

**Proceedings Document from the
Policy Conference on Pacemaker and ICD Performance**
presented by
the Heart Rhythm Society
and
the Food and Drug Administration

September 16, 2005

**16 September 2005
Washington, DC**

Table of Contents

Introduction.....	1
Technology, Performance, and Surveillance.....	3
Post-Market Analysis and Reporting	10
The Role of External Databases in Post-Market Surveillance.....	16
Risk-Benefit Communications	19
What Patients Need and Want to Know From Their Physicians	25
Closing Remarks	30
Glossary	31

1 **Introduction**

2
3
4 **Anne Curtis, MD**
5 **—President, Heart Rhythm Society**

6
7 Dr. Anne Curtis welcomed attendees and said that the conference was an opportunity for key
8 stakeholders to come together. She indicated that the forum offered all participants an opportunity
9 to share their experiences on the issues of technology, performance, and surveillance; post-market
10 analysis and reporting; the role of external databases; risk-benefit communications; and patient
11 information. Finally, Dr. Curtis said that it was important to come out of the meeting with a
12 framework for future action on the public policy front and on a direction for physician guidelines.

13
14
15
16 **Scott Gottlieb, MD**
17 **—Deputy Commissioner for Medical & Scientific Affairs, FDA**

18
19 Dr. Scott Gottlieb said that the Food and Drug Administration wants to take new and additional
20 steps to leverage its relationship with clinicians. We also want to work together to improve our
21 knowledge base and to find safe and effective uses for new technologies, he said, including
22 pacemakers and implantable cardioverter defibrillators (ICDs).

23
24 Dr. Gottlieb explained that a lot of what the FDA does involves helping patients manage risk and
25 improve health outcomes. He noted that the agency receives a great deal of data about both new
26 devices and medical products already on the market, adding that the FDA’s aim is to turn the raw
27 data into useful knowledge.

28
29 Next, Dr. Gottlieb emphasized that the information the FDA can provide is only as useful as the
30 data the agency receives. He stressed the need for physicians and the medical device industry to
31 generate information on what works and what doesn’t, and to communicate the information in a
32 way that is helpful to other providers and that benefits patients. Dr. Gottlieb also emphasized the
33 need for closer collaboration as medical devices become increasingly sophisticated and their medical
34 value enhanced.

35
36 Dr. Gottlieb noted that unprecedented advances in technology have enabled physicians to save lives
37 and save money, and that today’s ICDs are up to 99-percent effective. The risks that exist, he said,
38 need to be balanced. Noting that no one is sure what the trends fully mean, he said what was known
39 was that advances in technology are challenging health care providers to integrate multiple options
40 into their practices. In turn, he said, this challenges the FDA to ask the right questions about these
41 products, to get good data, and to turn that data into practical knowledge in a way that is easy to
42 integrate into clinical practices.

1 **Mark Carlson, MD, MA**
2 **—Conference Chair**

3
4 Dr. Mark Carlson said that the conference was a first step toward solving a complex issue of
5 national and international concern. He noted that everyone from physicians to patients to
6 government to industry was working toward the same goal: to provide patient confidence and
7 lifesaving technology.

8
9 “We are here to learn and gain multiple perspectives,” he said, “and we are here because of our
10 patients.” Dr. Carlson noted that 325,000 die from sudden cardiac arrest in the U.S. each year, many
11 of whom could be saved by implantable defibrillators. He said the goal of the meeting was to
12 provide a productive forum for discussion. “We won’t come away today with the perfect solution or
13 draft physician guidelines,” he said, “but we should leave here with a better understanding of
14 pacemaker and ICD performance.” “This understanding,” Dr. Carlson concluded, “is critical to
15 considering policy options and next steps.”

16
17 Dr. Carlson indicated that we need to put the device recalls into perspective, that they account for a
18 very small percent of manufactured devices, and that presently devices save thousands, if not
19 hundreds of thousands, of lives.

20
21

1 **Technology, Performance, and Surveillance**

4 **Session Chair: William Maisel, MD, MPH**

6 Dr. William Maisel offered a brief introduction. He said the aim of the session was to provide an
7 overview of the current state of post-market surveillance, including its strengths and weaknesses. Dr.
8 Maisel added that the discussion would also address the challenges of collecting data from the field
9 and what critical clinical data needs to come back to FDA and the manufacturer. Finally, he offered
10 a simple message: that pacemakers and ICDs save lives, and that the benefits of the devices strongly
11 outweigh the small risks that would be discussed during the course of the conference.

14 **The Panel**

16 **Presenters:** **Thomas Gross, MD (FDA)**
17 **William Maisel, MD, MPH (Electrophysiologist)**
18 **Stan Myrum (Medtronic)**
19 **Rachel Lambert, MD (Electrophysiologist)**

22 **Thomas Gross, MD**

23 **—Approaches to Post-Market Device Evaluation: The FDA Perspective**

25 Dr. Thomas Gross discussed the Food and Drug Administration’s three main avenues for post-
26 market surveillance:

- 28 • passive surveillance (including mandatory and voluntary event reporting and annual report
29 sharing, in a standardized format);
- 30 • enhanced surveillance (through the Medical Product Surveillance Network (MedSun)); and
- 31 • observational study (both required and discretionary).

33 Regarding passive surveillance, Dr. Gross explained that the FDA receives over 180,000 reports per
34 year through medical device reporting (MDR) and MEDWATCH. He said that reports are reviewed
35 from a variety of perspectives, and he noted that annual reports address both interpretation issues
36 and potential safety issues. Dr. Gross added that while the reports can be used for multiple
37 purposes, they are primarily intended to anticipate unintended consequences. The system of passive
38 surveillance was designed to promote the interaction of medical personnel with the FDA.

40 Dr. Gross also noted that passive surveillance is often seen as a “one size fits all” system. He said
41 the strengths of passive surveillance are that it entails nationwide reporting from various sources and
42 that it is relatively inexpensive compared to other reporting systems. The weakness of the system,
43 however, is a lack of standardized coding (i.e., data entry), or data reporting that is biased from
44 litigation and/or media attention.

46 Regarding enhanced surveillance, Dr. Gross explained that it includes an active component since the
47 MedSun system provides targeted surveillance and real-time data. As a result, he said, enhanced

1 surveillance is helpful in pinpointing issues and near misses in order to prevent serious injuries and
2 death. Dr. Gross added that the FDA is exploring the possibility of setting up subspecialty networks
3 on the system so that physicians can post data and colleagues can respond and amplify any signal
4 that may exist. MedSun is limited to 150 institutions, mostly hospitals, included in the National
5 Network of Health Care Facilities.

6
7 Regarding observational studies, Dr. Gross explained that these can be mandated by the FDA or
8 done at the discretion of either the FDA or a manufacturer. The approach is descriptive and
9 generally non-comparative, he explained, and there are no built-in controls. Observational studies,
10 he said, are designed to focus narrowly on real-world experiences in the post-market arena.

11
12 Finally, Dr. Gross outlined several possible future approaches to evaluating medical devices in the
13 post-market environment. These include

- 14
- 15 • developing more active surveillance (possibly through MedSun or professional networks);
- 16 • exploring other databases (including Medicare databases and CMS medical registries);
- 17 • improving passive surveillance (including electronic reporting, data mining, and enhanced
18 coding);
- 19 • strengthening the condition of approval studies; and
- 20 • establishing device identification standards.

21
22
23 **William Maisel, MD, MPH**
24 **—Pacemaker and ICD Generator Malfunctions**

25
26 Dr. William Maisel discussed new information obtained from analysis of 1990-2002 reports on
27 pacemaker and ICD generator malfunctions. He began by noting that the overall number of annual
28 malfunctions has increased (to over 2,000 malfunctions per year for the last few years of the study)
29 and that 80 percent of the malfunctions were related to hardware problems. He stressed that the
30 increase in pacemaker and ICD malfunction corresponds to an increase in the number of
31 procedures being performed but noted also that there was an increase in the overall rate of ICD
32 malfunction during the time period. In addition, he pointed out that the study did not analyze the
33 *impact* on patient health of the various problems that were reported, many of which have far less
34 severe consequences than device failure. (In fact, there were only 61 deaths reported and confirmed
35 due to device malfunction in the 1990-2002 period—compared to about 2.67 million implants.) Dr.
36 Maisel noted also that the malfunction rate for ICDs over the length of the study was higher than
37 that for pacemakers.

38
39 Dr. Maisel suggested that the recent trend upwards in the number of malfunctions could be
40 attributed to one of several possibilities:

- 41
- 42 • that physicians have become more aggressive in reporting problems;
- 43 • that physicians have lowered the threshold for replacing devices; or
- 44 • that the malfunction rate is truly increasing.

