advice, and working with medical and other professional societies to derive real-world data on device usage problems and to improve the way we disseminate information. The team will also analyze impediments to communicating postmarket information within the Center and recommend ways to improve cooperation and joint efforts among Center components, including consideration of a matrix flow of information.

2. Develop World Class Data Sources and Systems

We must assess the ability of our current structure to identify postmarket medical device problems and explore new ways to gain access to richer health care data.

As part of this effort, we will champion the development of a system to provide unique device identification, a standardized and globally accepted nomenclature for devices, and mechanisms and incentives for device users to include this information in healthcare records.

We will work to develop an electronic reporting system, so that all postmarket information is available to all who need to use it.

We will explore opportunities to partner with other groups and organizations such as the Center for Medicare and Medicaid Services, the Agency for Healthcare Research and Quality, and the States in order to gain access to population-based healthcare data, as well as partnering with practitioner, patient safety, public health and industry groups in order to sharpen our ability to rapidly identify and assess device problems as they occur.

We will develop strategies to derive better information from industry on postmarket device usage problems and performance data, using risk-based inspections, quality system reviews, required postmarket studies, and annual reports.

And we will develop ways to routinely and systematically search the healthcare literature and the popular media to find reports of adverse events, sharing this information throughout the Center.

3. Enhance Risk/Benefit Communication Efforts

Once we have accurate and timely postmarket information in hand, we must maximize our ability to communicate this information clearly and quickly to practitioners, patients and consumers.

We will assess the communication tools we now use, evaluate whether they meet the needs of our target audiences, and make improvements where needed.

We will ensure that CDRH staff are informed about these communication tools and that all Offices use them on a regular basis.

And we will ensure that Center leadership is kept appraised of the latest information that is being disseminated to user groups.

4. Focus Improved Enforcement Strategies on Postmarket Issues

When device problems are discovered, we must improve the coordination, consistency, quality and timeliness of inspections, reporting and enforcement actions. This requires that we facilitate cooperation and discussion among the Center's Office of Compliance and other Center components, ORA's headquarter and ORA field staff.

Working with these groups, we will assess the effectiveness of current enforcement strategies and tools as they apply to the Center's postmarket program, documenting those that are working well and those that are less effective, and recommending improvements where needed.