"PHYSICIANS' AND ALLIED HEALTH PROFESSIONALS' PERCEPTIONS ABOUT COMMUNICATING IMPLANTABLE CARDIAC DEFIBRILLATOR (ICD) AND PACEMAKER RISKS TO PATIENTS" FOCUS GROUP RESEARCH

Topline Report

U.S. Food and Drug Administration

Submitted by:

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Executive summary

The Food and Drug Administration contracted with Olchak Market Research to conduct four focus groups with the attendees at the 2006 Heart Rhythm Annual Meeting in Boston. Specifically, these focus groups were conducted with physicians and allied health professionals who implant, counsel, or monitor patients with ICDs and pacemakers. Two focus groups consisted of physicians and the other two consisted of allied health professionals.

The main purpose of these focus groups was to explore the information needs of physicians and allied health professionals in communicating implantable cardiac defibrillator and pacemaker risks to their patients.

These focus groups showed that for the physicians and allied health professionals, Class I recall of an implantable device typically implies serious possible consequences to their patients' health, and potentially removing this device and returning it to the manufacturer. However, the participants said that a recall does not always lead to the removal of the device. Many of the physicians believed that the device should not necessarily be removed if the risks of removing it are greater than the risks of leaving it in. The decision to remove a device can also depend on the degree of a patient's dependency on that device.

The participants' patients react to the term "recall" with fear with regard to their health and life. Typically, their first reaction, when they learn that their device was recalled, is that they want it to be removed.

Even though the physicians and allied health professionals are typically informed about a device recall by the manufacturer, either through an express mailing or through a visit from the manufacturer's sales representative, they complained that they often receive a manufacturer's information on a recall after it appears in the popular media.

Ideally, the health professionals would like to hear about a product recall before it is released in the media, so they have the information before their patients have it. Releasing information about a device recall in the media before physicians have that information might decrease patients' confidence in their health care providers and fuel patients' fear generated by the sensational/exaggerated tone of some media reports that present a simplified or misleading picture of the situation.

Health care providers see manufacturers as a potentially biased source of information about the recall issues relating to implantable devices; however, the providers would rather receive recall information from manufacturers than from other sources such as media.

Even though health care providers prefer to receive information from manufacturers, some participants believed that the FDA should regulate the process of manufacturers' communication with health professionals and patients about device recall. A few participants believed that the FDA should determine specific components of such a message and at what point it should become known.

The FDA is perceived as an organization that should verify, analyze, store and endorse information on recalled devices. However, many participants stated that the data itself should come from the manufacturer as the party that has the best knowledge about their device.

The FDA was perceived by the participants as a non-biased and objective source of information; however, many did not know how to obtain information effectively and quickly about device recalls from the FDA.

Those who sought information regarding recalled devices on the FDA's Web site said that the Web site offers too many resources and that it is hard to find specific and relevant information.

In the process of giving risk/benefit information about devices to patients, many participants said that printed information explaining existing and potential problems is indispensable. Such information should address patients' concerns and be written in a language that can be understood by non-professionals. A few participants mentioned that it is challenging for them to find simple and understandable language that they can use with their patients depending on their age, literacy level, etc.

The participants said that most of their patients want to know the following:

- The possible implications to their health when a device is being recalled
- The likelihood that they will experience problems
- Lay explanation of the technical information relating to a device defect
- Explanation of the seriousness of risks
- The interpretation of statistics and a translation of the statistics into plain language of small/moderate risk vs. large risk

The participants said that they would like to receive information on devices specific to their field of medical practice/expertise from the FDA. They need more information about the potential risks and benefits of devices to communicate to their patients before implanting a device.

The participants said that they would like to have information allowing them to fully explain and supplement what patients learn about recalls from the popular media.

The participants said that their preferred way to get information about the risks of recalled pacemakers and ICDs that they could give their patients would be e-mail, express mail or fax. The participants said that a letter, e-mail or fax that is clearly marked that it comes from the FDA would get their attention. They said that marking mail "urgent" and using a red font would not attract their attention as a lot of "junk" mail is marked that way.

Many participants admitted that they are not sure how the process of reporting adverse events of devices to the FDA works. The participants suggested that if they were getting communication from the FDA by e-mail, it would be convenient to them to report an adverse event by replying to the FDA's message. Others would like a form located on the FDA's Web site which, after it is completed is automatically sent to the FDA.

I. Project Background and Objective

In recent years, a number of implantable cardiac defibrillators (ICDs) and pacemakers have been recalled. Recalls of implanted devices prove to be a challenging risk communication issue. The Food Drug Administration (FDA) would like physicians and their patients to have the most timely, most complete, and most balanced risk information about ICDs and pacemakers, without unduly alarming the patients who depend on them. The FDA also does not wish to discourage the use of these life-saving devices.

The FDA contracted with Olchak Market Research (OMR) to conduct focus group research to explore the information needs of physicians and allied health professionals in communicating implantable cardiac defibrillator and pacemaker risks to their patients. The FDA will use the information from these focus groups in the design of appropriate risk communication information.

This report summarizes the main findings from the four focus groups conducted at the 2006 Heart Rhythm Conference in Boston, MA.

