

1 confused. Is this the total for the 14 hospitals or is this
2 an average for an individual hospital?

3 MR. WITTERS: I don't have that one right in front
4 of me.

5 MR. WILSON: What it is showing is, like, on adult
6 electrocardiogram, 200 to 600 patients, a pressure of 17 to
7 420, twelve sets of episodic data up to 500. Are those all-

8 -

9 MR. WITTERS: Which ones are you talking about,
10 the lower concurrent patient-use model or the upper chart?

11 MR. WILSON: What I am looking at says "current
12 telemetry monitoring needs."

13 MR. WITTERS: That is an average for the large
14 institutions.

15 MR. WILSON: So that would be on a single
16 hospital, then.

17 MR. WITTERS: Yes.

18 MR. WILSON: So we would multiply this times the
19 number of hospitals in the U.S.

20 MR. WITTERS: If you wanted to look at it that
21 way. But, remember, this is by region. It could be, like
22 she said, in New York, within a certain geographical region,
23 that that might be more problematic than others. But that
24 is an average by larger facilities some of which are
25 likelier to be the ones that specialize in heart type

1 treatments, cardiac type treatments.

2 The leader of that group is the head biomedical
3 engineer down at the Washington Hospital Center. So she was
4 very careful about looking at those particular institutions
5 that deal with these patients in large numbers. They may
6 have, down at the Washington Hospital Center, 200 to 300
7 right now.

8 DR. CARDELLA: I am curious about the AHA
9 proposal. If you look at this one slide, even if you spot
10 the need for 12 to 14 megahertz of band, the AHA has chosen
11 frequencies that put them smack in competition with digital
12 t.v., cellular phones and personal communicator systems all
13 of which are becoming more common.

14 Why didn't they just pick to be down by fm or am
15 radio or citizen's band where there is, apparently, much
16 more openness of the frequencies and not in development
17 area.

18 MR. WITTERS: Actually, that is not exactly
19 correct. These particular areas and frequencies are not in
20 competition with d.t.v. because Channel 37 is not allocated
21 for any d.t.v. and will not be because it is set aside for
22 radioastronomy.

23 The cell phones operate now in the PCS frequency
24 closer to 2 gigahertz and down below and around 1 gigahertz,
25 about 1000 megahertz, so they are not in competition. This

1 was chosen because these are the viable candidates that FCC
2 presented the group and it was analyzed for things like
3 propagation characteristics, determining how far it would be
4 from the central station through the kinds of things that
5 they typically have to go through, and one of the key areas
6 is that they wanted to maintain the ability to use a small
7 battery because they don't want to have to switch out
8 batteries every eight hours.

9 That becomes very expensive and very problematic
10 for them. Low power, short range; these are the frequencies
11 that seemed optimum in a list. The list that they did is
12 contained in the recommendations. There were at least ten
13 or twenty candidates.

14 DR. LIPOTI: I think it is quite remarkable that
15 FCC was take the AHA recommendations from January of '99 and
16 turn them into a notice of proposed rulemaking by August 2
17 of 1999. That is incredible and, Joanne, maybe you want to
18 model that here.

19 MR. WITTERS: That is in part due to direct
20 interest by the head commissioner, seeing the potential with
21 the d.t.v and the controversies that have been going on with
22 digital t.v. in general and the potential, quite literally,
23 for patients being harmed directly by d.t.v where it might
24 come off or appear that General Hospital is more important
25 than real hospital. That is not something that, politically

1 or any other way, FCC really wanted to do.

2 We, of course, have been pushing them. Dr.
3 Jacobson, in 1995, recommended this in a letter and we have
4 been talking to them before that. But this is the first
5 opportunity we have really had that they were very
6 interested and worked with us. After the d.t.v incident, we
7 went, really, like gangbusters.

8 DR. LIPOTI: Given their strong support, would
9 they be willing to let hospitals have these frequency bands
10 without going through auction?

11 MR. WITTERS: This is not an auction. This is a
12 setaside. No auction on this.

13 DR. LIPOTI: But in the Federal Register Notice on
14 page 41892, third column, number 14, they make no finding on
15 whether it will be made available through auction. I am
16 concerned about that.

17 MR. WITTERS: We have been told and understand
18 that this is not going to be an auction. There are two or
19 three different Congressional mandates, depending on the
20 date from 1993 and 1995 that set aside certain frequency
21 bands by Congressional mandate for auctioning off.

22 This was particularly chosen as not one of those.
23 That is our understanding at this point. They may have put
24 that in for some other reason. I can't comment on the
25 specifics of that particular point.

1 DR. LIPOTI: My last one is what the heck is a
2 little leo feeder link? What might it do to the medical
3 telemetry?

4 MR. WITTERS: Fair question because that is an
5 important thing. Leos are low earth orbit-satellite
6 transmission. These are low earth orbiting satellites, 125,
7 150 miles up, that are being planned and have been planned
8 for a number of years for business and other communication.

