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Commemorating the 40th Anniversary of the 1976 Medical Device Amendments

SUZANNE JUNOD*

2016 marked the 40th anniversary of the passage of the Medical Device Amendments, which charged the U.S. Food and Drug Administration (FDA) with implementing a unique law that required premarket approval for some kinds of medical devices, and offered alternatives for others. While providing better protection to patients and practitioners from under-tested medical devices, it was also specifically written to preserve and promote innovation in the nascent field of biomedical engineering. At the time the law was enacted, FDA's Bureau of Medical Devices and Diagnostic Products had a relative handful of employees. Today, the Center for Devices and Radiological Health (CDRH) has around 1700 employees. An inventory of medical devices on the market in the mid-1970s, prior to the passage of the device amendments, drew responses from 1000 firms who reported marketing 8000 devices. Today, there are some 18,716 medical device manufacturers (8,995 are U.S. based) and they market around 175,000 different devices. Moreover, 50% of imported product entries regulated by FDA are regulated in CDRH. The first device trade association, the Medical-Surgical Manufacturer's Association, was founded in 1903, three years before FDA's founding statute, the 1906 Pure Food and Drugs Act, was enacted. By 1973, there were still only 150 members, 66% of which were small businesses. Today, most medical device manufacturing companies are still small. 75% have fewer than 10 employees and only 3.7% have more than 100 employees. On this anniversary, it seems appropriate to look back at the history of the medical device amendments and the issues and historical circumstances surrounding its passage.

In 1966, FDA Commissioner James Goddard, speaking to the Association for the Advancement of Medical Instrumentation, spoke of the inspiration that Air Force Major Michael Collins had provided when he opened the hatch of Gemini 10, drifting some 250 miles above the earth. Collins had carried with him an array of medical instruments intended to withstand the rigors of space travel. "Medicine," Goddard observed, "is no longer practiced by prescription-pad alone. It hasn't been practiced that way for a long time."[1] The ensuing years were characterized by rapid advances in surgical implants, diagnostic tests, imaging technologies, and cardiac devices including pacemakers, replacement heart valves, and the current cardiac

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[1] James Goddard, FDA Commissioner, *Medicine is No Longer Practiced by Prescription Pad Alone*, speech to the Association for the Advancement of Medical Instrumentation, July 27, 1966. FDA History Office.

assist devices that serve as a "bridge to transplant." Every branch of medicine and surgery has been transformed by changes in medical technology that have worked to improve the diagnostic acumen of physicians and surgeons and provide new treatments and treatment options for patients of all ages.

Almost all medical changes, however, incur some risk and FDA has, over the past 110 years, assumed more and greater responsibility for anticipating, understanding, and mitigating risks posed by medical products and their testing. FDA began to create a new and separate organization to regulate medical devices even before the 1976 amendments were passed. Key to the law's success was the creation of a regulatory structure for devices that was different in some crucial ways from that established for new drugs in the 1962 New Drug Amendments.

In the wake of the world-wide crisis over the teratogenic drug thalidomide, the U.S. strengthened its oversight over the drug supply when Congress passed the 1962 New Drug Amendments mandating that drug manufacturers demonstrate to FDA that their new drugs were not only safe, but also effective, based not on anecdotal evidence, but rather on the results of controlled clinical trials. At the time that the drug amendments were being debated in Congress, a companion bill was under consideration that would have set up a system of premarket approval for new devices similar to that for new drugs. According to Peter Barton Hutt, FDA's Chief Counsel from 1971-1975, there was an "understanding" at the time that the decision was made to delete devices from the drugs legislation, that Congress would address the issue separately "within months." In reality, it took much longer to devise a regulatory structure to accommodate the rapidly growing field of medical devices.[2]

New drug approvals required "substantial" evidence of safety and effectiveness, but this evidence could only be obtained from "adequate and well-controlled" clinical trials. In the case of devices, however, standards required a "reasonable assurance" of safety and effectiveness, regulations required "valid scientific evidence" which included "well-controlled investigations" but the law itself provided a more flexible pathway to market for new devices that could demonstrate substantial equivalence to devices currently on the market. Although this 510 (k) provision set up a system that was intended to be temporary and protect pre-amendment devices, it has since become permanent and is often the principal path to market for many new devices.[3] The device amendments were also distinctive in relying on a comprehensive classification system that governed the level of regulatory oversight accorded to particular classes of devices based on the level of risk they pose to patients should they fail to perform as intended (Class I, Class II, and Class III). Realizing the critical role that expertise would play in the implementation and effectiveness of the 1976 amendments, the law uniquely mandated the use of outside advisory committees. The classification system combined with the 510 (k) marketing pathway gave the device authorization system under the 1976 Medical Device Amendments more flexibility than that accorded drugs under the 1962 New Drug Amendments.