1 Dr. Maisel also briefly addressed the limitations of the study’s data collection methodology,
2 including potential under-reporting of malfunctions and the fact that all malfunctions were treated
3 the same. Dr. Maisel also noted that several databases which allow for active reporting (the United
4 Kingdom, Danish, and Bilitch registries) showed trends in device performance similar to those
5 observed in the FDA annual report study.

6
7 In concluding his remarks, Dr. Maisel stressed that it was important to keep in mind that
8 pacemakers and ICDs have saved tens of thousands, if not hundreds of thousands, of lives.

9
10 **Stan Myrum**
11 **—Device Performance and Technology**

12
13 Mr. Stan Myrum discussed the terminology used to describe device performance and the need to
14 standardize the nomenclature associated with device performance, device failure rates, and device
15 failure classifications. He went through definitions for a number of common terms, including device
16 performance, device malfunction, device reliability, device failure, random component failure,
17 specific hardware and software failures, anticipated device failure, and non-anticipated device failure.
18 Mr. Myrum also looked at varying degrees of patient risk associated with different types of failures
19 and strategies for mitigating the risk of a failure (including programming and diagnostic testing). He
20 noted that malfunctions can be due to memory and component errors or to more serious loss of
21 therapy.

22
23 In wrapping up his remarks, Mr. Myrum said that a specific device failure rate would not be an
24 appropriate trigger for clinician notification. Other considerations are warranted to more thoroughly
25 assess patient risk, he said. Finally, Mr. Myrum stressed that overall device reliability has remained
26 constant or has improved alongside significant advancements in device therapy and diagnostic
27 clinical value.

28
29 **Rachel Lampert, MD**
30 **—The Role of the Physician in Device Surveillance**

31
32 Rachel Lampert discussed the limitations of the current passive surveillance system. She noted that
33 not all malfunctions (or suspected malfunctions) are detected or reported. She described potential
34 reasons for under-reporting, quoting first the Institute of Medicine report on device surveillance
35 which suggested that physicians routinely work around problems, do not understand how privacy
36 issues and the FDA’s work interrelate, and aren’t aware of adverse-reporting systems. Other
37 editorialists have suggested that faults are often suspected to be random; that the unit may be
38 replaced by one from another manufacturer, and that death may be attributed to heart disease (thus,
39 post-mortem interrogation of the device is not performed).

40
41 Next Dr. Lampert turned her attention to possible systems for active surveillance, including the
42 possibility of having all explanted devices returned for analysis. She also acknowledged the potential
43 hurdles to active surveillance, including logistical and consent issues and time and money
44 constraints. Dr. Lampert suggested several strategies to encourage and enforce active surveillance
45 systems, including an FDA mandate to return either all or a subset of explanted or post-mortem
46 devices, performance measures on institutional return of devices, and a compensation strategy to
47 encourage device reliability reporting. Finally, Dr. Lampert addressed data collection enhancements
48 regarding implantation, clinical follow-up, and post-mortem examination.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46

Panel Discussion

- Moderator: Michael Cain, MD (Electrophysiologist)
- Expert Panel: Mark Bruley, BS (Biomedical Engineer)
Lynn Elliott (Guidant)
Anne Gillis, MD (Electrophysiologist, Canada)
Thomas Gross, MD (FDA)
Joseph Levitt (FDA)
William Maisel, MD

The questions below came from the moderator and the audience.

- Q. How does patient ownership of devices affect post-removal analysis?
 - A. A panelist noted that for physicians or hospitals to take a device without a patient’s consent would be problematic. He added that it was important to request consent—either at the time the device is implanted or at the time it is explanted.
- Q. What is the FDA threshold for unique failures?
 - A. “Our threshold is very low,” replied one panelist. “The reports that FDA receive are often incomplete.” “As a result,” he said, “it is very important that the agency work closely with manufacturers to get a complete picture. If not, we are left to put the pieces of the puzzle together.”

The Moderator noted that the presentations had repeatedly mentioned three types of databases and how data collected through them have been used to draw conclusions. “I am impressed with the amount of data that comes into our systems,” he said.

- Q. “How confident are we of the data that are collected and monitored?”
 - A. One panelist noted that the MAUDE database represents a passive surveillance system. “The better the data,” he said, “the better we are to detect problems.” He added that the passive surveillance system is necessary but not sufficient. “There are other systems that also need to be put into place to get the data that we need and to get to more active surveillance,” he said. A second panelist noted that MAUDE reports address alleged *incidents* but do not report on *causes* of failures. “As a result,” he said, “the data have to be treated very carefully because they are very raw.”

Another panelist added that it was important to start to think about more active surveillance systems, and about implementing them on an international basis. He pointed out that most new-device technology is evaluated earlier in Canada and some European countries than it is in the United States. “If we wish to identify problems as early as possible,” he said, “we need to start the surveillance system as soon as a device is introduced.”

1 The Moderator asked the FDA panelist to take participants through the process the agency goes
2 through to when it receives annual report data. “What happens next?” he asked. In response, the
3 panelist cautioned that the data it receives are “behind the curve” and tend to raise as many
4 questions as answers. He added that the agency recognizes that it needs to streamline the annual
5 reports to make them more user-friendly for both patients and physicians.

6
7 Q. What changes could be implemented as a result of a policy conference such as this one? If there
8 is a consensus that certain changes need to occur, what does FDA need to do to implement a
9 change?

10
11 A. The FDA panelist stressed that it takes time for the government to reach a consensus on what
12 needs to be done and the appropriate course of action. He said, “the action needed could be
13 administrative, regulatory, or legislative. The FDA might be able to take action on its own, or it
14 might need new legislation, new funding, or perhaps new expertise to implement a policy
15 change.”

16
17 Q. How can data collection that relates specifically to ICDs and pacemakers be improved? How
18 may everyone work together to provide more timely data to physicians and patients to ensure
19 more informed decision making?

20
21 A. One panelist noted that improving outcomes depends on the data that are available and what
22 conclusions can be drawn. He said that one problem was getting data consistency across
23 manufacturers in order to generate more transparency. He also said it was important to
24 determine what information should be put into the public databases and that the MDRs do not
25 make it easy to evaluate the causes of device malfunctions in order to understand what action to
26 take. “From a physician standpoint,” said a second panelist, “there are a number of practical
27 issues associated with returning data from the field. Some of these can be overcome by having a
28 patient consent form for returning devices.” She suggested perhaps also developing a
29 standardized form with key information about the patient and the device in order to help
30 determine whether or not there was a malfunction. Finally, the panelist encouraged physicians to
31 take action. “There is no reason why there can’t be a performance measure for returning
32 devices,” she said. A third panelist suggested that the medical device industry should start to
33 prospectively follow devices. A fourth said that one of the key findings from the IOM
34 Committee on Post Market Surveillance was that many physicians aren’t aware of reporting
35 requirements. “We need greater FDA outreach, and collaboration with the Heart Rhythm
36 Society and physicians themselves,” he said. A fifth panelist echoed the previous comments and
37 stressed that health care reports are extremely useful to the extent that problems can be
38 identified and reported in real time.

39
40 Q. As we evolve the process and our current classification scheme, are the terms we are using broad
41 enough to define the problems?

42
43 A. “The terms are relatively well defined,” replied a panelist, “and most of the industry is using the
44 terms in a similar way.” “The challenge,” he added, “is to present the information in a way that
45 is useful for physicians and their patients.”

1 Q. Can the FDA protect the public from truly catastrophic problems with the current system?
2

3 A. “We recognize the limitations of the system,” replied the FDA panelist. “There are efforts in
4 place to look at these issues, the databases, and how we can better connect the dots,” he said,
5 “so that we are better prepared to respond in the future to those incidents to which you refer.”
6
7
8

9 Open Dialogue

10
11 The first comment came from a clinician who said that he was seeing more problems associated
12 with leads than with implantable devices. He noted that lead surveillance has additional problems
13 and that the consequences of a malfunction are potentially much more severe.
14

15 “This is an important point,” replied a panelist. “One of the challenges is retrieving the device—and
16 leads are rarely returned”. He added that the industry has been very aggressive in trying to do pre-
17 market testing, and that one strategy will be to look at lead performance in terms of durability and
18 usability.
19

20 One participant asked about the role of post-market surveillance in detecting low-frequency, serious
21 offenses that may lead to death and/or serious injury. “Does the FDA have the resources and tools
22 in place today to accomplish this mission?” he asked. “If not, what are we going to do about it?”
23 “The FDA can do a better job,” replied a panelist, who added that the agency has to be smarter in
24 allocating the resources that it has.
25

26 Another question addressed the possible need for an independent facility to test explanted devices.
27 At the heart of the question was whether or not individual manufacturers could police themselves.
28 In response, one panelist said that manufacturers cannot stay in business if they do not address their
29 liabilities. “We want to understand what is going on in these devices,” he said.
30

31 “From the FDA’s perspective,” asked one participant, “if a manufacturer says that nothing is wrong,
32 is that the end of it?” In response, the FDA panelist said that the agency does not take further
33 action unless there are other reports that suggest there might be a problem. “If so,” he said, “the
34 FDA has the authority to request additional information or to inspect the firm.”
35

36 One participant said that he was impressed by the industry’s reliability in investigating component
37 failures. Another participant compared device reporting to pharmaceutical reporting and pointed out
38 that hospitals have mandatory pharmacy reporting. “Is it time for medical device users to be
39 similarly monitored?” he asked.
40

41 On a separate note, the same participant observed that many countries rely on the FDA approval
42 process for their own drug and device approvals. In response, the FDA panelist noted that his
43 agency has an international, information-sharing system in place.
44

45 “These devices do save lives,” stressed a participant who said he had an ICD implanted in him. “We
46 really need to highlight the benefits of these devices,” he said. “How are we going to make sure that
47 this message gets out to patients? While everyone likes to hear the success stories, countered

1 another participant, there are also stories about the potential harm these devices can cause.” “We
2 have been deliberately denied access to data,” she said, “and many of us are potential ticking time
3 bombs.”

