



# Surgical technology:

## A perspective from the FDA

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In his Presidential Address that was published in the December 2002 issue of the *Bulletin*, ACS President Richard R. Sabo, MD, FACS, described the dilemma faced by surgeons who want to provide the latest technology for their patients and yet find the “transition from old to new ideas” difficult for a number of reasons, including issues of education and training.\* He further points out that the College, through its Committee on Emerging Surgical Technology and Education (CESTE), is helping surgeons by analyzing the implications of new surgical technology and providing guidelines on how to incorporate these technologies into practice.

We at the Food and Drug Administration (FDA) share the College’s concern that new technologies be incorporated safely and effectively into clinical practice. One concern, of course, is that new surgical devices be safe and effective before they are marketed. Under the law, the FDA is charged with assuring that this is the case. Although the FDA does not itself test or examine new devices, we review and evaluate the data submitted by manufacturers who wish to market a new device, working with them to develop preclinical and clinical study protocols that support their applications.

The level of data required depends on what is already known about the technology and the level of risk associated with using it. For well-known medical devices that evolve into newer models with only minor changes, bench testing may be all that is necessary. For cutting-edge technologies, we expect that the manufacturer-sponsored clinical trials include controlled studies with multiple investigators at several institutions.

Our goal is to be sure that the manufacturer’s medical claims for the device are supported by good clinical evidence. We must consider such factors as the proposed indications for use and the intended patient population, as well as the learning curve that new users undergo—that is, we assess the degree to which a new device is usable by a practicing surgeon. While performing this premarket review function, we work to ensure a level playing field among competing manufacturers, and in the process accumulate an extensive database on the results of medical device testing.

But even the most stringent program of premarket testing cannot eliminate the possibility of unforeseen adverse events. Some of these are so rare that they would not be detected during clinical investigations. Others may occur when the device is used by a wider variety of clinicians than in the study, on a broader patient population, or in different settings. This means that our job does

\*Sabo, RR: The challenge of emerging surgical technology: The College can help. *Bull Am Coll Surg*, 87(12):8-14, 2002.

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not end when we clear or approve a new medical product for clinical use. In fact, we have a nationwide post-market surveillance program through which we monitor adverse events, analyze their causes, and take action to remedy the situation. This may include sending safety alerts to clinicians, requiring manufacturers to make labeling changes, and, if necessary, requiring the recall of the device.

It is obvious that we in the FDA share with the College and its members the same ultimate goal—the successful introduction of safe and effective medical devices into clinical practice. We both want to see the seamless transfer of medical technology from the laboratory to the patient's bedside. We can best accomplish this by working in partnership.


How can the practicing surgeon help in this process and at the same time contribute to improving public health? First and foremost, he or she can report adverse events to us. We cannot effectively monitor the safety of devices already in use without good information from practicing surgeons. Reporting can be done easily through our Web site at [www.fda.gov/cdrh/mdr.html](http://www.fda.gov/cdrh/mdr.html).

Second, those surgeons who are involved in designing and conducting clinical trials of new devices should recognize that they have a special public health responsibility to provide complete and reliable clinical data. Without good data, we cannot make evidence-based decisions about the quality of newly marketed products.

Third, surgeons should consider applying their knowledge and expertise in our new product review process by serving as consultants or members on our various advisory panels. These panels consist of experts in various clinical specialties who help the FDA evaluate the results of preclinical and clinical trials sponsored by a device manufacturer, and make recommendations to the agency on whether the product should be approved.

Finally, some College members may want to consider going a step further and working for us on either a part-time or a full-time basis. Those individuals who might be interested in either panel membership or possible employment can explore the subject further at [www.fda.gov/cdrh/ode](http://www.fda.gov/cdrh/ode), or contact us directly at 301/594-2022.

We appreciate the proactive role that CESTE has taken in the American College of Surgeons and look forward to working with the committee in

helping ensure that medical devices are safe and effective. We hope this editorial has motivated practicing surgeons to play an active role in this partnership. 

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**Editors note:** The College's Division of Advocacy and Health Policy maintains a list of Fellows with device expertise and interest in serving as FDA advisory panel consultants and members. Those individuals who would like to be included should contact Adrienne Roberts in the College's Washington Office, at 202/337-2701, or via e-mail at [aroberts@facs.org](mailto:aroberts@facs.org).

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