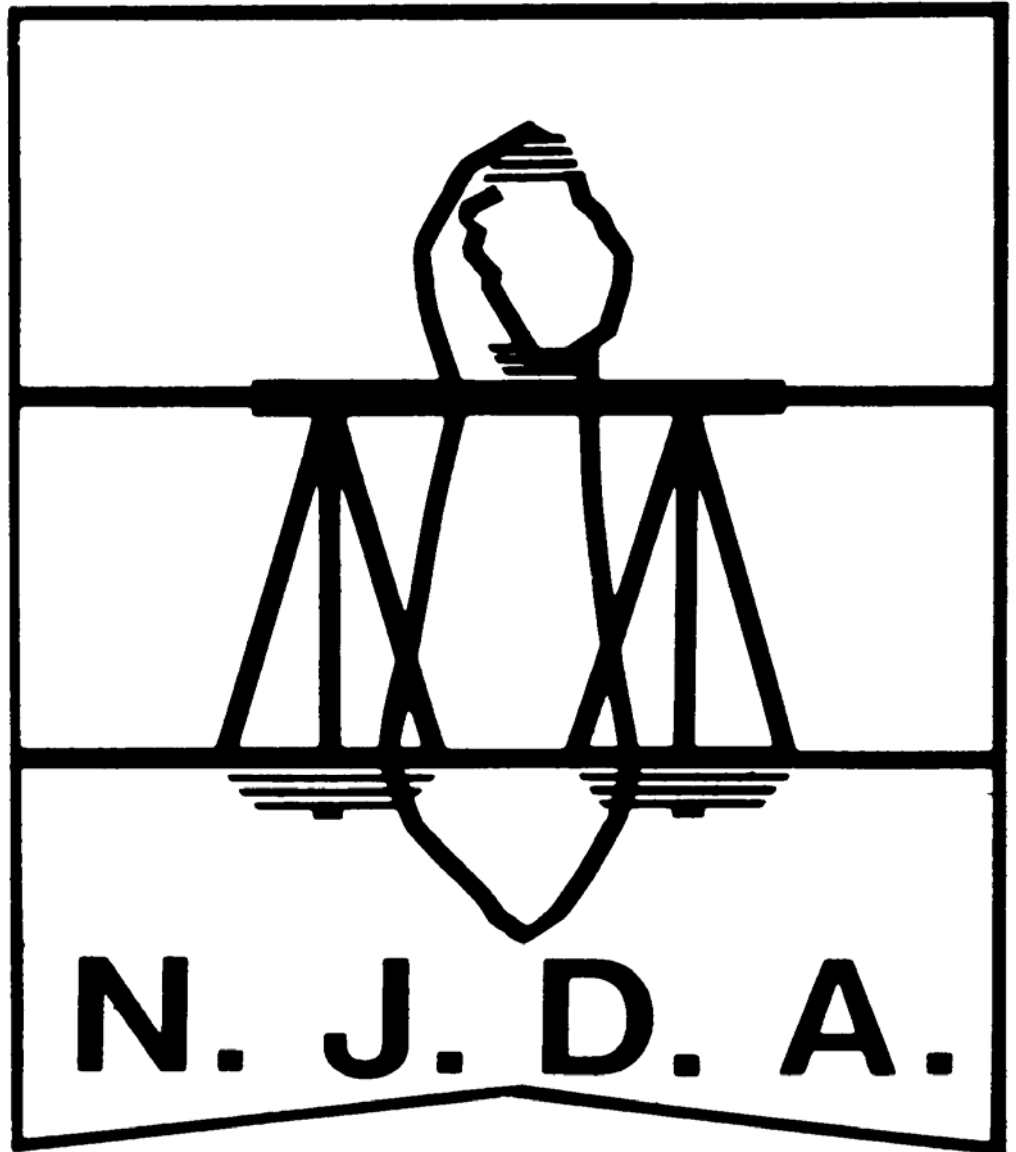


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***FDA ANNOUNCES MEDICAL DEVICE
POST MARKET SAFETY INITIATIVE***

By Charles W. Miller, Esq.

FDA ANNOUNCES MEDICAL DEVICE POSTMARKET SAFETY INITIATIVE

Charles W. Miller, Esq.

In 2005, as the opening step in an initiative to increase its ability “to identify, analyze, and act on problems more quickly, including alerting the public sooner of potential medical device issues”, the Food and Drug Administration (“FDA”) performed a “year-long inventory” of the tools it uses to monitor the safety of medical devices once they have been approved. The inventory considered how postmarket safety problems are identified by the FDA, how the FDA assesses the information, and how the FDA responds to problems through both stakeholder communication and through enforcement action.

In a 77-page report issued on January 18, 2006, the FDA summarized that inventory and set out the details of a new program, entitled the “Medical Device Postmarket Safety Program”, being developed by the FDA’s Center for Devices and Radiological Health (“CDRH”).

The report outlines the program’s basic goals and lists a series of recommended action steps CDRH will consider to strengthen its postmarket effectiveness. Those Action Steps are:

1. Develop a “Culture of Collaboration” on Postmarket Safety within the CDRH- The FDA looks to shift to a culture that places more emphasis on the importance of postmarket efforts and on collaboration in identifying and solving postmarket problems, as a senior-level team of FDA management and consultants will oversee implementation of the recommendations listed here.
2. Develop World Class Data Sources and Systems- The FDA will work to develop an electronic reporting system for collecting and analyzing information about potential safety risks.
3. Enhance Risk/Benefit Communication

Efforts- The FDA will assess its present communication tools to evaluate whether they allow for clearly and quickly communicating postmarket information to practitioners, patients, and consumers.

4. Focus Improved Enforcement Strategies on Postmarket Issues- The FDA will assess the effectiveness of its current enforcement strategies and tools and will recommend improvements, where needed.

The CDRH report also identified a number of special challenges that make it difficult to effectively monitor and assess the safety of already-marketed medical devices. These special challenges include:

- Adverse events related to medical devices are widely under-reported by device users.
- A large proportion of adverse events reports provide inadequate information about the way the device was used and what may have caused the problem.
- When an adverse event occurs, it is often difficult to identify the specific device involved, as device usage is generally not documented in patient records.
- Medical devices often lack unique identifiers. Manufacturers continually update their products, and name changes can occur when a device firm is purchased by another company, making it difficult to accurately identify the medical device involved.
- Medical devices are often used “off-label” for indications and patients not included in the product’s premarket testing and ap-

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proval, making it difficult to determine if the problem is inherent in the device or whether it resulted from inappropriate use.

- More non-professionals are involved in the use of the products, as the use of many devices is gradually shifting from hospitals and clinics to patient's homes. This makes it more difficult to diagnose the cause of a problem and to identify possible solutions.

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. If the initiative improves the ability of the FDA and manufacturers to promptly identify and analyze adverse events related to

devices once they are out in the market and to alert device users of potential risks, the FDA will have taken a major step to ensure the safety of medical devices.

Charles W. Miller is a member of the NJDA Products Liability Committee. He has been representing insureds and insurance companies for over twenty years, with his practice focusing on commercial insurance coverage litigation. He was elected into membership of the Federation of Insurance & Corporate Counsel in 1998. Chuck acts as a national coordinating counsel for products liability claims for several device manufacturers. He possesses a range of experience in the area of complex commercial litigation and has defended clients in actions involving negligence, products liability, construction defects, malpractice and torts.