4
5 A participant stressed the importance of individual physician reporting. At the same time, he
6 expressed frustration that physicians receive no acknowledgement that their data have been received
7 and no feedback on results.

8
9 “Do you think our current processes and procedures have enough wiggle room to accommodate
10 changes?” asked another participant.

11
12 “There are a lot of different ideas being put on the table,” replied the FDA panelist, “and the agency
13 is going to have to collect and sort through them.” He noted that the ideas fall into four broad areas
14 (funding, legislation, regulation, and policy), and said that the FDA would have to sort through the
15 recommendations in each area in order to develop its own recommendations for action.

16
17 One participant wondered whether ICD device failures have been broken down by manufacturer
18 and model. “If so,” he asked, “are there any recommendations for the appropriate course of
19 treatment in cases where a model may be more prone to failure?” In response, a panelist noted that
20 there have been no direct comparisons of manufacturers and models. He added that statistical
21 analyses are not possible when the data are broken up into small numbers.

22
23 Finally, a participant asked what recommendations were being made to ICD and pacemaker patients
24 who have been affected by recent recalls. “If you are suggesting that patients consult with their
25 treating physicians,” he said, “are you giving the physicians the information they need?” “We are
26 trying to provide data to physicians and patients as quickly as possible,” replied the FDA panelist,
27 who added that the data released to the public were, of course, redacted for proprietary and privacy
28 reasons.

29
30
31

1 **Post-Market Analysis and Reporting**

2
3
4 **Session Chair: Susan Gardner, PhD (FDA)**

5 **Session Moderator: Mark Carlson, MD, MA (Electrophysiologist)**

6
7 Dr. Susan Gardner provided a brief session overview. She noted that the aim of the session was to
8 look at post-market analysis to see how the FDA, industry, and other stakeholders could best
9 translate the data into useful information for physicians.

10 11 12 **The Panel**

13
14 **Presenters: Timothy Ulatowski (FDA)**

15 **Kathy Lundberg (Guidant)**

16 **William Midgette (Electronics Engineer)**

17 **Michael Barber, MD, PhD (Electrophysiologist)**

18
19
20 **Timothy Ulatowski**

21 **—Post-Market Analysis and Reporting: The FDA Perspective**

22
23 Mr. Timothy Ulatowski, FDA’s director of compliance, Center for Devices and Radiological Health,
24 explained that his office deals with inspections and takes enforcement action when people don’t do
25 things right. His remarks focused on three areas:

- 26
27
- the continuum of quality assurance;
 - FDA and manufacturer responsibilities to ensure continued safety and effectiveness; and
 - reflections on avenues for industry and FDA cooperation.
- 28
29
30

31 Regarding the continuum of quality assurance, Mr. Ulatowski explained that there were control
32 points in the regulations to identify and correct mishaps, including preventive actions and
33 corrections and removals. He noted that risk management lies at the core of the quality system. “The
34 message,” said Mr. Ulatowski, “is that at the core of all these systems is the importance of creating,
35 controlling, and managing all these systems so they work.”

36
37 Next, Mr. Ulatowski noted that both industry and the FDA bear certain responsibilities for ensuring
38 continued device safety and effectiveness. Industry’s responsibilities include a management
39 commitment to quality; control of processes and products; analyzing signals, investigating non-
40 conformance, identifying and validating action, implementing action, disseminating information, and
41 incorporating changes; reporting corrections and removals to reduce risk to health (or to remedy a
42 violation); and adverse effect reporting.

43
44 “FDA’s responsibilities,” continued Mr. Ulatowski, “include evaluating and rendering conclusions
45 on the safety and effectiveness or equivalence of devices that require such action before marketing;
46 monitoring compliance with regulations; identifying post-market problems from the signals; and
47 ensuring appropriate and timely corrective and preventive action.” He noted that only certain

1 changes to products require FDA approval or clearance. Discussing the threshold for FDA control
2 and action, Ulatowski noted that market withdrawals are not reported and that most recalls are
3 voluntary. “The agency generally assesses the manufacturer’s recall analyses and actions after the
4 fact,” he said.

5
6 Mr. Ulatowski noted that there are areas of contention between FDA and industry, and that these
7 often center around the scope and root causes of a problem. Finally, he discussed the importance of
8 cooperation between the FDA and industry. “Such cooperation,” said Mr. Ulatowski, “has proven
9 to be the quickest and most reliable means to remove potentially dangerous products from the
10 market.”

11
12 In conclusion, Mr. Ulatowski said there was room for improvement. He said there needs to be more
13 effective communication between industry and district staff; a quick and effective process to identify
14 and correct problems in the quality system and reporting mechanisms; and better feedback to
15 improve product quality.

16
17 **Kathy Lundberg**
18 **—Post-Market Analysis and Reporting: An Industry Perspective**

19
20 Ms. Kathy Lundberg stressed that there are a number of ongoing processes that take place once a
21 product has been released, and she began her remarks with a focus on the continuous improvement
22 process for design and manufacturing processes. She noted that multilayer test strategies assure that
23 many areas of a product are tested multiple times, providing redundancy throughout the building of
24 a device. Ms. Lundberg also stressed that there have been improvements in battery longevity and
25 overall reliability in successive generations of ICDs.

26
27 Next, Ms. Lundberg noted that manufacturers use several risk assessment tools to consider the
28 likelihood and severity of problems at various points throughout the lifecycle of a product. She
29 stressed that risk assessment is critical when signals from Corrective and Preventive Action (CAPA)
30 systems are received. The flow starts, she explained, with either an internal signal or a signal from
31 the field. After that, the root cause is analyzed, trend identification is undertaken, and an analysis of
32 trend information is performed. She noted that risks are continually assessed and that corrective
33 action is taken when needed. Ms. Lundberg added that manufacturers also draw upon data from
34 other sources.

35
36 Ms. Lundberg said that a key component of risk assessment is the health hazard evaluation. The
37 health hazard evaluation is used not only to assess device failure rates, she explained, but also to
38 gather information on when a device fails, how the failure manifests clinically, and what can be done
39 to mitigate the risk of failures (e.g., reprogramming or more frequent follow-up).

40
41 Ms. Lundberg also highlighted current industry reporting requirements to the FDA and outlined the
42 industry’s guiding principles for communicating information. She said that

- 43
44
- 45 • actions should be taken when it helps physicians provide the most beneficial treatment for
 - 46 • actions and decisions must be based on sound engineering and medical principles; and
 - 47 • actions must comply with applicable laws and regulations.