II. Methodology

A. Introduction

To meet the focus groups' objective outlined above, OMR conducted a series of four focus groups with physicians and allied health professionals who implant, counsel, or monitor patients with ICDs and pacemakers.

B. Recruitment

Participants were recruited from the attendees of the 2006 annual meeting of the Heart Rhythm Society. The Heart Rhythm Society sent a recruitment e-mail to all people registered to attend the conference, and the FDA continued recruitment at the conference with flyers and posters. The recruitment materials are included as Appendix A.

The main qualifying criterion for participation in these focus groups was that each participant was either a physician or an allied health professional who worked with patients with ICDs or pacemakers. The groups were stratified by participants' medical specialization; two focus groups included physicians and the other two allied health professionals.

The participants did not receive any monetary compensation for participation in a group discussion; however, the participants in all the groups were served refreshments.

C. Confidentiality Procedures

To eliminate the risk of a potential confidentiality breach of focus group participants, the following steps were taken:

- At the beginning of each focus group, the participants were informed about the confidential nature of their participation in this focus group project. The moderator informed the participants that none of their answers would be attributed to a particular person.
- The participants were asked to respect one another's confidentiality and to use only their first names during the group discussion. We did not use participants' last names when referring to them over the course of the focus group.
- The audiotapes from the focus groups were sent to Word Wizards Inc., a transcription company. Word Wizards was instructed not to transcribe any last names that participants might have used during the focus group discussions.

D. Audience Segmentation

The focus groups were segmented on the basis of the participants' medical specializations — two focus groups consisted of physicians and the other two consisted of allied health professionals (mostly nurses). All participants in these focus groups were attendees at the 2006 Heart Rhythm Annual Meeting in Boston. The participants came from varied geographical locations in the United States and Canada.

The segmentation of focus groups, and the dates/times of their occurrence are shown in the table below.

Focus Group Segmentation and Schedule

	Date & Time	Location	Medical Specialization
Group I	May 18, 2006 7:00 AM	Boston, MA	Allied Health Professionals
Group II	May 18, 2006 12:15 PM		Physicians
Group III	May 19, 2006 7:00 AM		Physicians
Group IV	May 19, 2006 12:15 PM		Allied Health Professionals

E. Moderator's Guide

The FDA staff developed the moderator's guide for this project. Ewa Carlton, the moderator provided by Macro International Inc., OMR's subcontractor, reviewed this guide to ensure it would provide the FDA with a clear understanding of the information needs of the physicians and allied health professionals regarding ICD and pacemaker risks to their patients.

The moderator's guide consisted of six sections. Section I introduced the moderator, provided ground rules and explained the purpose of the discussion; Section II focused on the content of and satisfaction with pacemaker/ICD risk information on recalled devices; Section III covered information gaps in communicating risk/benefit information to patients; Section IV discussed

participants' preferences regarding vehicles of disseminating information on product recalls; Section V focused on reporting and sharing information about medical device recall; and Section VI concluded a focus group discussion by asking the participants for any additional comments and thanking them for their time.

Because of the one-hour time limitation of the duration of each focus group, some sections of the moderator's guide were not fully covered.

The moderator's guide is attached as Appendix B.

F. Conduct of the Groups

All four focus groups were conducted at the 2006 Heart Rhythm Annual Meeting hosted at the Boston Convention Center. Two of the groups consisted of doctors, and the remaining two consisted of allied health professionals who work with patients with implantable cardiac defibrillators or pacemakers. Each group included different numbers of participants, specifically:

- Group I at 7:00 a.m. on May 18th with allied health professionals included twelve participants, two of whom joined after the group discussion started (in all, one male and eleven females)
- Group II at 12:15 p.m. on May 18th with physicians included four participants (three males and one female)
- Group III at 7:00 a.m. on May 19th with physicians included five participants (all males)
- Group IV at 12:15 p.m. on May 19th with allied health professionals included four participants (all females).

All four focus groups took place at a room located at the Boston Convention Center that provided ample space for participants, observers and the moderator. The focus groups were moderated by Ewa Carlton.

Aramark, the Boston Convention Center's food service provider, catered the focus group sessions, as arranged by the group interview supervisor. Breakfast was served to the participants in the two focus groups at 7:00 a.m., and lunch to the participants in the two focus groups at 12:15 p.m.

At the beginning of each group, the moderator obtained a verbal informed consent of participants and began each focus group by advising the participants that they were being recorded. Participants also were advised to use only their first names.

The duration of each focus group was approximately one hour. The moderator facilitating the groups followed the moderator's guide throughout each discussion, and tried to make sure that each group discussed all topics in the guide. Two FDA staff members observed each focus group. All four focus groups were completed as scheduled with no irregularities.

G. Audio Recordings and Transcripts

OMR arranged for audio recordings of each session with AVW, the provider of electronic and recording equipment for the Boston Convention Center. Upon completion of the focus groups, OMR staff duplicated each of the resulting audio recordings. A copy of each recording was sent to Word Wizards, a transcription company that produced electronic versions of the transcripts.

Before forwarding electronic copies of the transcripts to the FDA project officer, OMR staff redacted each transcript to remove all references to participants' identity beyond their first names.

