The Medical Device Amendments of 1976 which became law on May 28 will impose severe regulations on all persons involved in manufacture and use of medical devices, including biomedical engineers engaged in research and development. These major amendments to the Food, Drug, and Cosmetic Act delegate authority for insuring safety and effectiveness in medical devices and diagnostic products to the Food and Drug Administration. A serious disadvantage of the Amendments relates to the fact that the regulatory controls are patterned on the Food and Drug Act without the differing natures of drugs and devices being adequately considered; for example, modification of devices is not addressed. The Amendments define a medical device as an instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, including any component part or accessory, which does not achieve its principal purpose by metabolic or chemical action within the body.

Within one year, panels of experts must classify all medical devices into three categories: Class I, General Controls; Class II, Performance Standards; and Class III, Premarket Approval. A device will be assigned to Class I if General Controls can provide a reasonable assurance of safety and effectiveness. General Controls include regulations concerning misbranding, adulteration, registration and listing, repair, replacement or refund, records and reports, good manufacturing practices, etc.

If general controls would be insufficient to assure safety and effectiveness the device will be assigned to Class II, Performance Standards; under the assumption that standards can be established and would be sufficient to assure safety and effectiveness. Class III, Premarket Approval, will be assigned when there is insufficient information for Class I or II classification. Critical devices, intended for use in supporting or sustaining human life or of substantial importance in preventing impairment of human health, will be initially assigned to Class III. Each classification will impose rules and effectiveness requirements and there are criminal penalties for noncompliance. As implementation regulations and procedures are proposed, they will be published in the Federal Register.

In the August 20 Federal Register, the FDA outlined its plan for regulating investigational studies of any device intended for human use, including in-vitro diagnostic products. These regulations are not limited to investigations undertaken to develop clinical data for future commercial products but also apply to fundamental research on devices, and to the use of devices in experimental studies. Devices may be exempted from certain requirements, to permit investigational studies by experts, but a device will not be exempted unless the sponsor requests a specific exemption.

While the law may read satisfactorily, the potential for abuse by the FDA could result in forcing small manufacturers out of production, and larger firms to relocate their research and development outside the United States. In addition, investigational studies by biomedical engineers, involving innovative research, will be severely impeded if these regulations are adopted as proposed. It is necessary for the professional biomedical engineering community to remain alert and carefully scrutinize proposals for new regulations as they appear in the Federal Register, and respond with comments. Comments on the August 20 Investigational Device Exempt Regulations were requested before October 19, 1976, which did not provide much lead time for response.

If manufacturers, health care providers, and biomedical engineers can be effective in their comments, ultimate benefits of the law will be removal of unsafe and ineffective devices, improved design and manufacturing standards; and increased information on the use, maintenance, and safety of medical devices. Employment demands for BME's should also increase.

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