1
2 Finally, Ms. Lundberg noted that a key challenge is that communications to physicians often result in
3 recalls. “So what other types of communications should be considered?” she asked. Ms. Lundberg
4 offered several suggestions, including developing standardized product performance reports;
5 establishing concise definitions for use with each type of communication; and working to establish
6 useful criteria for triggering additional special communications to benefit patient outcomes.
7

8 **William Midgette**
9 **—A Perspective on Medical Device Risk Management**

10
11 Mr. William Midgette discussed risk management communications and how to best present
12 information to physicians so they can make case-by-case decisions. He said there were two common
13 approaches to risk management (bottom-up and top-down), and then briefly discussed fault-tree
14 analysis and risk control measures. Mr. Midgette also discussed hazardous situations, and said the
15 factors affecting intervention in a hazardous situation include the control measures in place (e.g.,
16 operator training, appropriate instructions, the availability of an automated external defibrillator at
17 home, and access to emergency care). Finally, Mr. Midgette noted the need to bring together causes,
18 risk factors, and information on hazardous situations to provide a meaningful way to guide
19 physicians.
20

21 **Michael Barber, MD, PhD**
22 **—Notification of Device Failure: A Physicians’ Survey**

23
24 Dr. Michael Barber discussed the findings of a survey about when physicians want to be notified of
25 device failures and the information they want to have. The survey was sent to over 100
26 electrophysiologists who are large volume implanters, and 37 responded.
27

28 Dr. Barber noted that regardless of the type of device, most physicians (both in private practice and
29 in academia) indicated a relatively high threshold for notification in many respondents, but there was
30 a wide range of levels of notification listed, with some physicians wanting to know if the problem
31 occurs at a rate of 1 in 5000, whereas others didn’t want to be informed unless the occurrence rate is
32 1 in 1000. In addition, he noted that survey respondents made little distinction between a Class 1
33 and a Class 2 recall. As a result, he concluded that either the type of device malfunction was less
34 important to physicians than the rate of the device malfunction or that many physicians do not
35 know the difference between Class 1 and Class 2 recall.
36
37

38 **Panel Discussion**

39 Moderator: Mark Carlson, MD (Electrophysiologist)
40 Expert Panel: Michael Barber, MD, PhD (Electrophysiologist)
41 Jon Brumbaugh (Biotronik)
42 Gabe Kohanyi (St. Jude Medical)
43 William Midgette (Electronics Engineer)
44 Eric Prystowsky, MD (Electrophysiologist)
45 Christopher Simpson, MD (Electrophysiologist, Canada)
46 Timothy Ulatowski (FDA)
47

1 The questions below came from the moderator and the audience.

2
3 Q. Why do you think Dr. Barber’s survey reported the same threshold for receiving information
4 regardless of the severity of the device failure rate?

5
6 A. “I think that part of the issue is the confusion over what constitutes a recall,” said one panelist,
7 “and that fact that physicians receive no guidance from industry, the FDA, or their medical
8 societies. When physicians ask what they’re supposed to do next, he said, and they are just told
9 to use their judgment.” The FDA panelist acknowledged that the terminology can be
10 problematic to physicians and patients alike. “We are trying to start to translate regulatory-speak
11 into plain language,” he said, “and to make the point that not all recalls mean the device needs to
12 be sent back.”

13
14 Q. Is there a potential for standardization?

15
16 A. “The problem,” replied one panelist, “is that individual physicians practice in very different ways.
17 He added that there were also risks associated with explanting devices.”

18
19 Q. “What additional information do you believe the physician community would find useful?

20
21 A. “There is an industry-wide belief that it is very important to communicate timely and meaningful
22 safety information,” said one panelist, who added that the industry would like to hear from
23 physicians and patients as to what information they would like to have. She also noted that
24 manufacturers were working through AdvaMed to standardize existing information. In addition,
25 she said that there was an opportunity to standardize the performance reports being issued by
26 companies so that physicians and patients can compare apples to apples. A second panelist
27 expressed concern about voluntary recalls. “Physicians view this as a failure in that system,” he
28 said, “and I’m concerned about when physicians get the information they need to manage
29 problems and best ensure patient safety.” Asked to respond to the concern, the FDA panelist
30 said that the manufacturer is in the best, most-immediate position to understand a problem and
31 take action. The interesting thing is how we, as physicians, perceive this issue, said the first
32 panelist. “As long as we all have the same information,” he said, it is alright if make different
33 decisions and respond differently to that information.” “The problem,” stressed another panelist,
34 “is getting accurate and timely information.”

35
36 Q. How could the industry and the FDA better work together to figure out whether an incident is
37 an isolated failure or part of something more systematic?

38
39 A. “The key is to have complete data,” replied one panelist. “Once the company has figured out
40 that it has something that comes up repeatedly and doesn’t fit its usual pattern—they have a
41 handle on it.” “The problem,” he continued, “is that every company has its own system for
42 deciding when to communicate more broadly.” “Physicians want to be a part of that process,” he
43 said.

44
45 Q. How do the FDA and industry know when they have a device problem on their hands rather
46 than a programming problem (e.g., something that might not be optimally set for an individual
47 patient)?

1 A. “The data are fully analyzed,” replied one panelist. “Companies are always looking at incidents
2 and putting those incidents in context.” “When we have doubts,” she continued, “we bring in
3 regulatory experts to help us with our analysis.” She added that companies also receive audit data
4 from the FDA and international regulators. At the end of the day, she acknowledged that what
5 probably matters most is whether patients and their physicians are satisfied. A second participant
6 added that a significant amount of information is collected from individual ICDs and
7 pacemakers. “We get a lot of information from physicians upon return of a device,” he said.
8

9 Q. Will gaps in post-market analysis still exist if the FDA and the industry do everything that is
10 required? Are there opportunities for improvements?
11

12 A. “There is room for improvement,” said the FDA panelist. “The FDA has discovered gaps
13 through lessons learned from past recalls,” he said. The panelist added that decisions are all over
14 the map on risk analysis, and stressed that continuous process improvement is necessary. One
15 industry representative, however, said he wasn’t sure there were any gaps in the system.
16
17

18 **Open Dialogue**

19
20 One participant said that everyone seems to recognize that these medical devices save lives and that
21 the present system of surveillance and reporting has some problems associated with it. He
22 wondered, however, whether the FDA has adequate resources to address problems and whether the
23 Heart Rhythm Society and others should form a task force to carry ideas forward. Finally, he asked
24 “who guards the guards?”—and whether there should be an independent analysis of the data. A
25 panelist also asked a similar question concerning industry self-monitoring.
26

27 The FDA panelist noted that the agency does the best it can with the resources it has (and focuses
28 on high-risk areas to try to identify problems before they occur). A second panelist said that it might
29 be feasible to develop an oversight committee.
30

31 “One of the things I’d like to see come out of this meeting is what the expected failure rate should
32 be,” said one participant, who suggested that the survey results imply that physicians need to better
33 understand the boundaries in order to decide whether they need to replace a device. In response,
34 one panelist noted that the rate of incidents is meaningless unless put into the context of a specific
35 patient. A rate of 1 in 5000 of an incident with little clinical significance or outcome is different from
36 a rate of 1 in 5000 where the incident is a major failure with negative outcomes.
37

38 “There appear to be control systems in place,” said another participant, “but are they the same in
39 every company?” “And are these control systems audited?” In response, the FDA panelist noted
40 that, while the agency’s quality system regulation is simply stated, the devil is in the details as each
41 company must tailor the controls to its own manufacturing processes. He added that there were
42 both similarities and differences in how companies with like products operate and the decisions they
43 make. We all have the same fourteen-page FDA guidance, added a second panelist. But how we
44 comply with this will vary from one company to another.
45

46 One participant noted that, under HIPAA, it has become more difficult for companies to get patient
47 and adverse event information. “From a manufacturing point of view,” he said, “we need guidance

1 on whether you want us to provide trend analysis data in percentages or raw numbers.”
2 Standardization methods for reporting these data are needed.

3
4 Another participant returned to the survey results and said that one explanation for them is that
5 there is a very poor understanding of the issues because everyone is operating in new territory. He
6 noted that there are currently three major repositories of information (data held by industry; data
7 held at FDA; and clinical data held by physicians). Physicians need to make decisions for unaffected
8 patients using the data from affected patients, he said. He added that physicians need practice
9 guidelines but cannot develop them until the recall process is better understood. “We need to get the
10 information flowing,” he concluded. In response, one panelist noted that the Heart Rhythm Society
11 would be convening a workgroup on physician guidelines.

12
13 There were several additional questions on the topic of monitoring and whether it was appropriate
14 for industry to be primarily responsible for this. There were also questions about the
15 appropriateness of establishing an independent organization, including one question on whether
16 there was a role for an entity analogous to Underwriters Laboratories.

17
18 “I would like to see some standardization,” replied one panelist, “so I can stop trying to wade
19 through volumes of data.” He added that he wanted to see a three or four-page report that cuts
20 through to the crux of the data.

21
22 In response to a comment about the infeasibility of notifying physicians and patients after every
23 incident, one panelist noted that the problem for physicians comes down to where a company sets
24 its bar. He said that while a company may not be willfully selling a defective device, it may just not
25 have reached its threshold for action. The issue, he said, is where that bar should be and who
26 decides that question.

27
28 A physician’s need for information is equivalent whether you’re talking about a Class 1 or a Class 2
29 recall, observed one participant. It’s our actions that might differ. He noted that there was a
30 definition problem between the actions of physicians and the device industry. Each needs to
31 document their actions in a standardized method. In response, one panelist noted that there may be
32 a role for the professional societies in this arena.