H. Report writing

The data recorded in the transcripts were used as a basis for this topline report. The textual data in the transcripts was reviewed and coded, and the major themes/findings were identified.

III. Findings

A. Content of and Satisfaction with Pacemaker/ICD Risk Information of Recalled Devices

1. Physicians' and allied health professionals' understanding of the term "recall"

Many participants said that the term recall brings to mind "bad news", "fear and confusion of patients", "sense of urgency" and the presumption that a "device needs to be taken out and sent back".

> "Bad news. You know that you have patients that you're taking care of that have devices that may potentially cause them harm." Allied health professional

> "I think that the term recall is a very negative connotation." Allied health professional

> "When they say recall, basically it means you have to take care of it relatively urgently." Physician

> "They [patients] see recall like, you know, with a car that you have to take it back to the dealer and get that thing changed right away. And that's not the way." Physician

Both physicians and allied health professionals, when asked "what does the term recall mean to you when you hear a pacemaker or ICD had been recalled?" immediately started talking about how their patients understand and react to this term. The participants' understanding of the term "recall" seemed to be strongly influenced by the understanding of this term by their patients.

> "Well, if you're asking me how I care about calling it 'recall' or not, I don't care. It's how the patient perceives it that's the most important thing. The bottom line is that there is some deviation from the normal function of the device. And it needs to be taken care of depending on the patient concern." Physician

> "I think just the term 'recall', patients get very anxious" Allied health professional

> "I still believe that […] they should take away the word 'recall.' Because most of the patients, when they hear 'recall' they want to find out from some physician what's going on. And if you happen to be not on call, your partner or maybe a general cardiologist, says I have no clue what you're talking about. The patient is getting nervous what's going on." Physician

Some of the participants said that the term "recall" is not appropriate because it implies that the device needs to be removed. They said that it is not always the case that the recalled device should be removed and sent back to the manufacturer. In their opinion, the risks associated with the removal/replacement of the device should be looked into within the context of the risks of keeping the device.

> "I have this big issue about using that word 'recall' so… I mean 'recall' to me means that you have a baby stroller that could collapse and injure the infant and so you need to take that back to the manufacturer or send it back or you know whatever. And so it kind of implies that whatever the device or the thing is, it [means] take it out and send it back." Physician

> "It's a bad term because it's like anything that gets recalled, you feel like it doesn't matter if it's going to affect you or if it's something that you should have taken out or whatever. It's automatic I say take them out because it's been recalled and, therefore, I don't want it." Allied health professional

The participants said that "recall" implies greater seriousness than "advisory".

> "Implies a greater seriousness than something compared to an advisory for example, where you're trying to inform the physician and the public that there's a potential issue with the device that may or may not impact severely upon the performance of the device for the (unint.) patient. The recall denotes a greater seriousness… a greater chance for a life-threatening or adverse effect." Physician

Another physician said that he used the term "advisory" instead of "recall" with his patients because of patients' negative connotations with this term.

> "I use 'advisory' simply because it avoids the connotations of the word 'recall' that many people (unint.) apply to that term." Physician

The participants said that recall does not always equate with explanting the device and returning it to the manufacturer. Many participants, especially physicians, were familiar with categorizing recalls into Class I, Class II and Class III and they understood that a Class I recall is the most serious type of recall.

2. Patients' reaction to a recall

The participants said that their patients react to the recall of a device that they have implanted with fear and uncertainty, wondering "is it my device?" The participants said that typically, when patients hear about a recall their first reaction is that they want their device removed.

> "Whenever you talk to patients and you have a recall… their responses is to take it out, I want something better." Physician

3. Sources of information on recalls and their usefulness

The participants said that they typically get an express mail letter (Dear Doctor Letter) from the manufacturer with information on a device recall. Most physicians said that they also get a visit from a manufacturer's sales representative. The physicians said that usually, especially in recent times, they receive manufacturers' information on a recall simultaneously or after it appears in the media.

The participants said that during the past year, they often first heard about a recall of a pacemaker or ICD from the press, TV or even from a patient who heard about a recall in the popular media.

The participants said that different sources of information—mass media, sales representatives, a letter from the manufacturer, professional publications, professional organizations and the FDA—provide varying levels of information. Many said that when a device is recalled they first expect to get information from manufacturers. Some also seek information from the FDA and from professional organizations and professional publications. However, some participants were not aware that the FDA provides information on device recalls.

> "I would usually go to the… the manufacturer's Web site first of all and then to the FDA. HRS Web sites, publications are all good sources of information, but it tends to take awhile before it appears in those places." Physician

The participants said that ideally they would like to hear about a product recall before it is released in the popular media, so they have the information before their patients have it.

Press

The participants were ambivalent about information on device recalls that appears in the popular media. While they appreciated that dissemination of information on recalls through the media is very fast, they had a lot of reservations about its content.

The participants said that typically their patients find out about recalls from the popular press or TV. Oftentimes, patients learn about device recalls simultaneously, or even earlier than health professionals. According to the participants, this causes problems such as a decrease of patients' confidence in their health care providers and an increase in patients' fear fueled by the sensational or exaggerated tone of some popular media reports that create a simplified or one-sided picture of the situation.

