

Letter to the Editor

Much has been said and written about the Medical Device Amendments of 1976. Some of this information has been accurate, some has not. Accurate assessments of the legislation describe a variety of control mechanisms and procedures for insuring that medical devices are safe and effective. Inaccuracies are found concerning requirements which have not materialized and may well never materialize, as well as the effects on the availability of new products.

The device amendments to the Food, Drug and Cosmetic Act clearly recognize the importance and value of useful new products and emphasize the need to encourage the development of such new products as well as ensure that they reach the marketplace in a timely and proper fashion. The professional users of medical devices are concerned (as they should be) as to the effects on them and the new product development process. Whereas it will be several years before an accurate assessment of the Medical Device Amendments of 1976 can be made, one can hope that the effects on the users of medical devices will be the continued availability of a wide variety of safe and effective products, as well as a degree of confidence that medical devices will operate as claimed in a consistent and reliable fashion. In addition, one hopes that time will not see the demise of the small innovative company and that low volume, but much needed products, will not disappear from the marketplace because of excessive development costs.

The users of Extra-Corporeal products should take a keen interest in the development of new regulations and procedures and have their comments and considerations properly heard as such requirements evolve. Such participation can only improve the regulatory process and result in more practical and appropriate procedures being developed. Such procedures will help in achieving the common goal of all, better health care.

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