Guidance for Industry and FDA Staff

Writing *Dear Doctor* Letters for Recalls of Implantable Cardioverter Defibrillators (ICDs)

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Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852.

When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/ocer/guidance/1645.html. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number (**1645**) to identify the guidance you are requesting.

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

This guidance provides best practices for manufacturers when drafting and issuing *Dear Doctor* letters to disseminate information about significant health hazards to users of implantable cardioverter defibrillators (ICDs). This guidance may also be used by FDA in reviewing manufacturers' *Dear Doctor* letters prior to their issuance. This guidance includes recommendations for technical content, formatting, and use of risk communication principles. These letters may also be titled *Dear Health Care Professional* when they are disseminated beyond the direct physician community.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less

burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman/.

Background

ICDs provide survival protection to patients at risk of sudden cardiac arrest. These devices significantly reduce the increased risk of sudden cardiac death due to sustained ventricular tachycardia or fibrillation, a leading cause of death in the U.S. However, like any medical device, ICDs can fail to operate as intended. These failures can be related to the design, manufacturing, and/or labeling of the device.

When these failures involve ICDs in distribution, a recall (correction or removal) should be initiated by the manufacturer with oversight by FDA. Manufacturers involved in a recall should notify all consignees, including physicians, of the reason for recall and the suggested actions to be taken to correct or minimize the risk to patients (21 CFR 7.49). Ideally, a well-written *Dear Doctor* letter will be the first line of communication to physicians in the event of a recall, accurately and rapidly conveying information in a way that helps physicians to make appropriate health care decisions with their patients.

The wording, formatting, and content of *Dear Doctor* letters are recognized as critical factors in helping physicians to comprehend and appropriately address potential ICD failures with patients in their practice. When *Dear Doctor* letters are poorly written, they may contribute to unnecessary device removal or replacement. Furthermore, *Dear Doctor* letters that are reissued with corrections or revisions may cause additional confusion.

The communication of ICD failures requires a specialized approach because of several unique characteristics. First, ICDs are life-saving devices. Patients rely on these devices to provide life-saving shocks in the event of an arrhythmia, and some rely on them for round-the-clock cardiac pacing. Therefore, certain types of ICD failures can directly result in patient death. Second, while recalls often require the return of products to the firm, ICDs are long-term implants with risks associated with explantation. These risks may be higher than the risk of continued use of the device. Therefore, specific information is needed so that physicians and patients can carefully consider whether or not the device should be removed and replaced in any individual patient. Finally, ICDs are programmable, so that some types of problems can be fixed non-invasively through reprogramming. The goal of communication in the event of an ICD recall is to help physicians, other health care professionals, and patients make the appropriate decision for each patient about explanting the device, reprogramming it, or taking a “watch and wait” approach.

Scope

This guidance provides FDA's recommendations for maximizing the effectiveness of *Dear Doctor* letters through completeness, clarity, and readability, and for enhancing utility in providing doctors with recommendations related specifically to implantable cardioverter defibrillators.

This guidance should be used by industry when information related to ICD failures and corrections or removals are being communicated to physicians. The recommendations in this guidance may also be useful in communicating risk when no recall action is being taken but new information is available about ICDs. These situations include communication about certain product updates, technical notes about product performance, recommended implantation techniques, or important labeling changes. These types of communications should also follow these recommendations for consistency and to minimize the need for subsequent revisions.

The recommendations contained in this guidance draw from FDA's own research, risk communication principles, and other efforts to standardize the information in *Dear Doctor* letters, including recommendations issued by the Heart Rhythm Society, Health Canada, and the United Kingdom's Medicines and Healthcare Products Regulatory Agency. They represent content elements demonstrated to be effective in conveying the most critical information sought by physicians in the event of a potential ICD failure. This guidance is limited to implantable defibrillators; however, some of the concepts may be appropriately applied to other implanted devices including pacemakers, and external defibrillators.

Research

FDA has conducted several qualitative research studies to better understand the content, format, and sources that health care professionals find effective for conveying risk information on medical devices and which convey the need for appropriate action. These studies identified "best practices" for communicating with health care professionals about device failures as summarized below:

a. **Present safety information in a consistent order.** Letters should lead with the name of the device and a plain-language description of the problem, including a clear description of deaths and serious adverse events. Recommended actions should be prominent and clearly identified.
b. **Format letters about safety concerns for easy readability.** Use large font sizes, bold type to highlight critical information, high contrast, subheadings, bullets or a table format, and short, specific paragraphs.
c. **Notify health care professionals about safety issues through multiple channels.** Use email, fax, express mail, and the Web.

d. **Make information about device failures available to health care professionals before patients hear about it in the media**. This helps them to be better equipped to address patients' concerns and mitigate undue alarm.
e. **Focus communications on the problem with the device and recommended actions for physicians.** Health care professionals perceive letters from manufacturers as less credible when they appear to focus on minimizing company liability rather than on safety concerns.
f. **Avoid promotional statements about the company.** Health professionals want safety communications that are limited to information about patient care.