> "I think the press uses it [a recall notice] to sell to the pubic. And it's manufactured, it's sensational." Allied health professional

The participants said that ideally, patients should learn about device recalls from their health care providers because they can offer individual/case-specific medical advice. Some also added that health care professionals are able to calm and support their patients by answering their specific questions.

Manufacturers' sales representatives

Physicians who said that they were visited by the manufacturers' sales representatives when a device was recalled seemed to be satisfied with the quality and timeliness of information they received. While physicians appreciated that sales reps, as representatives of manufacturers, are able to offer the most accurate technical information on the recall issue, some were concerned

that the presentation of the information by the sales representative might be biased to minimize the risks posed by the recalled device.

> "I think the reps are good sources of information, but obviously they're trying to put it in the best possible light and I'm not saying that they purposely try to deceive people, they don't, but they're really good about telling you quickly if there is an issue. But then I think you sometimes have to go other places to determine the severity of the issue, the appropriate action." Physician

"Dear Doctor" letters from manufacturers

Many physicians said that they receive "Dear Doctor" letters from manufacturers when a device is recalled and consider them a valuable source of information on device recalls. However, some participants complained that these letters do not reach them early enough, and that the language used was more legal than medical, without being as detailed as they would like. A few participants said that they would expect that such "Dear Doctor" letters from a manufacturer be reviewed and endorsed by FDA.

> "It's ["Dear doctor" letter] a lawyer written thing." Physician

> "I don't think there is much disclosure at all. They decide what are they going to disclose? I think that's how this process goes that they want the minimal stuff that they can get through. So I think that having regulations of this communication is also very important. I think that's what they are working on." Physician

> "I would be more comfortable to know that there is somebody else overseeing communications. […] Like the FDA. I would assume that they are, right?" Physician

In terms of informing patients, a few participants said that simply sending patients a copy of the "Dear Doctor" letter from a manufacturer would not be helpful, as the letters sent to physicians are not tailored to a patient audience.

> "I think the best way is to have them come in and talk to them in person." Physician

> "A doctor ["Dear Doctor"] letter is not necessarily very helpful to the patients." Physician

FDA

The participants perceived the FDA as an organization that ideally should verify, endorse, publicize and store information on recalled devices. The FDA was perceived by the participants as a non-biased and objective source of information. However, many did not know how to effectively and quickly obtain such information from the FDA.

> "I think having another source of information that would be honest and fair and (unint.) come forward if you have problems… [drug manufacturers] are for-profit companies, so there's a little bit of a bias. I think if you have another source like the FDA or other unbiased [that would be useful]." Physician

Even though participants said that the information they receive from manufacturers is highly desirable (first-hand, detailed), some believed that the FDA should regulate the process of manufacturers communicating to health professionals and patients about device recall. A few participants believed that the FDA should determine specific components of such a message and at what point it should become known.

> "I just think that the FDA's responsibility is to ensure that the manufacturer, like they're governing the manufacturer to say this is what you need to say in that letter." Allied health professional

FDA's Web site

Those participants who sought information regarding recalled devices on the FDA's Web site said that the Web site offers too many resources and that it is hard to find specific and relevant information. A few also added that the FDA's Web site is difficult to navigate.

> "When you go to the FDA's Web site, you definitely find there's too much information." Allied health professional

> "It's hard to navigate the [FDA's] Web site. Very difficult to find the information you're looking for." Allied health professional

> "It would be easier "(if) it was specific for cardiac devices… a section specific for our cardiac rhythm type of disease management.." Allied health professional

> "If you look something up on a Web site, it's nice but sometimes you don't know exactly where to look, where you can truly get a sense of what the importance of something is." Physician

4. Action taken when an ICD or pacemaker was recalled

The participants said that learning about a device recall makes patients feel scared and that they receive a lot of phone calls from patients questioning whether their device should be removed.

The participants said that when they hear of a Class I recall of an ICD or pacemaker that their patients have, they immediately call their patients (physicians ask their nurses to call) to schedule a visit. The majority said that that they also send a certified letter to each patient.

> "Every patient gets a certified letter [including information on] the nature of the problem and the gravity of the problem. They're asked to come in and then we discuss …" Physician

> "I talk to the rep of the company and come up with a line of action, what we're going to do. And we put it on the letterhead and send it merely to every single patient. In addition, what we do is we talk to our nurses. I don't call them personally. The nurses call them personally and tell them that, look, you know, this is what's going on. You will be receiving a letter in a day or two. It's possible you may have already heard it on either the Internet or in the news." Physician

> "We ask people to come in and then if there's a problem, we'll get in touch with them." Physician

> "The letter that I sent out, and then in the letter I had put that we will be contacting you within the next so many weeks. And then it's followed up with a phone call. We contact the patient and you schedule them to come into the office to have an oral discussion with a physician or with a physician's assistant, a nurse practitioner to discuss their personal (unint.) and have them schedule within the next month to come in and discuss that, and options of treatments, and we need to have a face-to-face with the patient." Allied health professional

The participants said that their patients do not receive any letters about a recall from manufacturers. A few believed, though, that patients should be contacted directly by the manufacturer.

