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I. LEGISLATION

Safe Medical Devices Act Of 1990
by Frank E. Samuel, Jr.

The Safe Medical Devices Act of 1990 (P.L. 101-629) was signed by President Rush on 28 November 1990. It is the first important device amendment to the federal Food, Drug, and Cosmetic Act since the Medical Device Amendments of 1976. The new law caps eight years of congressional review of implementation of the 1976 statute and gives to the Food and Drug Administration (FDA) significant new authority for regulating the safety and effectiveness of medical devices and diagnostic products.

The 1976 device law established a regulatory system based on the degree of risk posed by a product, as classified by FDA. New high-risk products were subjected to a premarket procedure similar to that for new drugs. This procedure required FDA approval based on clinical experience before a device could be marketed. “Me-too” products and product modifications were not required to adhere to this process if the product as introduced or modified was substantially equivalent to a product on the market before the 1976 enactment date. High-risk products on the market prior to that date were “grandfathered” but were supposed to be subjected eventually to premarket approval requirements. All products, regardless of the category of risk, were subject to a variety of controls, chief of which were adherence to good manufacturing practices and reporting of defects related to product malfunction or patient death or injury.

The first major congressional complaint about device regulation under the 1976 law concerned the process for determining substantial equivalence. The manufacturer initiates this process by notifying FDA under section 510(k) of the act. If FDA determines that the product subject to the notification is substantially equivalent to an existing product, the product may be marketed without undergoing complete premarket approval. After reports by the General Accounting Office (GAO) and its own review, Congress concluded that the 510(k) procedure had evolved into a loophole that allowed untested products onto the market without adequate regulatory oversight.

The second major criticism was that FDA lacked sufficient information about actual experience with devices following their introduction to be able to make informed regulatory decisions. The congressional testimony taken to prepare a basis for the new legislation depicted several instances in which device use had resulted in patient harm. In addition, GAO noted that providers reported only a small percentage of incidents involving devices. Reasonable people can differ over the force of this testimony. It is at least arguable whether the amendments enacted in 1990, if in place earlier, would have prevented the incidents cited or resulted in a noticeably greater degree of usable regulatory information. Criticisms usually focused on disagreement with FDA over the timing or nature of FDA action, not over its legal authority to take a step Congress thought necessary. The basis for device law changes was, it appeared, due as much to the conclusion that implementation had not turned out the way Congress had thought it would as it was to widespread public health
problems attributable to legal inadequacies.

Another factor contributed to the environment of congressional policy making: the revelation of bribery and submission of false and inaccurate information in connection with generic drug approvals. Although a variety of investigations continue into FDA’s internal procedures, no information made publicly available during consideration of the new device law suggested that these problems existed in the device area (or in any other, for that matter). Nor has any come to light since. Even though such evidence did not exist, Congress still appeared sufficiently concerned to augment greatly FDA’s penalty and postmarket authority.

The new law requires some seventeen sets of new regulations, many with specific timetables. For convenience, I group the changes into the following four categories: premarket approval, postmarket surveillance, penalties, and miscellaneous. I describe only the major features of this complex new law.

Premarket approval. Despite criticism of the 510(k) notification process, the legislative history of the new law explicitly confirms FDA’s treatment of product modifications and authorizes certain FDA practices that have grown up over the past fourteen years. These include comparing new product modifications to products introduced after 1976 and requiring submission of clinical information to support a 510(k) notification. Manufacturers had opposed the latter practice at first on the grounds that the 1976 device law did not authorize FDA to require clinical data to support a 510(k) notification. But as experience with that provision grew, the 510(k) process evolved so that the amount of information required by the agency varied in relation to the significance of the product modification in question. In sum, FDA matched its requirements for clinical information with its perception of the degree of risk posed by the product. This was congruent with the fundamental structure of device regulation established in 1976, even though disagreement could exist over whether it was specifically authorized or over FDA decisions in specific cases.

