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EDITORIAL

Benefit-risk paradigm for clinical trial design of obesity devices: FDA proposal

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Obesity is a serious contemporary epidemic, both in the United States and worldwide. Metabolic surgery is an important and expanding field, with investigation and innovation efforts among surgeons, physicians, and industry. In contrast to diets and weight loss drugs, many trials have shown that surgery and weight loss devices offer the obese patient the opportunity for significant, durable weight loss.

However, despite the importance of the clinical problem and the energy of those engaged, Lerner and colleagues point out in this issue of *Surgical Endoscopy* that only three devices for the treatment of obesity have been approved by the Food and Drug Administration (FDA) since 1985. In response to this situation, the FDA has proposed a unique potential modified pathway for obesity devices. Lerner and colleagues report the FDA's current initiative to create a new paradigm for obesity device submission and evaluation by the agency. The process used by the FDA to develop this proposal and the proposal itself represent important movement that hopefully will allow additional "safe and effective" devices to reach patients who can benefit from their use.

All medical and surgical therapies involve weighing the benefit of a therapy against the risk of that same therapy. Whether devices are engineered to create weight loss by calorie restriction, malabsorption, appetite suppression, or other means, those aiming for relatively low amounts of weight loss (i.e., level 1 devices) would not be judged on the same risk/benefit ratio as those aiming for substantial weight loss in this proposal. Their risk profile should more closely mimic medical therapy.

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In contrast, devices aiming for significant excess weight loss (similar to currently approved devices such as the Realize gastric band, the Lap-Band, or level 3 devices) carry a higher potential benefit and therefore would be permitted a greater degree of risk. Patients appear willing to assume that risk. An FDA survey demonstrated that obese patients would be willing to tolerate a fivefold risk of death to increase weight loss from 5 to 20 %.

Implementation of this new structure is a good thing not only for device manufacturers, physicians, and patients. The FDA also will benefit because ability to stratify these devices by complication will make decisions on clinical trial design easier. Additionally, new initiatives aimed at streamlining the FDA review process may encourage device manufacturers to submit more devices for review due to less uncertainty about the requirements for approval.

Finally, an increase in the number of devices brought to the market will help give patients and providers more treatment options. That potential for more and better therapies is the *raison-d'etre* for a device approval structure in the first place, namely, better care to help the greatest number of patients. If implemented and successful, the proposed paradigm could well be replicated for other devices and fields of endeavor.

In the accompanying report, the authors encourage open feedback to the agency on a number of specific questions. This represents a unique opportunity for experts in this field, many of whom are contributors and readers of *Surgical Endoscopy*, to speak into this process. We sincerely hope that this open request will bear fruit in both quality and quantity of response, both on these pages and directly to the agency.

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