> "I don't get a sense that the manufacturer contacts the patients as they might or should." Physician

> "The patients don't get informed, the patients move, it's a mobile population and you may have a patient that's new to the practice and find out that they had an advisory that nobody ever told them about because they were in transit or their device [was] implanted during the winter and they're now coming up to relocate up in Connecticut, we see that all the time and…" Physician

However, some other physicians questioned if a letter from a manufacturer sent directly to patients would be appropriate and beneficial to the patient.

> "I worry a little bit, the manufacturer can't possibly know what the patient's going to do. Sometimes even the physician doesn't… but the physician has a much better feel potentially for that…" Physician

Some participants believed that the Internet can help in reaching patients.

> "My answer is the Internet based surveillance that we provide, with Care Link and Latitude and House Caller, when they log on you know or transmit (unint.)" Physician

> "A modification of some fashion (unint.) patients with Care Link can log on or look at their data that they downloaded so patients who are involved in their care, not all patients are involved in their care, actually (unint.) they can log on to their Web site to see how many events they have and (unint.) by the way you need to go see a doctor about the latest advisory you know…" Physician

One physician said that some of his patients call manufacturers directly in the event of a recall.

> "My patients actually call the manufacturer directly. (Unint.) talking about the lawyers (unint.) and… they will instantly say call Medtronic or call the (unint.) and want to know is their model defective." Physician

B. Information Gaps

1. Providing risk/benefit information to patients

Many participants said that they provide information about the benefits and the possible risks associated with a device before the device is implanted, during the course of its use, and, of course, when there is a recall. The participants said that they usually provide risk/benefit information on devices to their patients orally during office visits before the device is implanted. The participants commented that patients have a lot of doubts before the procedure of implanting a device.

> "They're already hyped [before implanting a device]. I mean, a lot of patients when we recommend a device, some of the elderly said, no, no, no. I learned that these devices can kill you. So they're already having bad perception and bad publicity I guess. So some of them who don't understand are already it's hurting them to make the right decisions." Physician

> "Most of the time they want to know how long it's going to last. And what do you believe my likelihood it's going to help me? What my options are if I decide not to go for the device." Physician

In case of a recall, however, the process of giving risk/benefit information about devices to patients is different. Many participants said that in a recall situation, printed information explaining the problem is indispensable. The participants said that they usually write a letter to their patients based on the information in the "Dear Doctor" letter they receive from a manufacturer. Others believed that direct, person-to-person communication is the most beneficial in case of a recall.

2. Specific information about device recall sought by patients

The participants said that when a device is being recalled, most of their patients want to know what are the possible implications to their health and what is the likelihood that they will experience problems. The participants said that patients react in various ways—some insist on their device being immediately removed while some want to know whether it is necessary to extract their device and what will happen if it is not removed. The participants said that patients range from very inquisitive and distrustful of physicians to those who unconditionally trust the decisions of their health care provider.

"Female Speaker: The detailed information. They want to know what's wrong, how it happened, are they affected, what's the percentage, you know, and what they need to do about it.
Moderator: What do you mean by percentage?
Female Speaker: How many people are affected, how many devices are affected."
Allied health professional

"I think most patients want to know 'how is it going to affect me', that's really the bottom line." Physician

"You mean like statistics or what, sometimes I tell them it's more dangerous (unint.) than it is for them to have the device in." Physician

"They want to know percentages, they want to know the likelihood that they are going to be affected…" Physician

"The only data that sometimes is useful… is because the patients will ask for it and you'll say I'm going to… I recommend that we put in this device, from this manufacturer. And I've had families ask me how many recalls has that manufacturer had compared to how many recalls this other manufacturer had? And which one makes the most reliable, they recognize (unint.) device. They don't know that's really an unanswerable question but they often want to know how many advisories there have been per manufacturer." Physician

"From the patient's perspective, you know, the device that was implanted was, I mean, they're lifesavers, lifesaving they felt. And it's helped them for the most part and then when they hear the word recall, it's you know, they don't go hysterical, but, you know, am I going to die. That's their gut, on a recall, I'm going to die. And what's going to happen to me. And sometimes the patients [are/ kind of buying into it." Allied health professional

The participants said that their patients often have difficulties with understanding the technical side of a device recall.

"Well, the technical, the technicality of a failing mechanism oftentimes, they can't find something, they don't understand." Allied health professional

A few participants mentioned that it is challenging for them to find simple and understandable language that they could use with their patients depending on their age, literacy level, etc. The participants said that it is difficult for patients to understand the range of risk when it is expressed in numbers or percentages. For many patients, it would be better to translate numbers to what is a small/moderate risk vs. large risk.

> "[Communicating] risk/benefits and, you know, how, when you communicate with high school kids, (unint.) very simple and put it into language terms to communicate to the patient. Sometimes the statistics, like 60 out of 46,000 [are not comprehensible to a patient], and how does a patient relate to that? So we try to reduce it to, like one in how many thousands. And how many out of a thousand." Allied health professional

> "These numbers, you know, what do they mean? What's normal, patients don't know how to relate to these values. So we try to put it in terms of what, if you're a moderate risk, if you're a patient (unint.) that puts you at a higher risk, we try to explain to them in the letter." Allied health professional

> "I don't think they have the educational background to understand it." Allied health professional

The participants said that they would like to receive information specific to their field of medical practice/expertise from the FDA.