In addition to confirming these two important, evolutionary aspects of FDA’s device regulation, the new law requires a summary of safety and effectiveness in connection with a 510(k) submission. Review of pre-1976 devices is spurred by requiring submission, prior to 1 December 1995, of adverse safety and effectiveness data for the highest-risk products.

Under certain circumstances, FDA is allowed to use clinical and preclinical data in a premarket approval application to support its decision on subsequent applications for premarket approval. The data issue was exceedingly controversial for manufacturers. Firms that considered themselves to be innovators felt that any use of their data reduced unfairly the regulatory barriers for subsequent competitors. Proponents of change argued that repetitive clinical testing posed unneeded public health risks and, furthermore, that the proper determinant of competitive position was the patent law, not a regulatory law designed to advance public health. The result was a compromise that protects premarket approval data until four manufacturers of the same product type have received FDA approval.

Overall, the new law encourages FDA to continue the 510(k) process for the vast majority of device and diagnostic product changes and to begin seriously to address high-risk products that were on the market prior to 1976.

Postmarket surveillance. Here there are four major changes. With existing law, they mean that devices are subject to more scrutiny than any other FDA-regulated product class, including pharmaceuticals. (1) High-risk products introduced after 1 January 1991 must be subject to an FDA-approved protocol that provides for postmarket surveillance. (2) Manufacturers are required to adopt methods for tracking high-risk devices. (3) Product corrections or removals must be reported to FDA if the action was taken to reduce health risks.

(4) Hospitals, nursing homes, ambulatory surgery centers, and outpatient treatment facilities (but not doctors’ offices) are required to report to FDA whenever a device is thought to have caused or contributed to the death of a patient. In cases where
the device is related to serious illness or injury, reports must be made to the manufacturer (who in turn has the duty, under existing law, to report to FDA). This is the first time that providers have been required to report to FDA about incidents occurring in their facilities. Because these reports will be publicly available, greater scrutiny of provider behavior can be expected. It will be some time, however, before the effects of this novel requirement are understood.

**Penalties.** The law carries three new penalty provisions. The first allows FDA to suspend temporarily an approved premarket application in cases of serious adverse health consequences or death. The second authorizes FDA to order a manufacturer to recall a device and notify patients, hospitals, or physicians. Finally, for the first time, FDA is authorized to impose fines for violations of many device provisions of the act. These range up to $15,000 per occurrence, with a maximum of $1 million per proceeding. This authority has been urged for many years (although not by FDA), and its inclusion in the new law appears to have been facilitated by the generic drug scandal. Adding this civil penalty provision (with related subpoena authority) to device law is probably a precedent for extending similar FDA authority to other regulated products.

**Miscellaneous.** Several other provisions give FDA the opportunity to adjust device regulation to changing circumstances. First, FDA is given increased latitude to classify devices and to suit the degree of regulation to the risk posed by the device. (These changes mainly affect products in the intermediate risk category, the so-called standards class.) The agency is also required to address a small but resource-intensive group of products known as transitional devices, with the intent of reducing the burden these products have posed on agency operations.

For products that partake of the characteristics of devices and other products (for example, drugs and biologics), FDA is required to determine the primary mode of action and assign the product to the FDA office responsible for products that act in that way. Lastly, the agency is authorized to add requirements for design validation to existing good manufacturing practices.

One new provision is the device equivalent to orphan drug legislation. Called the “humanitarian device exemption,” it provides limited exemptions from the device law for devices intended to treat or diagnose rare diseases or conditions (affecting fewer than 4,000 persons). This provision lacks the product development incentives that have been enacted for orphan drugs. Finally, the new device law establishes an Office of International Relations within the Department of Health and Human Services (HHS), whose only specific authority is to enter into agreements with foreign countries to facilitate commerce in devices.

FDA is in the early stages of implementing the law. Unanswered questions abound. Definitions, priorities, and the locus of decision making are key issues to be resolved in the fullness of time—which, if the past is any guide, is likely to be full indeed.