The safety and worth of early devices claiming medical efficacy were originally evaluated under the auspices of the U.S. Post Office. In 1872, the Postmaster General

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[2] Peter Barton Hutt, *A History of Government Regulation of Adulteration and Misbranding of Medical Devices*, 44 FOOD DRUG COSM. L. J. 99 (1989).

[3] J. Kahan, *Premarket Approval Versus Premarket Notification: Different Routes to the Same Market*, 39 FOOD DRUG COSM. L. J. 510 (1984).

gained the authority to personally adjudicate the veracity and value of devices making medical claims. The Bureau of Chemistry in USDA, FDA's predecessor, assisted with the policing function and the Post Office simply returned devices it deemed worthless to the sender marked FRAUDULENT. In spite of evidence of abuses in the field, the first federal food and drug statute, the Pure Food and Drugs Act of 1906, did not address the issue of fraudulent devices. By 1917, this had become problematic in a marketplace inundated with products promising weight loss, pessaries, prostate "warming" devices, lead nipple shields and other fraudulent and dangerous devices. When the Roosevelt Administration began to draft a replacement law for the original 1906 statute, an early draft simply defined devices as drugs. One Senator found this to be imprecise and insisted on separate definitions for each. In the 1938 Food, Drug, and Cosmetic Act, a device was defined as

> Any instrument, apparatus or contrivance, including its components, parts, and accessories intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals, or to affect the structure or any function of the body of man or other animals.

Resources available to police medical devices under the 1938 Act, however, were always in short supply despite the recommendations of multiple advisory committees, several official reports, and the annual consumer addresses from President's Kennedy, Johnson, and Nixon. Meanwhile, the number of device firms was growing, device labeling requirements were new, and, following WWII, a glut of surplus military electronic parts dumped onto the civilian market inspired a post-war generation of "gadgeteers" whose marketing savvy seemed nearly limitless. Congress heard testimony on many of these devices, including a galvanometer in an impressive box that, when tested, had elicited a reading on a test corpse. The cost of prosecuting fraudulent devices could be exorbitant, requiring in some cases as many as 20-30 witnesses to testify in a single trial.[4] By 1969, the need for separate legislation governing medical devices had been underscored by an appellate decision in 1967 and by a U.S. Supreme Court ruling in 1969. Together, they upheld FDA's new administrative approach designed to regulate some borderline new devices more stringently by reclassifying them as new drugs.[5] For example, an appeals court upheld the re-classification of a new surgical ligation device as a new drug because it deemed it a form of suture and sutures were listed in the U.S. Drug Pharmacopeia.[6] Likewise, FDA's determination that a laboratory screening test, an antibiotic sensitivity test used to determine the particular antibiotic most appropriate for an individual patient, should be regulated as a drug was upheld by the U.S. Supreme Court which ruled it was an extension in support of the agency's overall purpose and mission: protecting the public's health. [7]

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[4] The recent television series "Mad Men" featured an episode on one of the most resource intensive devices of the 1960s: the "Relaxicisor." The device made extravagant claims but was little more than a passive exercise machine. The courts, however, ruled against the manufacturer, upholding FDA's concerns that it could pose a hazard to pregnant women, in particular. Subsequently, FDA issued an FBI style "warning poster" cautioning against its use.

[5] Vincent A. Kleinfeld, "Surgical Implants: Drugs or Devices, and New Device Legislation," 23 FOOD DRUG COSM. L. J. 510 (1968).

[6] AMP v. Gardner, 39 F2d 825 (2d Cir. 1968), *cert. denied*, 393 U.S. 825 (1968).

[7] United States v. An Article of Drug . . Bacto-Unidisk, 394 U.S. 784 (1969).

In 1969, President Nixon delivered his annual consumer message which focused, not on device quackery, but rather on the need for stronger premarket regulation to meet specific concerns about therapeutic devices such as contact lenses, hearing aids, and implantable devices such as artificial [heart] valves. Nixon's call for a thorough, year-long study of the "scope and nature" of future device legislation was set into motion by the appointment of Dr. Ted Cooper, then head of the Heart, Blood, and Lung Institute at the NIH, later the Assistant Secretary of the Department of Health, Education, and Welfare (HEW), to chair the committee. By all accounts, Ted Cooper was extraordinarily well respected, described by others as a remarkable scientific leader who "called a spade a spade."

The Study Group on Medical Devices met in Ted Cooper's Office at NIH once a week to interview inventors, device users, public officials, and others whose opinion they valued. In 1995, former FDA Chief Counsel, William Goodrich recalled that "the hearings were all very informal, and we didn't take any stenographic notes." As a result, the Cooper Committee report is quite short, less than a dozen typed pages in all.[8] Central to the report, however, was the results of a survey of 10,000 injury reports attributed to faulty medical devices. 731 deaths were associated with devices such as pacemakers and IUDS, but 512 deaths were attributed to faulty heart valves alone. The committee recommended a more flexible premarket authorization system for devices than those governing new drugs. Device classifications were basic to tailoring regulation to the type of device being regulated. The establishment of standards, including both safety and performance standards, rather than a reliance on full premarket approval and clearance processes (510(k)), was and remained industry's preferred regulatory approach. FDA, however, could specify the category it wished to apply to particular devices, and had to be notified of many devices, including the higher risk devices, prior to marketing. Establishments had to be registered, and good manufacturing practices regulations were authorized.