> "I don't want the FDA sending me recalls about every single thing that's being recalled. I only want it specific to my needs." Allied health professional

> "I want to be able to, you know, break it down to what I want. You know, like a check box. You know, I want the first five and you can keep the rest." Allied health professional

3. Up-front communication to patients [before procedure]

The participants said that in the recent times they began to communicate possible risks of devices to their patients before implanting a device. They said that in the past they would typically talk about the longevity of devices but not potential defects.

> "We all learn to talk more about malfunction now. But in the past, I don't even recall talking about malfunction. Maybe just the longevity of the lead and the longevity of the generator." Physician

> "Most of the time they want to know how long it's going to last. And what do you believe my likelihood it's going to help me? What my options are if I decide not to go for the device." Physician

One physician said that there should be a statement in the patient labeling that if the device is ever recalled, the company will communicate with the physicians, and therefore it is important to stay in touch with the doctor who implanted the ICD or pacemaker.

> "…that insert with the pacemaker, I think if they communicate right up front with the patients that there may be, in the future, an advisement or whatever [a recall], but the FDA will communicate that to physicians following you and how important it is for them to include their current information with the company. Discuss that, because there's a lot of patients that are lost to follow-up." Allied health professional

4. Need for information to counter what patients hear in the press

The participants said that they would like to have information allowing them to fully explain and supplement what patients learned about recalls from the popular media, ideally from an unbiased party such as the FDA.

> "To counter, you know, what they hear in the press and have someone be a public face to say this is (unint.) you will hear from your doctor, you know, put something out there." Allied health professional

> "We don't have good science about how we ought best to handle this. We don't know how patients perceive the word 'recall.' But our clinical experience suggests that recall's a pretty emotion laden term as opposed to some of the words that HRS has tried to advance. But truthfully, we ought to have science on that. We ought to be operating in a science empiricism context instead of what we think. And so to me, we need some studies on this." Physician

C. Information Vehicles

The participants said that their preferred way to get information about the risks of pacemakers and ICDs that they could give their patients would be e-mail, express mail (e.g., FedEx) or fax.

> "Yeah we get a lot of e-mails but if you get an e-mail from the FDA, you're likelier to pay attention to that and again so you don't get bombarded, it has to be the ideal frequency like once a week or once a month is likely too much but it could be quarterly or twice a year… twice a year at the current rate I think may not be enough, quarterly probably is not a bad idea." Physician

> "This may not be a bad idea for the FDA to do. What they can do very easily is to ask for the e-mail address of practicing cardiologists who are implanting devices. I mean, just e-mail us. The thing is e-mail for us is going through to us pretty quick. And all of us get a lot of junk e-mail. All of us get good e-mails. So if it is too much, I mean, deleting for us takes one second." Physician

The participants said that a letter, e-mail or fax that is clearly marked that it comes from the FDA would get their attention. They said that marking mail "urgent" and using a red font would not attract their attention as a lot of "junk" mail is marked that way.

D. Reporting Adverse Events to FDA

Many participants admitted that they are not sure how the process of reporting adverse events of devices to the FDA works.

> "It's not as entirely clear if you're discovering things, how that reporting process most efficiently takes place." Physician

> "I bumped into a friend of mine who works at the FDA recently, he says oh, there's a 1-800 number and so I said, what is it? And they blanked." Physician

Some participants said that when they encounter an adverse event in a patient, they report it through their hospital so they are not familiar themselves with the details of reporting to the FDA. A few said that the form for reporting problems related to devices should be simpler to fill out and submit than the current general reporting form.

> "Fill out this form and you mail it. I get it through the hospital." Allied health professional

The participants suggested that if they were getting communication from the FDA by e-mail, it would be convenient to them to report an adverse event by replying to the FDA's message. Others would like a form located on the FDA's Web site which, after it is completed, is automatically sent to the FDA. Some participants also said that they would like to receive communication from the FDA that is specifically tailored to their clinical area.

> "Electronically [would be most convenient]." Allied health professional

> "[Form] not if you went to a Web site to get it where you could then fill out a form on the Web and then it automatically goes [to the FDA]. It has to be done appropriately so that it doesn't become a very difficult time consuming task to do that. If you want to… when you know the problem, you want to get that to them as quickly as you can." Physician

> "To either confirm it or you know what your perspective is and what (unint.). And actually you could have a return feature where if the physician has become aware of a problem in the reply, he can say by the way, we've noticed a side effect, check it out. And it would be a short-tracking problems so that… sort of a traditional way of informing the FDA of potential problems, it would be a timely, a regular way of doing it. You know people respond by e-mail all the time nowadays… but if it was a regularized format… then… because it does take extra effort to access the site, try to figure out how to use the site, try to figure out where you are going in the site." Physician

> "But if something is sent to you, it would be easier to reply." Physician

Some of the participants said that having a mechanism for sharing early information on device problems among their colleagues would be useful, such as a blog or internet chat room. A few

raised concerns about how the security of the information shared would be protected, and suggested that it be password-restricted to healthcare professionals only.

