

Guest Editor

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Federal Regulation of Medical Devices

Did you realize that your pump oxygenator is a drug? So is your monitoring equipment and your defibrillator, as well as all of the prosthetic heart valves and pacemakers that you use. These statements are based upon no lessor authority than the Supreme Court of the United States. Since the Food and Drug Administration (FDA) is responsible for the regulation of drugs, where do we stand in regard to FDA regulation of what most of us consider to be medical devices?

Federal drug regulation first was enacted in 1906. In response to numerous injuries caused by certain sulfonamides, the concept of premarket clearance of drugs for safety was incorporated into the Food, Drug and Cosmetic Act of 1938. Medical devices also were included under the authority of this Act, but regulation of devices was limited largely to requirements that they be properly labeled and free of adulteration. The Kefauver-Harris Amendments of 1962, influenced in part by the thalidomide tragedies, first introduced the concept of drug efficacy, but they did not mention medical devices.

In the middle 1960's various proposals were introduced into the Congress for the Federal regulation of medical devices. These proposals were basically drug law into which medical devices were substituted, and Congressional hearings were never held. Two major court decisions then clouded the regulatory waters in regard to medical devices. In the first (*AMP Inc. v. Gardener*, 389 F2d 825 [1968] **cert. denied**, 393 U. S. 825 [1968]) the court of appeals held that a disposable applicator holding a suture and a locking disc, used to ligate vessels, was a drug. This decision was based largely on the fact that sutures were classified as drugs under the 1938 Act. In the second and more important case (*United States v. Bacto Unidisk*, 394 U. S. 784 [1968], the Supreme Court held that an antibiotic sensitivity disc was a drug within the intent of the 1938 Act and that the Act, “. . . read in the light of its remedial purpose, directs us to read the classification ‘drug’ broadly, and to confine the device exemption as nearly as is possible to the types of items Congress suggested in debates, such as electric belts, quack diagnostic scales and bathroom weight scales, shoulder braces, air conditioning units, and crutches.”

Therefore, according to this Supreme Court decision, your pump oxygenator is a drug and subject to Federal regulation by the FDA. The only reason that this has not occurred is that it would be a logistical impossibility for the FDA to regulate medical devices on a case by case basis in the courts and would prefer to do it on the basis of improved legislative authority. In an effort to determine the best method of

improved legislative authority for medical devices, the Association for the Advancement of Medical Instrumentation (AAMI) held a conference for this purpose in 1969, funded by a grant from the National Heart Institute and attended by approximately 130 physicians, biomedical engineers, representatives of industry, and representatives of government.

This AAMI Conference recommended new legislation, defining medical devices different from the legal definition of drugs and providing for a regulatory mechanism for devices different from that used for drugs. Also recommended were provisions for good manufacturing practices, registration of manufactures and of devices, factory inspection, and reporting of device defects. Additionally, the Conference recommended the creation of a study group to determine the most effective use of standards and premarket clearance as regulatory tools.

Based in part upon these recommendations, the Secretary of the Department of Health, Education and Welfare composed a study group under the chairmanship of the Director of the National Heart and Lung Institute, Dr. Theodore Cooper, now Assistant Secretary for Health of the Department of Health, Education and Welfare. The Cooper Committee, after an extensive and intensive period of study, released its report in September of 1970. This report recommended a regulatory scheme based on the classification of medical devices into those requiring only general controls, those requiring standards, and those requiring premarket clearance. Significantly, the report strongly recommended the use of experts from outside of the FDA and the regulation of initial clinical investigation of devices at the local level under peer group control.

Following the Cooper Committee report, numerous bills were introduced into the Congress, but no significant legislative activity occurred until the 93rd Congress (1973-1974). During the 93rd Congress, hearings were held in both the Senate and the House of Representatives regarding an Administration sponsored bill, as well as bills (almost identical) sponsored by the chairmen of the appropriate Senate and House Subcommittees, Senator Kennedy and Representative Rogers. Subsequently, a bill was passed by the Senate, but the 93rd Congress adjourned before a bill was reported out of the House Subcommittee on Public Health and Environment.

In the 94th Congress (1975-76) a bill identical to that passed in the 93rd Congress was introduced in the Senate. This was reported out of the Subcommittee on Health without hearings and passed by the Senate with a floor amendment requiring premarket clearance for all implants. An entirely new bill, eliminating most of the objections expressed regarding bills considered by the 93rd Congress, was introduced in the House, and extensive hearings were held in July 1975. As of this writing (November 1975) the House Subcommittee is still in the process of "marking-up" the bill, so it is difficult to predict exactly what type of bill will be passed by the House. However, certain aspects of the Senate passed bill (S.510) that will be extremely detrimental to the delivery of health care and that are not now included in the bill under consideration by the House (H.R. 5545) can be enumerated.

First, while both the Senate and the House bills create outside panels of experts to advise the FDA regarding the classification of medical devices into the three basic regulatory categories, language of the Senate bill is so explicit that it legislatively pre-empts the scientific judgements of these panels. Second, in contrast to the Cooper Committee recommendation that control of initial clinical investigations be at the local level by peer groups, the Senate bill requires affirmative FDA approval before the first clinical use of any investigative device. Third, the Senate bill's con-

cern for “conflict of interest” essentially requires that all decisions regarding standards must be made by those who know absolutely nothing about the subject. The three major standards organizations in the country, AAMI, the American National Standards Institute (ANSI), and the American Society for Testing and Materials (ASTM) are effectively eliminated from the standards writing process, due to the fact that some of their members come from industry. Finally, language of the Senate bill regarding defects and replacement requirements is such that a medical device could become retroactively defective years after it was sold, entirely due to improvements in the state of the art in biomedical engineering, at which time the manufacturer would be responsible for **all** costs of replacement. The effect of this latter requirement would be such that many medical devices, especially all implants, no longer would be sold at any costs.

The next step in the legislative process after the House passes a bill will be a Senate-House Conference. This Conference Committee will be charged with developing a compromise bill which then goes back to both Senate and House for passage. One can only hope that the House bill that goes to Conference Committee will be a workable bill and that the House Conferees prevail in the Committee. Otherwise, availability of medical devices will be severely limited, improved medical devices will not appear, and our ability to provide health care will take a giant step backwards.