Following the Cooper Committee Report, and aided by new computer technology, FDA immediately began a survey to identify all currently marketed medical devices. One thousand manufacturers submitted data on 8,000 devices. FDA created an Office of Medical Devices in the Office of the Commissioner and FDA began to work on initial classifications of these 8,000 devices into the risk categories of Class I (general controls); Class 2 (performance standards); and Class 3 (premarket approval), which included all implantable devices. The classification process also relied on the work of fourteen classification panels of experts. When legislation seemed to stall, FDA Commissioner Charles Edwards elevated the small Office of Medical Devices into a Bureau of Medical Devices and Diagnostic Products with four divisions: Compliance; Classification; Device Standards; and Diagnostic Products Standards (in vitro diagnostics) making it clear FDA was moving forward in anticipation of the law's eventual passage.

Legislative efforts also moved ahead. Negotiations with individual constituents as well as with the newly organized Health Industry Manufacturer's Association, the Department of Commerce, and the Department of Defense yielded compromises and a growing consensus on the substance and structure of a new law. In spite of the distractions of myriad Congressional hearings, primarily on drugs, Watergate, the

[8] Study Group on Medical Devices, "Medical Devices: A Legislative Plan," Sept. 1970. Also, Theodore H. Cooper, "Device Legislation" FOOD DRUG COSM. L. J. 26 165 (1971).

Sunshine Act and Freedom of Information issues, a final draft of the law was in place by January of 1975.

The final nudge to enactment came as Congress considered the classification of intrauterine devices (IUDs). Thromboembolic problems associated with the early high-dose oral contraceptives had enhanced the appeal of IUDs as a birth control option. There were many types on the market, however. FDA reviewers and other agency officials testified at joint hearings before the Senate's Subcommittee on Health on January 28, 1975 about the dangers of one in particular—the Dalkon Shield. It quickly became evident, however, that FDA struggled to distinguish its regulation of IUDs that contained biologically active components such as copper and progesterone as a drug, while IUDs that were biologically inert, such as the Dalkon Shield, were regulated under the more limited system of device controls under the 1938 Act. It had become obvious that a bifurcated system of regulation for a single category of product such as IUDs was nonsensical, unworkable, and did not adequately protect the public. The disastrous consequences for many women using the Dalkon Shield became increasingly clear. At its peak in the early 1970s, about 2.8 million women had them in place, and it was estimated that they faced a five-fold higher risk for pelvic infections as other IUD users. Over 200,000 American women sought compensation for significant injuries, and the litigation and settlement costs bankrupted the company.

The 1976 Medical Device Amendments were sponsored by Congressman Paul Rogers (D-FL) and Senator Edward Kennedy (D-MA) and signed into law by Gerald Ford on May 28, 1976. The 1976 White House signing ceremony was modest, especially considering the significance of the legislation, but last minute funding concerns delayed the process and the principals themselves reported that they were given only an hour to arrive at the Oval Office for the signing ceremony. In the end, the official photo shows an unidentified White House intern standing next to President Ford while Ted Cooper, FDA's Commissioner Alexander Schmidt, and HEW Secretary David Matthews gathered around the desk.

In the intervening 40 years since the Medical Device Amendments were enacted, the entire landscape of medical devices has changed and would be virtually unrecognizable to scientists, physicians, and regulators from that era. In vitro diagnostics, for example, have moved far beyond the simple blood tests and antibiotic sensitivity tests that helped define the field initially, into complex tests that are used to diagnose serious and terminal illness with the potential to more greatly affect patients' health and medical-decision making. Many tests for cancer and other diseases have become so sensitive and complex that understanding them and interpreting the results to patients presents a growing challenge. Robotics, both in surgery and as an element of health care diagnosis and delivery is a growing field as are rapidly evolving and innovative uses of 3-D printing. Sophisticated medical software and machine-based learning programs now come under FDA scrutiny. Miniaturization has transformed the diagnosis and treatment of many medical conditions, while nanotechnology as both tool and treatment is also edging closer into the medical mainstream. Throughout all the changes in the biotech landscape, however, and although Congress has modified the federal Food, Drug, and Cosmetic Act several times over the past four decades, the basic innovative structure of the Medical Device Amendments has remained intact and, overall, has been judged to have served the country well.

Photo of the signing of the 1976 Medical Devices Amendment, May 28, 1976. Center: Gerald Ford. L to R: HEW Secretary David Matthews, unidentified White House intern, Dr. Ted Cooper, NIH, and Alexander Schmidt, FDA Commissioner. Source: Gerald Ford Library and FDA History Office.