> "I wonder if there're any chat rooms for people, you know, now people are using the Internet like if they see a problem and chat about it. […] Like a blog. [Moderator: Chat rooms so you can talk to your peers, you can talk to other professionals?] Right." Allied Health Professional

IV. Conclusions

- These focus groups showed that for the participating physicians and allied health professionals, Class I recall of an implantable device typically implies serious possible consequences to their patients' health, and potentially removing this device and returning it to the manufacturer. However, the participants said that a recall does not always lead to the removal of the device. Many of the physicians believed that the device should not necessarily be removed if the risks of removing it are greater than the risks of leaving it in. The decision to remove a device can also depend on the degree of a patient's dependency on that device.

- The participants' patients react to the term "recall" with fear with regard to their health and life. Typically, their first reaction when they learn that their device was recalled is that they want it removed.

- Even though the physicians and allied health professionals are typically informed about a device recall by the manufacturer, either through an express mailing or through a visit from the manufacturer's sales representative, they complained that they often receive a manufacturer's information on a recall after it appears in the popular media.

- Ideally, the health professionals would like to hear about a product recall before it is released in the media, so they have the information before their patients have it. Releasing information about a device recall in the media before physicians have that information might decrease patients' confidence in their health care providers and fuel patients' fear generated by the sensational/exaggerated tone of some media reports that present a simplified or misleading picture of the situation.

- Health care providers see manufacturers as a potentially biased source of information about the recall issues relating to implantable devices; however, the providers would rather receive recall information from manufacturers than from other sources such as media.

- Even though health care providers prefer to receive information from manufacturers, some participants believed that the FDA should regulate the process of manufacturers' communication with health professionals and patients about device recall. A few participants believed that the FDA should determine specific components of such a message and at what point it should become known.

- The FDA is perceived as an organization that should verify, analyze, store and endorse information on recalled devices. However, many participants stated that the data itself should come from the manufacturer as the party that has the best knowledge about their device.

- The FDA was perceived by the participants as a non-biased and objective source of information; however, many did not know how to obtain information effectively and quickly about device recalls from the FDA.

- Those who sought information regarding recalled devices on the FDA's Web site said that the Web site offers too many resources and that it is hard to find specific and relevant information.

- In the process of giving risk/benefit information about devices to patients, many participants said that printed information explaining existing and potential problems is indispensable. Such information should address patients' concerns and be written in a language that can be understood by non-professionals. A few participants mentioned that it is challenging for them to find simple and understandable language that they can use with their patients depending on their age, literacy level, etc.

- The participants said that most of their patients want to know the following:

    - The possible implications to their health when a device is being recalled
    - The likelihood that they will experience problems
    - Lay explanation of the technical information relating to a device defect
    - Explanation of the seriousness of risks
    - The interpretation of statistics and a translation of the statistics into plain language of small/moderate risk vs. large risk

    - The participants said that they would like to receive information on devices specific to their field of medical practice/expertise from the FDA. They need more information about the potential risks and benefits of devices to communicate to their patients before implanting a device.

    - The participants said that they would like to have information allowing them to fully explain and supplement what patients learn about recalls from the popular media.

    - The participants said that their preferred way to get information about the risks of recalled pacemakers and ICDs that they could give their patients would be e-mail, express mail or fax. The participants said that a letter, e-mail or fax that is clearly marked that it comes from the FDA would get their attention. They said that marking mail "urgent" and using a red font would not attract their attention as a lot of "junk" mail is marked that way.

    - Many participants admitted that they are not sure how the process of reporting adverse events of devices to the FDA works.

- The participants suggested that if they were getting communication from the FDA by e-mail, it would be convenient to them to report an adverse event by replying to the FDA's message. Others would like a form located on the FDA's Web site which, after it is completed is automatically sent to the FDA.

Appendix A: Participant Screener (E-mail)

The Food and Drug Administration (FDA) is sponsoring 4 one-hour focus groups at the annual meeting of the Heart Rhythm Society to discuss **perceptions on communicating risk information to patients about recalled ICDs and pacemakers.** FDA will use this information to develop appropriate risk messages and design patient outreach materials.

We are looking for physicians and other health professionals who regularly advise patients about recalls of ICDs and pacemakers. We are not looking for participants from industry at this time.

If you can answer yes to the questions below, FDA needs your help! Please consider attending one of our sessions.

1. Are you a doctor, nurse, nurse practitioner, physician's assistant, or technician?
2. In the past year, have you regularly advised patients about ICDs or pacemakers that have been recalled?
3. Do you work for a medical practice, clinic, or hospital (and not for industry)?

The focus groups will take place at the Boston Convention Center during breakfast and lunch on May 18 and 19. Meals will be provided for participants.

Focus groups for physicians will be held on May 18 (12:15 – 1:15 pm) and May 19 (7 – 8 am). Focus groups for other health professionals will be held on May 18 (7 – 8 am) and May 19 (12:15 – 1:15 pm).

If you are interested in attending a focus group, please e-mail FDA-HRSfocusgroup@fda.hhs.gov. In the email, please indicate:

- The time and date of the session you would like to attend;
- Your professional title; and
- Your employer.

