In this issue of the Journal, Natale et al. (1) present their findings in 91 patients with previous sudden cardiac death or ventricular tachycardia refractory to antiarrhythmic medications. The patients were assigned to two groups on the basis of device availability. The experimental group of 36 patients received a hybrid combination system consisting of the Ventritex Cadence pulse generator (selected for its biphasic waveform) and the Cardiac Pacemakers Inc. (CPI) Endotak nonthoracotomy lead system. Although the Cadence pulse generator and the Endotak lead system have been approved individually by the Food and Drug Administration (FDA), the performance of the two in combination has not been evaluated by the agency.

The FDA commends the authors for their acknowledgment that the Cadence/Endotak combination is not FDA approved. The FDA has been concerned about the use of hybrid combinations of implantable cardioverter-defibrillators and leads. For example, off-label use of the Endotak lead system with implantable cardioverter-defibrillators in unapproved combinations has been reported to result in the failure to redetect ventricular fibrillation if the initial shock is unsuccessful in terminating the arrhythmia (2). Although the FDA is not aware of such reports for the Cadence and Endotak combination, a clinical trial using this combination would be incomplete without an evaluation of this possibility.

If the combination of a biphasic waveform and a nonthoracotomy lead system is truly beneficial, the public health would obviously be best served by early availability of such combinations. However, widespread adoption of such combinations is inappropriate without adequate data being available to guide practitioners and patients. Such data should be submitted to and reviewed by the FDA. The FDA is the principal agency charged by Congress to evaluate such data as part of its role in the oversight of medical devices marketing and promotion.

To make product evaluations meaningful, it is best if researchers share their insight and expertise and combine institutional experience in a joint study. Single-center studies are usually too small to allow adequate device evaluation. Multicenter studies or a meta-analysis of many similar small studies, if combined, may provide enough information for the FDA to more quickly decide about a device's safety and effectiveness.

Viewed in this light, Natale et al. might have provided a greater service to the medical community if they had worked with the manufacturers under their Investigational Device Exemption (IDE) in evaluating this combination. Alternatively, the authors could have applied for an independent IDE to study this combination. Their data could then have been evaluated by the FDA in conjunction with data submitted by the industry. This would most likely increase the speed of the accumulation of the clinical data necessary to support the FDA's evaluation and proper labeling of the Ventritex Cadence and CPI Endotak lead system combination.

References