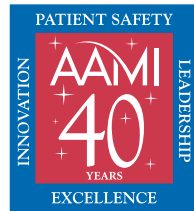




AAMI's Role in Medical Device Regulation



We doctors knew that regulation was inevitable. We wanted to get in there and help write the regulation to ensure that it was sensible, that it did not hamstring physicians, and that it spoke to the issue of safety. We didn't want politicians or bureaucrats writing it.

W. Gerald Rainer, MD, a heart surgeon and AAMI founder



1960s Bring Mounting Pressure for Device Regulation

In the 1960s, the specter of government regulation of medical devices was looming over the medical community. While FDA had been actively regulating drugs since 1906, it rarely exercised its power in the field of medical devices.

By the late 1960s, though, the agency was seeking authority to regulate medical devices the way it did drugs. Concern about device safety was prompting Congressional leaders to introduce bills on device regulation, and both President Johnson and President Nixon called for device regulation in messages to Congress.

Key Milestones in Device Legislation

- 1906 • Federal drug legislation first enacted.
- 1931 • The Food, Drug, and Insecticide Administration, which was formed in 1927, is renamed the Food and Drug Administration.
- 1938 • The Food, Drug and Cosmetic Act introduces the concept of premarket clearance of drugs for safety and extends coverage to devices, making it illegal to sell therapeutic devices that are dangerous or marketed with false claims.
- 1962 • The Kefauver-Harris Amendment first requires proof of drug efficacy.
- 1967 • President Lyndon B. Johnson includes a call for medical device legislation in his message to Congress.
- 1968/1969 • In two legal cases, the AMP case and the DIFCO case, the courts establish a basis for treating conventional medical devices as drugs, opening the door to subjecting many devices to drug preclearance.
- 1969 • President Richard M. Nixon delivers a special message to Congress on consumer protection calling for regulation of medical devices.

President Nixon's 1969 Call for Device Regulation

"Another important medical safety problem concerns medical devices—equipment ranging from contact lenses and hearing aids to artificial valves which are implanted in the body. Certain minimum standards should be established for such devices; the government should be given additional authority to require premarketing clearance in certain cases. The scope and nature of any legislation in this area must be carefully considered, and the Department of Health, Education, and Welfare is undertaking a thorough study of medical device regulation. I will receive the results of that study early in 1970."

—Richard M. Nixon in his October 30, 1969, Special Message to Congress on Consumer Protection

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1969

AAMI holds "A National Conference on Medical Devices," supported through funding from the National Institutes of Health. This conference led to the release of the Cooper Report, which outlined a practical context and framework for legislation that was ultimately approved in the 1976 medical device law.



AAMI should not become involved in the impending controversy associated with federal legislation, but instead assert its policy of being a fact-finding, impartial, expert, objective, but active organization.

AAMI Policy on Government Legislation, 1967

To put the subject in perspective, it has been pointed out that toilet valves must undergo several preclearances before they can be used. Yet a pacemaker inserted in the body to regulate the heart need not be tested or examined at all.

Virginia Knauer, special assistant to President Nixon for consumer affairs, opening the meeting with remarks that highlighted the government's concerns over device safety



Device photos from early issues of Medical Instrumentation.

Two Legal Cases in the Late 1960s Threatened Drug-Like Regulation for Devices

AMP Case. The company brought suit against FDA in 1967 when the agency sought to classify its device—a nylon locking disc used to tie off or ligate severed blood vessels during surgery—as a drug. AMP lost its case and the Supreme Court declined to hear its appeal.

DIFCO Case. Also known as the Bacto-Unidisk case, it concerned a cardboard disc impregnated with antibiotics for use as a laboratory testing device. The government condemned the product from interstate commerce in 1968, contending it was a drug and therefore misbranded. The Supreme Court did agree to hear an appeal in this case, concluding that FDA does have the power to regulate that product as a drug.

1972

First AAMI/FDA conference on medical device regulation held.

1974

AAMI board member David Link appointed head of FDA's Bureau of Medical Devices and Diagnostic Products.

AAMI Organizes 1969 National Conference on Medical Device Regulation

AAMI, under Dwight Harken’s leadership, organized a conference in Bethesda, MD, in 1969 to address device safety concerns of the medical community and the government. The National Institutes of Health (NIH) offered start-up funding for the conference, giving AAMI a grant of \$20,000. Harken authored a letter to the AAMI membership and industry outlining the importance of the event and raised an additional \$100,000.

