



# Interventional Rhythm Management, Inc.

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January 4, 2006

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
Division of Dockets Management (HFA-305)  
5630 Fishers Lane Rm. 1061  
Rockville, MN 20852

I would like to provide my comments to the "Functional Indications for Implantable Cardioverter Defibrillators" document published on October 6, 2005. The creation of such a document to streamline FDA approvals is an impressive initiative. As you know, the penetration of approved ICD indications is one of the lowest in all of cardiology. With the AHA statistics reporting >450,000 Americans dying of sudden cardiac death each year, the importance of new technologies that could improve access to ICD therapy is critically important.

The terminology in the guidelines, I would suggest, should be written broadly enough to encourage new, innovative technologies to be brought to the market to address this large health care issue. Specifically, I would encourage you to focus the guidelines on "defibrillation therapy", which is the definitive therapy that saves lives in this patient population. The addition of "new features" like antitachycardia pacing have increased the patient/physician convenience and sometimes comfort, but have not significantly changed the overall efficacy of the therapy from the early devices with defibrillation only. I would advocate that when the references are made to the functional indication, it reads as stated in the last paragraph on page 3 of the document: "*While different model ICDs may offer different features and functions, the life-saving attributes of most ICD models are based on similar concepts of sensing, detecting, classifying, and treating ventricular arrhythmias using pacing therapy (antitachycardia pacing) and/or high energy shocks (defibrillation).*" There are other references in the document that read differently (page 4), suggesting the need to have both antitachycardia pacing and defibrillation. I'm assuming this is an oversight or typographical mistake since it is inconsistent with the correct wording on page 3.

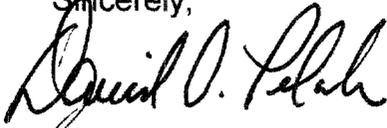
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I support the position on page 3 that keeps the guideline broader to enable new more cost effective technologies that can streamline the implant procedure and expand access to more patients.

I appreciate your consideration of my comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Daniel A. Pelak". The signature is fluid and cursive, with the first name being the most prominent.

Daniel A. Pelak  
President and CEO  
Interventional Rhythm Management, Inc.