1 **The Role of External Databases in Post-Market Surveillance**

2
3
4 **Session Chair: Stephen Hammill, MD (Electrophysiologist)**

5
6
7 **The Panel**

8
9 **Presenters: David Malenka, MD (Associate Professor of Medicine at Dartmouth Medical**
10 **School)**

11
12
13 **David Malenka**

14 **—The Role of External Databases in Post-Marketing Surveillance**

15
16 Dr. David Malenka discussed the value of incorporating administrative (claims) data from various
17 sources into post-market surveillance. He listed some of the potential sources of administrative data,
18 including the Centers for Medicare and Medicaid Services (CMS), the Veterans Administration, and
19 payers. Managed care organizations also collect both administrative and clinical data.

20
21 “Administrative claims data have a number of advantages for post-market surveillance,” said Dr.
22 Malenka. This includes the fact that the data are routinely collected (so there are no added collection
23 costs). The data also cover virtually the entire population of patients and providers, and it is tied to
24 reimbursement. “Most importantly,” he said, “administrative claims data include unique patient
25 identifiers.” Dr. Malenka noted that this allows episodes of care to be linked for complete follow-up.

26
27 “Hospital and physician claims data are also very useful,” he said. Dr. Malenka explained that
28 hospital claims data include unique patient and hospital identification, dates of admission and
29 discharge, admitting diagnosis and acuity, procedures performed, medical diagnosis, discharge status,
30 and discharge destination. “Physician claims data,” he said, “include unique patient and physician
31 identification, surgical and diagnostic procedures, date of service, and diagnosis for which a service
32 was performed.”

33
34 “The implications for post-market surveillance,” said Dr. Malenka, “is that all patients receiving a
35 device could be identified. He added that all billable events could be temporally related to the date a
36 device was implanted.” Dr. Malenka also noted the unique identifiers make locating additional
37 clinical data easy and reliable, and suggested that the Quality Information Organizations are a ready-
38 made vehicle for this task.

39
40 Turning specifically to ICDs, Dr. Malenka noted that claims data provide critical information about
41 use, who is receiving a device (i.e., appropriateness), short-term outcomes (including in-hospital
42 adverse events), and long-term outcomes (including survival).

1 **Panelist Remarks**

2 Moderator: Stephen Hammill, MD (Electrophysiologist)

3 Expert Panel: Dale DeVries (Guidant)

4 Robert Hauser, MD (Electrophysiologist)

5 David Malenka, MD (Associate Professor of Medicine at Dartmouth Medical
6 School)

7 Thomas Gross, MD, MPH (FDA)

8 Lukas Kappenberger, MD (Electrophysiologist, Switzerland)

9 Steve Phurrough, MD, MPA (Center for Medicare and Medicaid Services)

10
11
12 **Dr. Steve Phurrough** discussed the agency’s (CMS) efforts to develop a national data registry that
13 brings together information from multiple data sources. The first iteration was rolled out in January
14 2005, and CMS hopes to transition soon to the next version. Once the data are transferred, he said,
15 then hospitals can start to send data to the new registry.

16
17 Dr. Phurrough noted that a separate Medicaid database includes information on when a patient dies.
18 This can be merged with other data from the registry, he said, to try to answer the question of why a
19 patient died.

20
21 Dr. Phurrough also stressed that claims data can provide useful information. For this to work, he
22 said, it must be transparent and as open as possible. Finally, he noted that CMS has talked to the
23 industry about the possibility of incorporating device firing data into the National Data Registry.

24
25 **Dr. Robert Hauser** said, the Multicenter Registry gathers pacemaker and ICD pulse generator and
26 lead failure data from its participating centers. He said that while the average life of a defibrillator is
27 4.1 years, only 73 percent of ICDs function for more than three years. He indicated that most are
28 replaced due to battery depletion; another 10 percent are replaced due to recalls. Dr. Hauser said he
29 believed the registry has been successful. At the same time, he emphasized the need for more
30 participating centers.

31
32 **Dr. Lukas Kappenberger** offered a brief international perspective. He said that science tells us
33 what we can do; guidelines what we should do; and registries what we are actually doing. He noted
34 that the incentives for undertaking science and creating guidelines are clear, but that there is less
35 incentive for physicians to participate in registries. “The best European registry,” he said, “is the
36 Danish one because physicians must comply before they receive reimbursement.”

37
38 **Mr. Dale DeVries** offered an industry perspective on registries. He contended that several elements
39 must be in place for a registry to be successful. “First,” he said, “there must be a benefit for the
40 people who are contributing to the registry. Second, there must be a clearer definition of the end
41 value.” “Third,” said Mr. DeVries, “it is critical to improve the ease of data collection.” “We need to
42 collect more information on a patient at the time of implantation,” he said. “But we also want the
43 ability to collect information over time in real time. We want to get to the issue of root causes as
44 quickly as possible,” said Mr. DeVries, “so we need good data as soon as possible.”

45
46 Next, Mr. DeVries turned his focus to the National Data Registry. Referring to the flow chart
47 presented by Steve Phurrough, he indicated that there were opportunities for device manufacturing

1 companies to provide data. The key issue, he said, is standardization. Mr. Devries stressed the need
2 for interoperability.

3
4 In conclusion, Mr. DeVries warned conference participants about the danger of being overwhelmed
5 by too much data. The challenge is to get good data, he said, and to be able to translate that data to
6 make decisions for a patient.

7
8
9

1 **Risk-Benefit Communications**

2
3
4 **Session Chair: Leslie Saxon, MD (Electrophysiologist)**
5 **Session Moderator: Michael Cain, MD (Electrophysiologist)**
6
7

8 **The Panel**

9
10 **Presenters: Megan Moynahan (FDA)**
11 **Joseph Smith, MD, PhD (Guidant)**
12 **Leslie Saxon, MD (Electrophysiologist)**
13 **Michael Barber, MD, PhD (Electrophysiologist)**
14 **David Ropeik (Risk and Health Communication Expert)**
15
16

17 **Megan Moynahan**
18 **—Risk-Benefit Communication: The FDA Perspective**
19

20 Ms. Megan Moynahan opened her remarks on the FDA’s public communications in the post-market
21 period by acknowledging that people need to balance advice about risks and benefits. “Recalls,” she
22 said, “are not intended to convey balance.” “The ‘take-away’ from a recall,” she said, “is that one
23 size fits most.” Ms. Moynihan added that while recalls are intended to give instructions to physicians
24 on what to do with the recalled product, they offer no guidance on what do to with a product that is
25 still inside a person.

26
27 “The Dear Doctor letter,” Ms. Moynahan said, “provides more information.” “Much of that data
28 comes from the health hazard evaluation,” she said, “including
29

- 30
- 31 • a description of deaths and/or injuries that have already occurred;
 - 32 • a discussion of existing conditions that could contribute to the hazard;
 - 33 • an assessment of the hazard to various segments of the population (e.g., children, older
34 Americans);
 - 35 • the degree of severity of injury;
 - 36 • the likelihood of occurrence of the hazard; and
 - 37 • the immediate or long-range consequences of the hazard.”

38 There is also usually a recommendations section. Ms. Moynahan noted that this section generally
39 provides guidance on how to tell whether or not a patient’s device has failed (if such a test is
40 available) and what to do for those patients whose devices have already failed. “The problem,” she
41 said, “is that recall notifications do not, as currently drafted, adequately inform physicians of what to
42 do in cases where at-risk devices have not failed.”
43

44 “Pacemakers and ICDs are unique for several reasons,” said Ms. Moynahan. “They are lifesaving
45 products, and catastrophic failure is often causally linked to a patient’s death. They are also
46 permanent implants (which makes it easier to calculate patient exposure).” Ms. Moynahan added

1 that because these devices are active implants (they include electronic and computer-like circuitry),
2 software problems themselves can be a huge source of potential failure modes, which fortunately
3 can be easily fixed with reprogramming. “In sum,” she said, “pacemakers and ICDs have unique
4 characteristics that shape the recall process and should shape the content of recall notifications.”
5

6 **Joseph Smith, MD, PhD**

7 **—Risk-Benefit Communication: An Industry Perspective**

8

9 Dr. Joseph Smith discussed the continuum of communications to patients, to the physician
10 community, and to regulatory agencies. He noted that communications to patients have historically
11 come primarily from their physicians, although there is also information available from
12 manufacturers and from the FDA.
13

14 Dr. Smith outlined the guiding principles for product advisory communication. These include
15

- 16 • patients come first;
- 17 • actions and decisions should be based on sound engineering and medical principles;
- 18 • communications should be initiated when it benefits patients or physicians; and
- 19 • actions must comply with applicable laws and regulations.
20

