FDA Hit on Device Regulation

What do Band-Aids, contact lenses, cardiac pacemakers, and nuclear magnetic resonance machines have in common? They are all medical devices, according to federal law. Judging the safety and effectiveness of these four products and 41,500 other medical devices is the job of the Food and Drug Administration (FDA). But for a variety of reasons, says a government report released last week, federal regulation of medical devices is beset with major problems. As a result, little information is available to determine whether medical devices, which are becoming increasingly sophisticated, are safe and work as intended.

In 1976, after several reports of hazardous medical products were investigated by Congress, federal lawmakers passed legislation that significantly broadened FDA's authority to regulate medical devices. Since then, however, FDA "has not implemented major portions of the law," according to a report by the Office of Technology Assessment (OTA), "Federal Policies and the Medical Devices Industry." The comprehensive, 2-year study examined federal policies, including FDA regulations, that affect the thriving $17-billion medical devices industry in the United States. The report says that while there do not appear to be any obvious, major risks that are not being addressed by FDA, this situation may reflect either a true lack of significant risks or lack of knowledge about hazards that do exist.

The weaknesses in current regulation of medical devices stem from two factors, the study suggests. There are inherent problems with the 1976 legislation that limit FDA's ability to monitor these products. But the agency itself is to blame for many of the deficiencies as well.

The 1976 legislation sought to strengthen consumer protection while ensuring that the law would not overburden a young and growing industry. With this latter goal in mind, Congress passed a significant provision that exempted a large number of medical devices from immediate stringent regulation. The OTA report suggests that this exemption has greatly restricted FDA's authority to collect safety and effectiveness data on medical devices.

The legislation divided medical devices into two categories, those marketed before 1976 and those marketed after 1976. All products that pose potentially high risks, such as cardiac pacemakers, are required to pass strict standards. But according to the exemption, high-risk devices marketed after 1976 that are "substantially equivalent" to a pre-1976 device do not require FDA approval before they are marketed. In essence, companies are only required to submit safety and efficacy data when FDA classifies a device as posing a potentially high risk, and by that time, it may have been on the market for years. Congress reasoned that a double standard would exist if a new device, which was similar to an earlier version, must be approved by FDA before marketing. Legislators were also concerned that, without the exemption, a monopoly would be created for the company manufacturing a pre-1976 device.

While the reasoning may be legitimate, the OTA report explains, an overwhelming majority of devices have come on the market in the past 8 years under this exception. As a result, there is a paucity of data about the potential hazards of these devices and whether they work as intended. Between fiscal year 1977 and 1981, FDA received 17,000 notices of new medical devices of which only 300 were not deemed equivalent to earlier products.

FDA's method of classifying devices based on risk has also contributed to delays in the gathering of safety information. FDA set up a three-tiered classification system according to potential risk—high, medium, and low. Consumer groups and the medical device industry agree that the agency created a cumbersome system.

The OTA report points out that FDA still has not finished classifying many devices. The agency has not yet developed standards to evaluate products in the medium-risk category and they have, in effect, been regulated as if they are in the low-risk category, the report says. This is by far the largest category of medical devices and "as a practical matter, there is little possibility that [performance] standards can be formulated. . . ."

Even when FDA completes the classification task, manufacturers of pre-1976 products will still have additional time to submit safety and efficacy data to the agency, thanks to Congress. The 1976 legislation allows these manufacturers a grace period of at least 30 months—once their product is classified—to supply the information to FDA. Under the Reagan Administration, the agency also proposed to give further leeway to companies that manufactured potentially high-risk devices before 1976. FDA has suggested that these companies be allowed to apply for an experimental permit so that the device could continue to be used. The proposal would, in effect, let companies continue to sell their potentially high-risk devices even if they cannot provide the necessary information, the OTA report says. "The rationale for this use of the [permit] is weak," notes the report. "Manufacturers have had years to prepare" the necessary data for their devices.

Until recently, companies submitted data about hazards associated with their marketed products on a voluntary basis. Although Congress vested FDA with the authority to require these data, it has declined to do so. Late in the Carter term, FDA proposed rules for mandatory reporting, but the plan languished after the change in administration. Shortly before a House hearing was held last month to investigate the malfunction of anesthesia machines, however, Secretary of Health and Human Services Margaret Heckler announced that FDA would now require manufacturers to report hazards associated with their products.

The OTA report notes that the voluntary system was "not an adequate substitute" for mandatory reporting. Few companies voluntarily supplied FDA with data. Many of the reports of hazards of a particular product originated from a competing company, the study says. In some cases, the manufacturers report device problems "only after a product recall or other remedial action is completed."

The report says that Congress may need to revise the 1976 legislation to narrow the scope of FDA's task. It represents the second government study that has recently criticized the regulation of medical devices. The other report was issued in September 1983 by the General Accounting Office. Despite problems with existing law, says OTA staff analyst Lawrence Miike, some legislators are reluctant to propose any changes for fear that it would be vulnerable to radical change in the current antiregulatory environment.—**MARJORIE SUN**