Recommendations

Dear Doctor letters should be issued in a timely manner so that physicians have the proper information to respond to patient inquiries generated by other public warnings, including recall letters, media reports, and trade publications. *Dear Doctor* letters should be concise (less than two pages, when possible). The letters should be formatted for easy readability, using large font sizes, bold type to highlight critical information, high contrast, subheadings, bullets or a table format, and short, specific paragraphs. FDA recommends that companies avoid lengthy background information at the beginning of *Dear Doctor* letters. Rather, they should provide only succinct descriptions of the problems and refer physicians to attachments containing full or more complex discussions, if necessary. Immediately following the brief description of the problem, letters should contain a bulleted list or table addressing each of the following areas of concern to physicians in order as they appear below:

- **What is the nature of the device malfunction or failure?**
  This should include, whenever available:
  - A detailed description of the failure mode and its root cause.
  - An explanation of how the failure would manifest clinically.
  - A description of the features of the ICD that are compromised by the device failure. It is important to convey whether life-saving or life-sustaining therapies are affected, versus secondary therapies or diagnostics.

- **What is the scope or likelihood of the problem?**
  This should include, whenever available:
  - The number of active implants in the U.S.
  - The number of devices that are already known to have exhibited the failure.
  - The number of remaining devices that could be subject to the failure.
  - Specific patient populations at higher risk for device failure.

- **What is the severity of the problem?**
  This should include, whenever available:
  - The number of deaths that have already occurred due to the device failure.
  - The number of deaths that have occurred that are associated with the device failure, even if a direct causal link has not been established.

- The number and type of injuries that have occurred that are associated with the device failure, even if a direct causal link has not been established.

- **Can the failure mode be observed or predicted in clinical follow-up?**
  This should include, whenever available:
  - An interrogation step or clinical test that can be used to identify devices that have already exhibited the failure mode.
  - An interrogation step or clinical test that can be used to identify devices that have the potential to fail.
  - A self-test that can be used by patients to determine whether their device has already exhibited the failure mode.

- **Can the failure mode be corrected *in situ* by reprogramming or upgrading the software?**
  This should include, whenever available:
  - A recommended follow-up schedule for patients whose devices are subject to the recall. For example, should patients wait for their next scheduled visit to have the correction performed, or should they be directed to come in sooner?
  - A clear explanation of whether the reprogramming step or software upgrade addresses the root cause of the problem, or whether it is an interim fix.
  - A description of the adequacy of any interim fix in minimizing risks to the patient.

- **What is the recommended treatment for patients?**
  This should include:
  - A reminder that most devices will not fail (if that is supported by the facts).
  - The percentage or number of devices that are expected (or not expected) to fail.
  - A reminder that the term "recall" does not necessitate device removal.
  - A reminder of the risks associated with device explantation and replacement.
  - A recommended follow-up schedule for patients whose devices are subject to the recall.
  - A recommendation to consider explantation if:
    - the failure mode is catastrophic (affecting life-saving or life-sustaining therapies),
    - the failure mode cannot be predicted by clinical tests or interrogation,
    - the failure mode cannot be fixed through reprogramming or other minimally-invasive procedures, and
    - the individual patient is dependent on the device.
  - A recommendation to reprogram the device if the failure mode has a root cause that can be corrected through reprogramming.
  - A recommendation to watch-and-wait if explantation or reprogramming is not warranted, for example, if the risks of explant outweigh the likelihood of failure.
  - Any actions physicians may take to minimize risks to their patients.

- **What advice can physicians give to patients with affected devices?**
  This should include:
  - Company-recommended actions patients and health care providers can take to identify affected devices and/or recognize indications of device failure (i.e., audible sounds, physical reactions, etc.).
  - A reminder that patients should keep routine follow-up appointments with their physicians.
  - A list of symptoms that would warrant going immediately to the emergency room.
  - Company contact information for consumers/patients (e.g., toll-free telephone number, email address, Web address).

- **What should be done with explanted devices?**
  This should include:
  - Instructions for returning any explanted devices to the manufacturer for analysis.

- **Where can health care professionals get additional information and updates?**
  This should include:
  - Phone number and email address for company point-of-contact.
  - Company Web address. *Dear Doctor* letters should be posted and easy to find on the company Web site, along with updated information as it becomes available.

In addition to these recommendations, the authors and editors of *Dear Doctor* letters for ICD recalls should also follow 21 CFR 7.49 Recall Communications and FDA's Guidance for Industry on Product Recalls, Including Removals and Corrections (11/3/03).

Other Resources

For more information, see:

1. 21 CFR 7.49 Recall Communications
2. Recommendations from the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines (http://www.hrsonline.org/uploadDocs/HRSTaskForceRecsFull.pdf).
3. Guidance for Industry on Product Recalls, Including Removals and Corrections (11/3/03) (http://www.fda.gov/ora/compliance_ref/recalls/ggp_recall.htm).