Manufacturers saw AAMI and its physician members as a means of helping to secure constructive legislation and were eager to sign on to support the conference. Doctors, heavily dependent on devices and afraid that their promise could be throttled by government regulation, were also eager to participate.

Leaders from all sectors were pulled into the conference—people from the highest levels of government, industry, and medicine. The 1969 conference had an impact on device regulation like no other meeting before or since. The report from AAMI’s conference was published simultaneously in many major engineering, medical, industrial, nursing, and other journals and trade publications. The report included task force recommendations on device regulation that outlined the framework of the legislation that was ultimately adopted in 1976.



A detailed report of discussions at AAMI’s 1969 Bethesda conference was published in the Nov/Dec 1969 issue of AAMI’s journal, Medical Instrumentation, and simultaneously in every major medical journal of the time, along with engineering, industrial, nursing, and other journals and trade publications.

This conference was a huge event. It was the first time that the presidents of every American Medical Association-recognized society were present in one room.

John Abele, AAMI founder and Board member



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1976

Medical Device Amendments to the Food, Drug & Cosmetic Act of 1938 are enacted to ensure safety and effectiveness of medical devices.

1978

FDA good manufacturing practices (GMP) regulations become effective.

This collection of photos was taken at the 1974 AAMI/FDA Conference on Medical Devices. AAMI sponsored such meetings frequently to provide a forum to discuss issues related to the emerging legislation and continues to hold them today as The AAMI/FDA International Conference on Medical Device Standards and Regulation.



Mort Levin, Hewlett-Packard Co.



Michael J. Miller, JD, AAMI



Robert J. Cangelosi, FDA



Herbert H. Ley, MD, Consultant



*Charles A. Hufnagel, MD,
Georgetown University Hospital*



*Dwight E. Harken, MD,
Harvard Medical School*

Great care must be exercised on the part of all concerned to ensure that we do not deprive the patient of the benefit of scientific advancement either by strangling initiative in development or by crippling the mechanisms for widespread utilization of effective methods and mechanisms.

Dwight Harken, MD, in a letter to Congress sharing the results of AAMI's 1969 National Conference on Medical Devices

1984

Medical Device Reporting regulation published requiring manufacturers to report device-related incidents to FDA.

1990

Safe Medical Devices Act requires user facilities to report device incidents to FDA.

AAMI Leadership Works to Ensure Effective Legislation

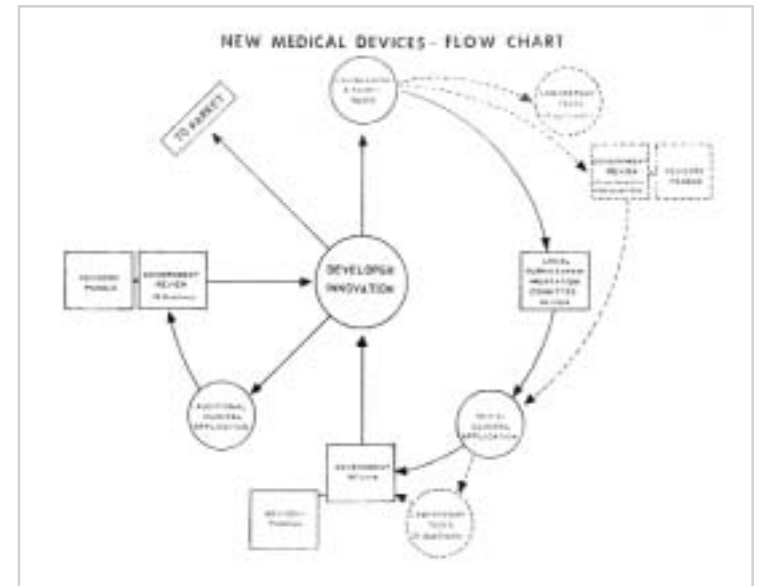
Following the 1969 conference, the Department of Health, Education, and Welfare organized the Study Group on Medical Devices chaired by Theodore Cooper, MD, director of the National Heart and Lung Institute. The group's report—known as the Cooper Committee Report—built on the AAMI report and fed directly into subsequent device-related bills introduced into Congress.