21 Dr. Smith also noted that there are four key communications challenges. These include the role of
22 continuous quality improvements; the fact that components and processes integral to the building of
23 an ICD are well characterized with a low likelihood of failures; the distinction between *reporting* to
24 FDA and *informing* through other channels (Dr. Smith said that, in practice, both occur
25 simultaneously); and consideration of unintended consequences. Dr. Smith stated, “returned
26 product analysis typically reveals that for any individual device model, clusters of repetitive failure
27 modes predominate in distinction to each failure being unique. Even with reliability in excess of
28 99% over a device lifetime with tens of thousands of people being treated by a single device model,
29 hundreds of failures could still occur.” He reflected, “should actual numbers or percentages drive
30 advisory communication?” Dr. Smith continued, “actual performance data as presented earlier by
31 Dr. Maisel (during session one) and current understanding of component reliability, engineering
32 design and production may yield an estimated failure rate of a typical ICD of nearly 1% over the
33 device’s life-time. It is the responsibility of our efforts together to best understand how to compare
34 the known and low rates from an advisory population with what may be numerically greater rates for
35 total aggregate failure of the replacement device.”
36

37 Wrapping up his remarks, Dr. Smith stressed that both physicians and patients need to understand
38 the risks and benefits of device therapy. In addition, Smith noted that communication of device
39 performance today occurs across a broad spectrum—from initial labeling and instructions for use, to
40 aggregate performance measures as published in periodic product performance publications, to peer-
41 reviewed publications, to publicly available reports of individual device failures, to industry-initiated
42 product advisory communications.
43
44
45
46
47

1 **Leslie Saxon, MD**
2 **—A Standardized Device Advisory Communication for Physicians**

3
4 Dr. Leslie Saxon began her remarks by noting that current industry and FDA advisory
5 communications vary considerably, and she noted that this reflects the unique nature of each
6 advisory and the medical, legal, and patient safety issues inherent in an implanted device advisory.
7 “Because these advisories vary so much,” she said, “it is very difficult for physicians to extract
8 meaningful data.”
9

10 Dr. Saxon’s presentation focused on a model for a standardized advisory communication to
11 physicians to supplement industry and FDA communications. “This has potential benefits,” she
12 said:

- 13
- 14 • it can provide physicians with concise clinical information to facilitate rational patient
 - 15 communication and clinical action that is better informed;
 - 16 • it can objectify information; and
 - 17 • it can be easily referenced and subject to updates.
- 18

19 “There are also some potential risks,” said Dr. Saxon, “including the fact that more complexity
20 requires more oversight.” She added that there was also a danger that condensing everything into a
21 single format might leave out key information that should be communicated. Dr. Saxon also noted
22 that there might be legal implications.
23

24 Dr. Saxon took conference participants through an example of how such a standardized form might
25 be shaped—and the data that it might contain. She then summed up her remarks by stressing that
26 standardized, physician advisory data should be considered as a supplement to more comprehensive
27 individualized industry and more generic FDA communications. “Such supplemental information,”
28 said Dr. Saxon, “will help provide a clearer clinical data set to inform physician action on a
29 continuous basis.”
30

31 **Michael Barber, MD, PhD**
32 **—Benefits of Standardized Device Advisory Communication to Patients**

33
34 While Dr. Saxon’s presentation focused on what physicians need to know, Dr. Barber’s remarks
35 focused on what patients want to know. “Patients,” he said, “want to be appropriately, truthfully,
36 and completely informed.” They don’t want to be misinformed, over-informed, or under-informed.
37 “Most important,” said Dr. Barber, “they want to hear information directly from both their device
38 manufacturers and their physicians.”
39

40 Dr. Barber suggested that one solution for informing patients would be to create a Dear Patient
41 letter that a company can send to patients so each feels as though he or she is getting the same
42 information as everyone else. “The letter,” he said, “should be similar in content to those sent to
43 physicians, but should focus on the generalities and issues surrounding the specific device.” Dr.
44 Barber added that the letter should outline the extent and severity of the problem, but leave out the
45 specifics. “Discussions about specifics, including possible courses of action, are best left to the
46 physician,” he concluded.
47

1 **David Ropeik**
2 **—Risk Perception and Communication**

3
4 Mr. David Ropeik opened his remarks by saying that risk communication should be based on the
5 way that people *feel* about a risk. If information is going to resonate and help patients make the
6 healthiest choices for themselves, he said, it needs to address how people feel.

7
8 Mr. Ropeik said that studies suggest that risks have different characteristics. “We have to live our
9 lives every day,” he said, “and we are always taking risks.” He added that, as a result, it is naïve and
10 counterproductive to think that people will make fact-based, risk analyses. Rather, he said, decisions
11 are filtered through risk characteristics—and risk is perceived differently when it is personal.

12
13 “Information gives people a sense of control,” said Mr. Ropeik, “which is what people want to be
14 able to manage their risk.” He added that trust is an important component of risk management.
15 With information and trust, he said, physicians and their patients will make more informed choices.

16
17 **Panel Discussion**

18 Moderator: Michael Cain, MD (Electrophysiologist)
19 Expert Panel: Susan Alpert, MD, PhD (Medtronic)
20 Kenneth Ellenbogen, MD (Electrophysiologist)
21 Megan Moynahan (FDA)
22 Leslie Saxon, MD (Electrophysiologist)
23 Richard Brown (Patient)
24 Lukas Kappenberger, MD (Electrophysiologist, Switzerland)
25 David Ropeik (Risk and Health Communication Expert)

26
27
28 The questions below came from the moderator and the audience.

29
30 Q. Does the current system hinder less-formal types of communication?

31
32 A. In response, one panelist noted that today’s litigious environment places constraints on
33 everyone’s ability to communicate information. He noted that, from a regulatory perspective, the
34 FDA would like to be able to communicate with physicians without raising everything to the
35 level of a recall. A second panelist noted that there is nothing in the regulations that mandates
36 that every communication be a recall. A third panelist suggested that it is possible to
37 communicate more efficiently without increasing legal risks. “The challenge,” he said, “is to
38 communicate more effectively. As we learn more about a problem, our risk-benefit calculation
39 might change, commented another panelist. He stressed the need for a timetable, pointing out
40 that a recall is a dynamic, ongoing process.” We don’t just want to be told there’s a problem,
41 here’s what we know, and good luck,” he said. “Timing is a challenge,” said another panelist.
42 “You make a decision to communicate, and then the timing is important.” “This is an evolving
43 process,” he added, “and physicians want to be able to communicate directly with their patients
44 on high-risk issues.”

1 Q. From a patient’s point of view, would a standardized form be desirable?
2

3 A. “Yes,” replied one panelist, who said that Dr. Barber had gotten it “absolutely right” regarding
4 what patients want to know. “The most important thing, he said, is that patients want to hear
5 information from their physician.” “That’s where the level of trust exists,” he said. The panelist
6 added that while physician-initiated communication is the ideal scenario, the reality is that
7 patients get recall and advisory information from multiple sources (including the government,
8 physicians, the industry, and the press). “Standardization has to provide enough information for
9 most people to work with,” said another panelist. “The issue isn’t really standardization *per se*,”
10 he said, “but how we address the nuances so that the communication around each issue is
11 complete enough for patients to make informed decisions.” One panelist suggested that a
12 guidance document should be developed to spell out what the recall notification should look like
13 with input from industry, AdvaMed, and the Heart Rhythm Society. Another stressed that
14 anything that could make future advisories easier to interpret would be of value. A third stressed
15 the need to test any risk communications in advance. “An untested risk communication should
16 no more be released to the public than an untested device or drug,” he said. Finally, one panelist
17 said that while he believed that it was possible to develop a Dear Doctor letter, he was less
18 certain that the approach was appropriate for patients. Another panelist added that any Dear
19 Patient letter should originate with the physician and not the FDA.
20

21 Q. What is the impact on a patient when he or she reads or hears through the news that there is
22 something wrong? How do the media play into this?
23

24 A. In response, one panelist said that he thought it was important to get information, even negative
25 information, out. “The problem, he added, is that the information coming out is often two or
26 three years old—and this raises concerns among patients about why the information was not
27 released sooner.” “We need to be more transparent about getting information out,” he
28 concluded.
29

31 Open Dialogue 32

33 One participant said that while it was very important to look at how patients are alerted overall, not
34 just in a single advisory. He wondered whether there was perhaps a Web site where patients could
35 get additional information as it becomes available.
36

37 “This discussion is really about risk versus risk (not risk versus no risk),” commented another
38 participant. “How does that play into the discussions that physicians have with their patients?” he
39 asked. In response, one panelist noted that a patient should, whether possible, have complete
40 information as soon as possible. All the risks should be stated up front to eliminate the element of
41 surprise and to avoid headlines, he said. A second panelist added that the challenge is that that the
42 risk-benefit calculus is very different for someone who is 43 as opposed to 73, or someone with
43 children versus someone without kids. A third panelist also noted that there is also a risk associated
44 with taking action (i.e., removing a device).
45

1 “Transparency and honesty are key,” said another participant. “We are here today because of a lack
2 of transparency in the past,” she said, adding that patients need the industry and physicians to be
3 honest and to present accurate and complete information.

