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## Notifying Physicians and Patients About Medical Device Safety Issues: Thoughts from the FDA

Mark Barnett\* & Daniel Schultz\*\*

Over the past few months we have had the opportunity to interact with a number of groups who have a vital interest in device safety issues, and we are convinced that all of the key players—clinicians, patients, manufacturers, and regulators—share the same overall goals: to assure that physicians have reliable and effective devices that will improve and even save patients' lives, to be sure that adverse events, when they occur, are reported promptly and fully, and to provide physicians and patients with timely, usable information about these events so that they can take appropriate action. Having said that, we also realize that each group brings to the table certain specific mandates and constraints that inform its viewpoint. And so this colloquy serves an important function by providing an opportunity for the different views to be aired and discussed.

We will begin by exploring the possible reasons for the recent upsurge of interest in patient and physician notification when medical devices malfunction. We have recently experienced significant and widely publicized recalls of heart rhythm devices that have stimulated a great deal of public and professional interest. But medical devices have been recalled in the past with far less discussion among manufacturers, physicians, and regulators. What is different this time?

Perhaps the most fundamental difference is that the FDA is now more frequently notifying the public, using press releases and website postings, in certain cases in which it is

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vital that patients with the affected devices promptly seek medical advice. Of course our traditional approach in getting the message out is to ask manufacturers, whom we regulate, to notify physicians, who in turn notify their patients. That basic formula has not changed. So why has FDA seen the need to supplement it with additional public notifications when serious adverse events occur?

On the most basic level, the answer stems from a concern that patients may not always receive adequate notification from their physicians or that notification of physicians is not always adequate to reach all the patients that are affected. Despite good intentions and conscientious effort, some patients will inevitably fall through the cracks. Recordkeeping, after all, is not always perfect, office staffs are busy, and patients move, change physicians, or change names. Even those patients who are notified can misunderstand what they are told. And so public notification by FDA adds an element of constructive redundancy to the system.

There are also larger, societal trends that underpin and reinforce FDA's increased involvement in patient notification. One is the increasing desire of patients to be active participants in their own health care and in making decisions that affect the treatment they receive. Patients cannot carry out that role without receiving accurate, timely information about the drugs, vaccines, and devices that affect them. Increasingly, patients seek this information from the Internet, which includes dozens of health-related websites operated or supported by the government. And so people today expect federal agencies like the FDA to provide them with the latest news—both good and bad—on medical products.

Another impetus for FDA to take a more active role in notifying the public is a changing culture among federal agencies in which “transparency” is increasingly valued and encouraged. To be “transparent” is to let people know about your agency's decisions promptly and comprehensively, to explain why and how you took a particular action, and to provide this insight as early as possible. But it is important to understand that while FDA is committed to transparency, it must also protect the confidentiality of trade secrets and confidential commercial information, as required by federal law. Our goal is to provide the public with as much useful information as possible while at the same time meeting our legal obligations.

It is interesting to note that these two trends—patients seeking autonomy and federal agencies seeking to practice transparency—tend to reinforce one another. The public desires information, and the government is motivated to provide it.

But what does that do to the doctor-patient relationship? Everyone involved in this discussion will agree that a patient's primary source of information about an implanted device should be the physician. Only the physician can discuss a device problem with a patient in the context of that individual's medical condition, history, lifestyle, and values, and only the physician can provide the personalized advice the patient needs to decide on a course of action.

And so that presents a potential dilemma: how can we in the FDA continue to provide “constructive redundancy” by notifying the public about medical device problems, and yet at the same time avoid compromising the doctor-patient relationship?

Part of the answer is to ensure that the content of FDA's message to the public is consistent with what patients will hear from their doctors. Although the FDA must speak with an independent voice, it is important to coordinate what we say, whenever possible, with manufacturers and clinicians, so that the patient receives one message that is accurate and consistent. In crafting our messages for patients, our primary objective is to explain the situation and suggest a course of action—in most cases, to arrange to see their physicians—while at the same time not instilling needless anxiety.

A second way to avoid compromising the doctor-patient relationship is to make sure that FDA's messages are timed so as to avoid having patients learn about device problems from the news media before their physicians are informed. Does this mean that we are promising to always inform clinicians before we inform the public? No. There will be instances when we will have to inform all groups simultaneously. But we are mindful of the doctor-patient relationship, and we will make every effort to reinforce it.

There are other, broader questions that also have a critical bearing on the issue of notifying physicians and patients about device malfunctions. For example:

- From a public health standpoint, how serious must a problem be in order to trigger a notification to physicians and patients? Should a notification take

place even when a malfunction is not considered life-threatening?

- How widespread must it be in order to trigger a notification? Is just one report of a potentially life-threatening malfunction sufficient? How do we factor into this decision the worrisome question of underreporting?
- How certain must we be about the nature of the problem, its causes, and its potential consequences before we decide to notify? Early notification can potentially save lives, but notification before we have all the facts can invoke needless confusion and anxiety on the part of both patients and their doctors, and may actually compromise patient care.

These are the kinds of questions all of us need to consider carefully as we move ahead to make decisions in this area.

Of course even the best system for communicating information to physicians and patients cannot be effective without accurate, meaningful, up-to-date information to transmit. And that brings us to the quality of the data that we receive from device manufacturers and our performance in acting on this information. It has been all too apparent from recent news reports and editorials that in some cases manufacturers present adverse event data to us in a way that makes it difficult to identify and interpret the information, and that in some cases we are not as prompt as we should be in taking action.

This is going to change. We are committed to strengthening our postmarket surveillance system, better coordinating our postmarket and premarket activities, and facilitating more rapid response to critical device problems as they arise. Here are just a few examples of this commitment.

- We are more actively monitoring and enforcing the requirement that manufacturers of certain devices continue to conduct clinical studies after the product is approved.
- We are developing a process through which more device manufacturers will be able to report adverse events electronically through our Medical Device Reporting (MDR) system, which should facilitate rapid reporting and more efficient interpretation of the reports on our end.
- We are continuing to redirect our inspections of

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device manufacturers in order to concentrate on those whose products pose the greatest risk, allowing us to target limited resources to areas of greatest public health concern.

- We are developing guidance for companies that will more clearly define the kinds of manufacturing changes that will require notifying FDA, and what kinds of submissions will be needed.
- We are developing a standard format for the annual reports that some manufacturers are required to submit to FDA in order to ensure that the information is complete and presented in a way that facilitates efficient FDA review.

Like the other participants in the colloquy, we want patients to derive maximum benefit from medical devices at minimum risk. To make that happen, we all must continue to develop a monitoring and reporting system that provides accurate information with rapid turnaround and gives physicians and patients useful information for making clinical decisions. We look forward to working with the medical community, patient groups, and manufacturers to achieve that goal.