FDA will contact you to confirm the date, time, and location of the focus group.

Appendix B: Moderator's Guide

Physicians' and Allied Health Professionals' Perceptions about Communicating Implantable Cardiac Defibrillator (ICD) and Pacemaker Risks to Patients

I. Introduction – (5 minutes)

A. Moderator introduces self

B. Purpose of discussion: to hear your perceptions about communicating risk information to your patients about recalled ICDs and pacemakers.
(Definition: Risk information encompasses risks associated with the device itself (not functioning correctly, or has a failure). Includes the hazard as well as the likelihood (when known) of the hazard.) Risk discussion balanced with discussion of benefits

(Definition: We are talking about Class I recalls --- the most serious type of recall. In a Class I recall, there is a reasonable chance that the product will cause serious health problems or death.

C. Timeframe: 1 hour

D. Mention audiotape, obtain verbal consent

E. Ground rules: (e.g., everyone participate, talk one at a time, avoid side conversations, no "wrong" answers, anonymity protected)

F. Housekeeping items

G. Participants introduce themselves

II. Content of and Satisfaction with Pacemaker/ICD Risk Information of Recalled Devices – (30 minutes)

A number of pacemakers and ICDs have been recalled. FDA is particularly interested in finding out how most effectively to communicate the recall of these devices to meet your needs and your patients' needs.

A. What does the term "recall" mean to you when you hear a pacemaker or ICD has been recalled?
Probe: How do you know this is what the term "recall" means?
Moderator – Take note to see if participants equate "recall" with explanting the device and returning it to the manufacturer.

Probe: What have your patients perceived the term "recall" to mean?

B. Where do you first hear of a recall of a pacemaker or ICD?
Probe: press, Dear Doctor letter from manufacturer, patient who has received a Dear Patient letter or heard of the recall via the press, professional organization such as HRS, FDA – how specifically?

Probe: Do you get the recall information before it appears in the press?

Probe: Have your patients received Dear Patient Letters from manufacturers? What are your feelings about your patients receiving a Dear Patient letter directly from the manufacturer?

Probe: Do you receive Dear Doctor letters? Useful/not useful? How so?

C. How useful is the recall information you receive from different sources? (FDA, manufacturer, patient, press, professional organization, other)
Probe: amount of information, appropriateness, content, device performance and failures, denominator data, accuracy

Probe: Who would you rather first hear from when a pacemaker or ICD has been recalled?
(FDA, manufacturer, press, professional organization, no difference)

Probe: Tell me more about why that is.

Probe: In your experience, what is the usual sequence and timing of the source(s) you get recall information from, and when you get it? (FDA, manufacturer, patient, press, professional organization, other)

Probe: What would be the ideal situation of the source and timing of getting this recall information? (Probe: hear from FDA/manufacturer/press/professional organization – Who do you want to hear from1st, 2nd, 3rd? How soon do you want recall information?)

Probe: What is your opinion/reaction about the recall information on ICDs/pacemakers you have seen in the press?

Probe: What have been your experiences with your patients who heard about recalls of ICDs/pacemakers in the press? Lots of calls?

Probe: How do your patients usually first hear about recalls?

D. What do you do when you hear of a recall of an ICD or pacemaker that your patients have?
   Probe: get more information and from whom, contact, treat and/or educate patient & if so how much time passes between hearing of recall and talking to patient, ignore

   Probe: How satisfied do your patients appear to be with the recall information you give them? What questions do you often hear from your patients that you can answer? Can't answer?)

III. Information Gaps (10 minutes)

Pacemakers and ICDs save peoples' lives. But, there are risks.

A. How do you usually give risk/benefit information about these devices to your patients? (pre- and post- operatively) Print? Oral?
   Probe: What are the problem areas in the risk/benefit conversations you have with your patients?
   Probe: What questions do you hear over and over again?
   Probe: What do your patients seem to not understand?

B. What information gaps are there in the risk information you currently receive about pacemakers and ICDs?
   Probe: What gaps are there in the recall information you receive? What do you want to know that you are not getting? What do you want FDA to tell you that it is not currently telling you? What do you want to give your patients that you are not currently receiving?

IV. Vehicles (5 minutes)

A. How do you prefer to get information that you can give your patients about the risks of particular pacemakers and ICDs?
   Probe: e-mail, fax, print, hand-held device, website? Why is that?
B. What gets your immediate attention and action when you receive device information?
   Probe: envelope says Urgent? Recall? FDA? Bold? Red?
C. Do you know how your patients prefer to get risk information? (Probe: oral, print, go to website) Why is that?

V. Reporting/Sharing (5 minutes)

A. *We have spent quite a bit of time talking about how you learn about medical device recalls and how you communicate information to your patients. FDA is also interested in helping you share any emerging problems you may be observing in your patients.*
   1. How would you like to let FDA know when you begin to see a problem with a particular device?
      Probe: call in, website, fill in form, etc.
   2. How would you like FDA to feed information back to you about the problems that others are seeing?
      Probe: post on website, direct email, letter, communication with professional group, etc.

VI. Conclusion (5 minutes)

a. Is there anything else you would like to say about information on the risks of pacemakers and ICDs?
b. Thank you for your time and opinions.