4
5 Recalls present particular challenges for hospitals, commented one participant. Part of the issue is
6 figuring out when they are affected. He wondered whether something could be done to make it
7 easier for manufacturers to get out detailed information along with the standardized form.

8
9 “We really need to consider risks to the entire community when talking about standardized
10 communications,” said another participant, “and I’m not sure how to do this with letters.” “A
11 physician needs to talk to his patients one on one.” “Patients are reluctant to have defibrillators
12 implanted,” he said, “and we need to communicate with the population that needs these devices.”

13
14 “Do we need to reestablish trust over device issues?” asked the moderator. “Trust is a paramount
15 issue, replied one panelist.”

16
17 The device industry should be able to withstand this controversy, commented a participant, because
18 the therapy is very effective. “We are clearly fractured, however, on our opinions about the nuances
19 of recent communications,” he added.

20
21 “If trust weren’t damaged, we wouldn’t be in the room,” concluded one panelist, “so it behooves
22 everyone to find out how much it has been damaged, why perceptions have been shifted, and how
23 to fix them.”

24
25
26

1 What Patients Need and Want to Know From Their Physicians

2
3
4 **Session Chair: Michael Cain, MD (Electrophysiologist)**

5 **Session Moderator: Mark Carlson, MD, MA (Electrophysiologist)**

6 7 8 **The Panel**

9
10 **Presenters: LCDR Brian Lewis, MD (US Public Health Service and FDA)**

11 **Tim Samsel (Medtronic)**

12 **Eric Prystowsky, MD (Electrophysiologist)**

13
14
15 **LCMR Brian Lewis, MD, USPHS**

16 **—What Patients Need and Want to Know From Their Physicians: An FDA Perspective**

17
18 Dr. Brian Lewis began his remarks by stressing that the FDA recognizes and supports an individual
19 patient’s right to make informed decisions and the importance of expert physician advice. He added
20 that the FDA also recognizes the need for timely, accurate, updated, and complete information that
21 is clearly communicated. Dr. Lewis said that each patient’s needs determine what action should be
22 taken, and he stressed that, within the context of a single recall, one patient may have very different
23 needs from another.

24
25 Dr. Lewis noted that while the most critical or timely device functions need the most attention when
26 considering all recall patients *as a group*, the care of individual patients is considerably more complex.

27
28 “From an individual perspective,” said Dr. Lewis, “patients make informed decisions by drawing
29 upon their own experiences, asking questions, and enlisting the help of their physicians.” “They also
30 consider what they have learned about treatment risks, benefits, and options,” said Dr. Lewis, “and
31 they ask, ‘what would the doctor do if he or she were me?’” “Most important,” he said, “informed
32 decision making requires clear communications and a good understanding of both the issues and
33 available options.”

34
35 “While the FDA’s informed decision-making process is similar,” said Dr. Lewis, “managing care is
36 different from managing a recall.” Dr. Lewis pointed out that care is individualized, episodic, fluid,
37 ongoing, and evolving, and that individuals approach different issues differently. He added that
38 implants are long-term, so the calculation on what to do involves the fact that removal has its own
39 risks and complications.

40
41 “Recalls must address all affected individuals,” said Dr. Lewis, “so it is a real challenge to recognize
42 that individuals need widely varying information.” Using the Accufix Lead recall as an example, Dr.
43 Lewis cited three lessons learned. He said that the recall showed that not all recall devices require
44 removal and that removal may be associated with its own risks. Finally, Dr. Lewis, said, the Accufix
45 Lead recall case showed that there is no substitute for long-term follow-up data.

1
2 **Tim Samsel**

3 **— What Patients Need and Want to Know From Their Physicians: An Industry Perspective**

4
5 Mr. Tim Samsel said that the industry has three key responsibilities:

- 6
7 • to provide physicians with a clear description of the issue, patient risks, and options for
8 patient management;
9 • to provide a list of affected devices and patients to facilitate timely patient communications;
10 and
11 • to provide support for physician and patient questions.

12
13 Mr. Samsel said that physicians have the primary responsibility to inform their affected patients
14 about device performance advisories. “The patient’s physician,” he said, “is in the best position to
15 explain the issue, any patient risk, and the best options for managing a patient’s care.” “As a result,
16 physicians in consultation with their patients can consider the individual patient’s medical history
17 and the relative risk of device replacement,” he said.

18
19 Next, Mr. Samsel listed the role of industry in developing and sending out advisories. These include

- 20
21 • developing communications to physicians, hospital administrators, and field representatives;
22 • formulating a coordinated communication plan;
23 • identifying affected devices and patients;
24 • creating lists of affected patients based on patient registration to be provided to affected
25 physicians;
26 • identifying and locating affected un-implanted devices that need to be returned to the
27 manufacturer (if applicable);
28 • contacting field management and representatives to educate them on the advisory so they
29 can support physician questions;
30 • communicating the advisory to FDA (if patient risk is involved); and
31 • delivering advisory letters and supporting materials to affected physicians.

32
33 Mr. Samsel also discussed industry follow-up activities and the role of technical support.

34
35 Finally, Mr. Samsel noted that there is fallout when a patient finds out about a recall from a source
36 other than his or her physician. As a result, he reiterated that it is important that patients are
37 informed first by physicians.

38
39 **Eric Prystowsky, MD**

40 **— What Patients Need and Want to Know From Their Physicians:**
41 **A Physician’s Perspective**

42
43 Dr. Eric Prystowsky briefly discussed the reasons physicians gave in the device recall survey for
44 explanting devices. He said that many physicians said they did so for patient safety; some did so at a
45 patient’s request.

1 Dr. Prystowsky also provided his perspective on appropriate patient communications and decision
2 making. He stressed that each patient is unique, and that it is important for a physician to review the
3 details of the device problem and the risks and benefits of observation versus device replacement.
4 Dr. Prystowsky concluded by stressing that physicians must give guidance to their patients, and he
5 said that guidance must be based on what the physician feels is the best course of action.
6
7

8 **Panel Discussion**

9 Moderator: Mark Carlson, MD (Electrophysiologist)

10 Expert Panel: Eric Fain, MD (St Jude Medical)

11 Ralph Hall (Associate Professor of Law at University of Minnesota)

12 Lisa Salberg (Patient)

13 John Sanders, MN,ARNP (Electrophysiology Nurse)

14 Christopher Simpson (Electrophysiologist, Canada)

15 Ron Yustein, MD (FDA)

16 Douglas Zipes (Electrophysiologist)
17
18

19 The questions below came from the moderator and the audience.
20

21 Q. We've heard what patients need to know, but what do patients want to know?
22

23 A. "As patients," said one panelist, "we want to hear from our physicians." "But that's not all," she
24 said, "We feel that we also have a relationship with the manufacturer." "If Daimler Chrysler can
25 send me a recall notice when there's a bolt loose in my car, then my manufacturer must too. We
26 also want to hear what the FDA has to say, she said, and have the information in a format that is
27 clear. The panelist added that there needs to be an up-front process to educate patients that
28 these devices are manmade and may fail."
29

30 Q. What changes could we make to implement these patient recommendations as we move
31 forward?
32

33 A. "A number of speakers have talked about communications changes," replied one panelist, who
34 contended that there would never be a system in which patients heard first from their physicians.
35 He pointed out, as one example, that most of the device companies are publicly traded and thus
36 have SCC reporting obligations. He also pointed to the explosion of communications
37 technologies (including blogs and message boards) and to cross-border communications. "As the
38 physician asks for and receives information," he continued, "the physician now has more
39 responsibility to use that information." "In the context of a recall," he said, "the physician has to
40 address both the affected and unaffected populations, because many patients may think they
41 have the model at issue and will be calling to check on the safety of their devices. Physicians also
42 need to put in place a formal process for identifying affected patients and communicating with
43 them in a logical manner." "Communication between a patient and a physician is absolutely
44 fundamental," said another panelist, who added that he believed that physicians should be the
45 first to communicate with patients (not the industry or the FDA). He also noted that it was
46 important for physicians to discuss the risk of device failure with patients at the time of implant,
47 and that establishing trust was paramount. "When communications should take place is a very

1 contentious issue,” said another panelist. He stressed that it was very important for physicians to
2 have access to data. From a risk management perspective, he said, this also reduces a patient’s
3 feeling of vulnerability. Another panelist suggested that guidelines for effective communications
4 be developed and tested prospectively.
5

6 Q. What is the international perspective on this?
7

8 A. “There are many areas where we can find commonality,” replied one panelist. “All physicians
9 want access to timely information in order to make informed decision for clients and to foster a
10 culture of trust,” he said. A second panelist noted that different countries have different
11 regulatory regimes and tolerances for risk. A third noted the need to establish an internationally
12 agreed-upon threshold for raising a red flag and a risk management assessment for all courses of
13 action. “Where there would be divergence,” he said, “is on how patients and physicians use this
14 information.” “Our goal should be to empower patients to make decisions,” he said, “and they
15 need information to accomplish this.”
16