**The legislative process.** The first congressional oversight hearing was in July 1982 before the House Commerce Subcommittee on Oversight and Investigations. A report followed in 1983, pointing to deficiencies in FDA’s implementation of the 1976 law.

Congressional discussions with FDA, industry, and other representatives began in August 1985. These discussions were led by staff of the House Commerce Subcommittee on Health and the Environment but with steady, active participation of full committee staff. They continued, with only the usual number of fits and starts, until final congressional action in October 1990.

The House passed a bill in July 1988, which arrived in the Senate during the hectic period that customarily precedes congressional adjournment in a presidential campaign year. The Senate committee had not reviewed device law implementation, so the Senate leadership had only two choices: approve the House bill without much consideration, or postpone action. Given the lack of preparation and the Senate’s views of its own prerogatives, it is not surprising that action did not occur before the 100th Congress adjourned in October 1988. The Senate committee resumed device law consideration in the 101st Congress, and, after it
became clear that the Senate was seriously moving forward, House activity resumed as well. Both bodies worked roughly in parallel (if a geometric term is apt to describe a legislative process) through final congressional passage in October 1990.

The roles of certain key players deserve comment. FDA was active in briefing congressional staff in the early stages of the process and from time to time thereafter. During the key period in the House, late 1987 and early 1988, the agency became convinced that legislation could not pass in that Congress nor for some time, so it effectively withdrew from any day-to-day involvement in the negotiation process. Even though it gave technical support and formal legislative testimony in the late drafting stages, FDA was simply not a full participant in consideration of this key legislation.

Also, no administration position on the final legislation was sent to Congress. Early on, the administration submitted bills narrowly focused on certain standard-writing and classification provisions. All in all, there was a remarkably low level of participation, given the significance of the statutory changes under consideration. The lack of administration interest undoubtedly had an effect on FDA's involvement.

The industry's position was ambivalent. At first, it had opposed the need for any legislation. As congressional activity continued, industry leaders gradually came to the conclusion that passage of a bill was inevitable. When the House passed its bill in July 1988, industry for the most part acquiesced unenthusiastically. A few industry representatives strongly opposed the bill, arguing that a better bill could be expected from the Senate.

With House action occurring late in a politically charged year with no Senate preparation, this industry division was not the sole reason for the failure of legislation before Congress adjourned in 1988, but it certainly did not smooth the process then or later and probably had a detrimental effect on the final bill. In the 101st Congress, industry predictions of propitious Senate action proved illusory. The enacted law includes several provisions adverse to industry interests that were not in the bill passed by the House in 1988.

Health care providers were notable by their absence; for them, regulatory legislation rarely ranks above the financial problems posed by Medicare proposals. The only exception was the modest involvement of hospital organizations in consideration of the new provider reporting requirements.

The Safe Medical Devices Act authorizes or requires significant additional agency action affecting medical devices. From the preliminary comments of FDA leaders, it is clear that this action cannot be carried out within existing capacities. The outlook for significant new resources is far from clear. In 1988, prior to passage of the House bill, a comparatively serious congressional effort was made to ascertain the resources needed for implementation. But FDA's estimates were not adopted, and no serious effort was made thereafter to come to grips with the discrepancies between FDA and Congressional Budget Office estimates.

As is typical with regulatory statutes, there was no provision for appropriations. Nor was there any attempt to estimate the size or distribution of the new cost burden that will be imposed on the health care system and its users.

In conclusion. The Safe Medical Devices Act has been placed on the books at a time when many factors are complicating FDA's life. A new FDA Commissioner, David A. Kessler, took office in early December 1990. There is new leadership as well in several top positions in the Center for Devices and Radiological Health. The international dimensions of regulatory decisions are changing, especially with respect to imports and an emerging regulatory system in the European Community. In addition to the device law, the 101st Congress passed an important food labeling program and some twelve other laws that affect FDA operations. An HHS Advisory Committee on FDA is expected to issue its report in May 1991. Technological innovation and demanding, often conflicting, public expectations continue unabated. The new device law, in sum, creates important new challenges for FDA at a difficult and complex juncture.