Arthur Beall, Dwight Harken, John Collins, W. Gerald Rainer, and other AAMI leaders worked tirelessly to ensure that the evolving legislation would protect patient safety without hampering innovation of medical devices. They literally wrote sections of the legislation. They worked closely with FDA executives like David Link, who would eventually become Director of FDA's Bureau of Medical Devices and Diagnostic Products and Larry Pilot, another FDA executive who wrote many of the regulations that would put the legislation into practice.

As the legislation worked its way through the halls of Congress, FDA was already beginning its implementation efforts. AAMI members were actively involved in those efforts as well.

A year-long effort was launched to inventory the medical device industry, and AAMI helped the agency gather information. In the early 1970s, a series of meetings was held to classify devices according to risk. AAMI president John Collins chaired the committee evaluating cardiovascular devices and AAMI board member Harlan Amstutz chaired the committee on orthopedic devices. AAMI also held a series of conferences to bring the diverse medical device community together to consider regulatory issues.

On May 28, 1976, Gerald R. Ford signed the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act into law and a new era in device regulation was born.



The Cooper Committee Report, published in September 1970, built on the ideas formulated during AAMI's 1969 Conference on Medical Device Regulation. This flow chart from the Cooper Report depicts the route that new devices would take to reach the marketplace.

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1991

AAMI holds series of highly successful seminars on Safe Medical Devices Act of 1990 in partnership with ECRI.

1997

FDA Modernization Act signed into law; new quality systems (QS) regulation takes effect. AAMI launches successful course series based on the new QS regulation.

**1976 Medical Device Amendments:
Key Requirements**

- Medical devices must be classified according to their comparative risk, and regulated accordingly.
- Three classes of medical devices were created, each requiring a different level of regulatory scrutiny, up to premarket approval.
- Good Manufacturing Practice regulations also were authorized—a set of procedures to ensure that devices are manufactured to be safe and effective through quality design, manufacture, labeling, testing, storage, and distribution.

Theodore Cooper, MD, for whom the Cooper Committee was named, delivers a keynote address at AAMI's 1973 Annual Meeting. Pictured listening from left are AAMI leaders W. Gerald Rainer, Mike Miller, and Arthur Beall.



It took until 1976 to pass the law because of the complexity of the process, the size of the effort, and the interruption of Watergate. The finished legislation was more extensive than any other product-type legislation passed before or since. Ultimately, the final legislation was essentially the same as that outlined at the AAMI conference and detailed in the Cooper Committee Report.

Larry Pilot, attorney and FDA executive in the 1970s



This 1972 photo shows AAMI leaders participating in an Annual Meeting session on proposed regulation of medical devices. Pictured from left are Larry Pilot, then of FDA; John J. Collins, MD, of Peter Bent Brigham Hospital; Arthur C. Beall, Jr., MD, of Baylor College of Medicine; and [standing] Earl Bakken of Medtronic.

THE WASHINGTON POST Saturday, May 29, 1976

Ford Signs Medical Device Bill

Associated Press

President Ford yesterday signed the first federal legislation to protect consumers against faulty or deceptive medical devices.

The law permits the Food and Drug Administration to set safety standards for thousands of medical devices, ranging from tongue depressors to artificial hearts.

Previously, the FDA "has had inadequate authority" to regulate the enormous advances that have been made in the use and manufacture of medical devices, Mr. Ford said.

The law affects about 1,300 manufacturers of 12,000 kinds of medical devices already on the market. It also gives the FDA regulatory muscle over any new products introduced.

A federal task force estimated that in 1970 medical devices caused an estimated 10,000 injuries, including 741 deaths during the previous decade.

The report attributed 512 deaths and 300 injuries to heart valves, 89 deaths and 186 injuries to cardiac pacemakers, and 10 deaths and 8,000 injuries to intrauterine devices.

Injuries and deaths from medical devices have mounted since then, authorities said.

Mr. Ford said the Medical Device Amendment of 1976 "does not represent another expansion of government into affairs we might better manage ourselves."

"Instead, this is an example of government doing for the individual what he or she cannot do unaided," he said.



By capitalizing on its unique membership mix—an alliance of physicians, manufacturers, engineers, and others with an interest in medical devices—AAMI was able to bring different factions together to advance the field. Through the years, AAMI would play this role again and again, laying the foundation for its success on future government programs.