17 Q. What can realistically be accomplished to bring about this type of notification?
18

19 A. One panelist noted that the main stakeholders (industry and the FDA) need to look at what
20 information each provides—and should provide—to physicians. A second panelist stressed the
21 need to do a better job at patient communications. “We need to be more transparent,” he said.
22 “From a consumer perspective,” replied another panelist, “the key is for the FDA to keep it
23 simple.” She offered two examples: a Web site where a patient could enter a device name and
24 serial number, and a toll-free number a patient could call to get information.
25

26 Q. What role do nurses and other non-physician practitioners serve?
27

28 A. “We are very much involved in contacting patients,” said a panelist who is a nurse
29 practitioner. “Non-physician practitioners are more than willing to discuss risks with
30 patients.” “Describing the level of risk and recommended actions is a complex issue
31 complicated by a patient’s fear of his/her device not functioning when it is needed.” “Part of
32 the problem,” he continued, “is that some patients, even when reassured that their device
33 has little chance of failing, would feel safer if their device was replaced.” “In addition,” he
34 said, “we look incompetent (and our patients are confused) when we call them more than
35 once for repeat recalls on the same device.”
36
37

38 Open Dialogue 39

40 “Is it really appropriate to tell people about every problem?” asked one participant, who wondered
41 what the trigger level should be and who should set it. “How do we decide who should decide when
42 a problem exists that requires action?” he asked.
43

44 “This is the central question today, replied one panelist, and a very difficult one to answer.” Not all
45 failures are the same, he said, and neither are all patients. He noted that, as a result, getting to a
46 standardized trigger level would be very difficult—and might not be appropriate. The panelist added
47 that there were risk management tools available, including an International Organization for

1 Standardization (ISO) standard. I think we need to get everyone together who understands these
2 tools and how they can be used, he said.

3
4 “I would feel better if there were a third party monitor that doesn’t have a financial motive,
5 commented another panelist.” A third panelist noted that there is an independent data safety
6 monitoring group responsible for pre-market approval studies. “I don’t see why post-market data
7 surveillance should be any different,” he said. He added that he believed that an independent group
8 was needed to monitor the data because companies have an inherent conflict of interest.

9
10 One participant reiterated the need to emphasize that communications should also focus on those
11 patients who do not currently have a device but could benefit from one. Another participant
12 suggested that it was time to look at next steps and said he believed that a standing task force on
13 ICD recalls should be created.

14
15 “In a recall, who pays for a procedure?” asked one participant. In response, a panelist said that a
16 patient has to go through his or her primary insurance company—and acknowledged that a number
17 of insurance companies are fighting such claims. “This is a major issue that needs to be addressed,”
18 he said, noting that people have maximum lifetime benefits on policies and don’t believe the
19 insurance company should be responsible for paying for these procedures.

20
21 One participant asked how trust could be restored. In response, one panelist stressed that the
22 industry, but not physicians, had lost the public trust. Another panelist noted that the conference
23 was a step in the right direction because it was providing an opportunity to make clear that patients
24 want to hear from everyone—the industry, physicians, and the FDA. A third panelist said a key
25 unresolved question is when information should flow and who makes that decision.

26
27 In response to a question about creating a safe harbor to incentivize industry to report post-market
28 data to the FDA, one panelist said that he did not believe the U.S. Congress was likely to enact a
29 safe harbor provision that eliminates corporate liability. A second panelist said he believed that the
30 industry tends to report more data rather than less to the FDA. “The question,” he said, “is when to
31 issue an overall advisory as opposed to reporting individual device failures to the FDA.” A third
32 panelist added that it was critical not to lose important information in a sea of data. Trust cannot be
33 created when a patient dies and then we hear there were problems with a device, said a fourth
34 panelist.

35
36 In response to a question about capturing data from other countries, one panelist said that the real
37 question is how to capture information that adds to the knowledge base. He said that most other
38 nations have much lower reporting rates and different definitions of what needs to be reported. He
39 said there were two key inputs: information from inside the company (testing and manufacturing
40 information), and physician information (which relies on voluntary reporting).

41
42 One participant noted that there appeared to be a variety of responses to recalls, notifications, and
43 advisories. “What are the implications of this variability,” he asked, “and what is the potential for
44 more predictability?”

45
46 Predictability will always be helpful, replied one panelist, but it is difficult to achieve because the
47 issues come down to types of devices, the patient populations, and the perceived risks. A second

1 panelist added that it was important to keep in mind that reasonable people can look at the same
2 information and come to different conclusions.
3
4
5

6 **Closing Remarks**

7
8 **Daniel Schultz, MD**

9 **—Closing Remarks: The FDA**

10
11 Dr. Daniel Schultz said that listening to conferees talk had strengthened his conviction that everyone
12 shares the goal of ensuring that physicians have access to these devices and to timely, useful
13 information. He said that there were some difficult issues to be resolved, including when and what
14 manufacturers should report to the FDA and physicians; how to ensure that physicians receive the
15 information they need to report to their patients; and how to determine what the threshold for
16 action should be.
17

18 “The answers,” said Dr. Schultz, “ultimately depends on trust and goodwill.” He added that while
19 consensus documents are helpful, the decisions will ultimately depend on the unique circumstances
20 of each event and the physician-patient relationship.
21

22 “The answer also depends on the perspective you come from,” he said. “At FDA, we have both
23 legal obligations and an educational role.” “The information we’ve learned today will be used to help
24 guide us in managing problems with heart devices in the future,” said Dr. Schultz. He said that while
25 it was too soon to answer specific questions on next steps, his agency was committed to continuing
26 the dialogue. Finally, he noted that everyone recognizes the benefits pacemakers and ICDs have
27 brought to patients and said that to do nothing is simply not tolerable.
28
29
30

31 **Mark Carlson, MD, MA**

32 **— Closing Remarks: The Conference Chair**

33
34 Dr. Mark Carlson said the conference was the first of many steps that should ultimately lead to a
35 better regulatory system for patients and other stakeholders. He said that Heart Rhythm Society
36 members provide care for patients who need ICDs and pacemakers and that the Society would not
37 waiver in its commitment to ensure that the devices are effective. He pledged that the Society would
38 continue to work with the industry and the FDA so that physicians and patients are appropriately
39 informed once problems occur and better able to make decisions.
40

41 Dr. Carlson noted that there appeared to be areas where consensus exists. He cited several, including
42 the need to have devices returned to the manufacturer; the need for improved surveillance in order
43 to get timely and appropriate data; and opportunities to standardize and simplify product reports.
44
45
46
47

1 **James Youngblood**
2 **—Closing Remarks: The Heart Rhythm Society**

3
4 Wrapping up the conference, Mr. James Youngblood thanked all the participants for their
5 unprecedented collaboration. In addition, he stressed that the Heart Rhythm Society was poised to
6 continue to take the lead and work to develop appropriate recommendations in order to ensure the
7 best possible patient care.
8
9

10 **GLOSSARY**

11
12 **Device Identification Standards**

13 A list of informatics standards that establish naming rules and conventions along with definitions for
14 medical devices.
15

16 **Medical Device Recalls**

17 A recall is a correction or removal of a product that is defective; could be a risk to health; or is in
18 violation of the U.S. Food and Drug Administration regulations. The risk to public health associated
19 with a recall is represented by three categories: Class I, II, and III. The FDA classifies recalls into
20 one of these three categories (source FDA website):

21 **Class I**

22 Class I recall is a situation in which there is a reasonable probability that the use of or
23 exposure to a product will cause serious adverse health consequences or death.

24 **Class II**

25 Class II recall is a situation in which use of or exposure to a product may cause temporary or
26 medically reversible adverse health consequences or where the probability of serious adverse
27 health consequences is remote.

28 **Class III**

29 Class III recall is a situation in which use of or exposure to a product is not likely to cause
30 adverse health consequences.
31

32 **Medical Device Safety Alerts or Notifications**

33 Safety Alerts are issued voluntarily by manufacturers and Notifications are issued at the request of
34 the FDA. Both inform health professionals or other appropriate persons or firms of a risk of
35 substantial harm from a medical device in commercial use. A medical device safety alert or
36 notification is issued in situations where a medical device may present an unreasonable risk of
37 substantial harm. In some cases these situations also are considered recalls.
38

39 **Participant**

40 Everyone present, except the active session panelists, during the Policy Conference.
41

42 **Signal**

43 A device-related adverse event or product problem. For use in a network, when an event and/or
44 problem is detected and shared within a network, such alerts when shared by others who have
45 experienced similar events will amplify or “signal” the adverse event or problem to the network.
46