Mike Miller, AAMI chief executive since 1969

A New Era in Government Regulation

With the passage of legislation, a new era in regulation of devices began. FDA had to determine how to implement the new regulation, and educate industry about its requirements. In a ten-day, ten-city blitz, Larry Pilot and two colleagues introduced the new requirements to industry and geared up for implementation.

Regulations implementing the legislation were completed over the next few years, including the Good Manufacturing Practices (GMP) regulation published in 1978. Throughout this period, AAMI maintained its neutrality, playing a nonpartisan role as the facilitator of discussions, holding frequent conferences and educational sessions and not advocating for any one position except for patient safety.

The rising importance of voluntary standards in device regulation, both in the United States and abroad, led to the explosive growth and international expansion of AAMI's standards program in the 1980s and 1990s.

In 1990, when the Safe Medical Devices Act required user facilities to begin reporting adverse events to FDA, AAMI commented extensively on the regulation and, after its passage, sponsored a series of seminars to educate the user community about the new requirements. Similarly, AAMI held a series of seminars on reuse of single-use devices when the user community was affected in the late 1990s by new FDA requirements.

The 1990s would also bring a new role for AAMI in the realm of government regulation. When FDA issued in 1996 a new GMP regulation, which laid out strict requirements for medical device manufacturers, the agency turned to AAMI to help with its implementation. In this groundbreaking effort, AAMI and others created a process where FDA and industry learned together what meeting the new regulation would require. AAMI's government education program grew out of this effort and is now a mainstay of the association.

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Larry Pilot

Larry Pilot joined the Food and Drug Administration in 1969. He was responsible for the development of many aspects of FDA's regulatory program for medical devices prior to and after the passage of the Medical Device Amendments of 1976. He was responsible for the development of the agency's Good Manufacturing Practice regulations in 1978. When he left FDA in 1979 to go into private practice as an attorney, he was Associate Director of Compliance, Bureau of Medical Devices. Today he is a partner with McKenna, Long & Aldridge based in Washington, DC. A longtime AAMI member, he has frequently spoken at AAMI events and written about government affairs for AAMI publications. His law firm has provided counsel to AAMI for many years.



David Link

David Link came to FDA in the early 1970s from positions in engineering and marketing with Hewlett-Packard. He managed FDA's first regulatory program for medical devices, and was appointed head of FDA's Bureau of Medical Devices and Diagnostic Products in 1974, where he served until 1980. After leaving FDA he went on to manage the regulatory affairs, quality assurance, sales, and manufacturing functions at several medical device companies and served as an industry consultant. As a member of AAMI's Board of Directors for many years, he played an active role in AAMI's standards program and chaired AAMI's government relations committee. Link is now executive vice president of Boston Healthcare Associates.



AAMI Comments on SMDA User Reporting Requirements

The Food and Drug Administration's (FDA) user reporting regulations were published on 26 November 1991 as a tentative final rule, and the comment period ended 26 February 1992. The regulations implement the requirements of the Safe Medical Devices Act of 1990 (SMDA). These regulations represent the first FDA regulatory activity directly affecting over-the-counter facilities.

AAMI's corporate and institutional membership reviewed the comments outlined below. The comments were also reviewed by the 1100 registrants of the eight SMDA seminars AAMI held in 1991, in cooperation with the FDA, national nursing organizations, and other health care organizations.

AAMI and its MEMBERS SUPPORT THE INTENT of the regulations. Some AAMI members believe that the regulations will enhance patient care by improving internal reporting and management of medical device incidents.

AAMI urges that the regulations be developed to comply strictly with the intent of Congress until it has been clearly established that more extensive regulations are required. If the regulations are carefully developed, the FDA can obtain the information it desires and Congress intended and avoid a significant number of unnecessary reports. Unfortunately, the regulations as currently drafted are likely to produce a significant number of reports, many of which will be unnecessary, burdensome, and costly.

The regulations should foster cooperation between manufacturers and the health care community if they are to accomplish the intent of Congress and if they are not to impose major resource burdens on manufacturers, health care facilities, and the Agency. The regulations as currently drafted could potentially create a conflict between manufacturers and hospitals that would not only thwart the intent of the regulations but also result in a major diversion of resources from the health care community. These costs would be in addition to the health care cost pressures being brought to bear on the domestic economy and competitive pressures affecting the ability of the industry to compete in the international marketplace.

AAMI proposes that a conference be held to provide FDA a