9 I don't know if you have heard of iridium that
10 made a big thing and is now going bankrupt. It is similar
11 to that. These would have certain earth stations that are
12 fixed that are always pointing up, catching the next
13 satellite coming around, and then they have downlinks.

14 Their concern, and our concern, is that either the
15 uplink or the downlink, which looks a little bit more over
16 the horizon than straight up, could, potentially, interfere
17 with that. That, again, is something out of our control.
18 It is something that has been looked at because it, again,
19 points to the competition. That is just one of the
20 competitors for this spectrum.

21 MS. KAUFMAN: The AHA report--I presume that those
22 patient numbers are at any one point in time where they are
23 talking about 200 to 600 for EKG, electrocardiograms and
24 stuff?

25 MR. WITTERS: They can have that many. Larger

1 institutions can have that many at one time.

2 MS. KAUFMAN: Because that is a concern in terms
3 of the future because they do come right out and say that
4 the band that they are requesting only accommodates today's
5 patient needs. One of the things that they talk about is,
6 and this is, I think, especially true with managed care,
7 that more and more of these patients will not be located in
8 a hospital. They will be located outside.

9 MR. WITTERS: Yes.

10 MS. KAUFMAN: You talked about short range of the
11 system. It is not clear from report how long a range these
12 will operate within.

13 MR. WITTERS: A few hundred yards, at the most.
14 It is well under one watt of transmit power. It is well
15 under that. It is not even close to what you are going to
16 put with a cell phone, typically.

17 MS. KAUFMAN: It seems like this approach isn't
18 going to be satisfactory for very long and, as long as we
19 are doing it, maybe we need to just plan a little bit better
20 for the future.

21 MR. WITTERS: If you look closely, you will see
22 that their current use of that is 6 megahertz, and the
23 proposal is for 12 to 14. So there is room for expansion in
24 the proposal now. And, with everything else, all the
25 competition, we are extremely glad to get that much with

1 everything that is going on.

2 MR. FLETCHER: I am going to cut off discussion at
3 this point. We will have another committee discussion
4 period later one. I hope Mr. Witters will be able to stay
5 around, if possible should the committee have some more
6 questions.

7 MR. WITTERS: Okay. I will try.

8 MR. FLETCHER: At this time, we are scheduled for
9 our break, so please be back by 3:35 so that we may
10 continue.

11 [Break.]

12 MR. FLETCHER: As many of you may recall from last
13 year, we had quite a long session on electronic article
14 surveillance systems. Today, we are going to get an update
15 from John Casamento on the EAS.

16 **Update on Electronic Article Surveillance Systems**

17 MR. CASAMENTO: Good afternoon.

18 [Slide.]

19 Since last we met--last year, we brought before
20 you the issue of electronic article surveillance systems and
21 metal detectors interfering with medical devices. We
22 presented some data that we had and some clinical research
23 and publications that have been made up to that point in
24 time.

25 So this presentation is to update the committee on

1 what has been happening since that time.

2 [Slide.]

3 While it still appears that ambulatory device
4 electromagnetic interference from security systems does not
5 pose a major public-health issue at this time, FDA continues
6 to be concerned about the potential for adverse patient
7 interactions. FDA continues to believe that a comprehensive
8 study of the public-health risk of medical-device EMI with
9 security systems is still needed and that such a study must
10 include a fully representative sample of security systems
11 and ambulatory medical devices.

12 [Slide.]

13 The medical devices include, but are not limited
14 to, implanted pulse generators, implanted
15 cardiodefibrillators, spinal-cord stimulators, and infusion
16 pumps.

17 [Slide.]

18 The objective--I will provide a background on
19 laboratory research programs and activities related to
20 electromagnetic interference from EAS systems and metal
21 detectors and I will discuss an in vitro published study
22 that has come up this year.

23 The following speaker, Mitchell Shein, will
24 present a summary of incident reports on clinical studies,
25 standards activities related to medical-device EMC with

1 security systems.

2 [Slide.]

3 What are electronic article surveillance systems
4 and metal detectors?

5 [Slide.]

6 They are devices that emit electromagnetic fields
7 that cause anti-theft tags or metal passing through the
8 systems to emit a detectable electromagnetic signal. Metal-
9 detector systems include walk-through as well as hand-held
10 metal detectors. People and products are exposed.

11 [Slide.]

12 Our concerns; the medical-device reporting system
13 continues to receive reports of device interactions. Two
14 clinical studies published since last year show that
15 electromagnetic fields emitted from electronic article
16 surveillance systems can interfere with pacemakers and
17 cardioverter defibrillators.

18 These will be addressed in more detail by the
19 following speaker, Mitch Shein.

20 [Slide.]

21 Health Canada, Dr. Tan, presented a study he has
22 been doing in Canada where he tested a number of pacemakers
23 with a number of different electronic article surveillance
24 systems, walk-through metal detectors and hand-held metal
25 detectors.

1 He took the pacers--he had 21 for the EAS systems-
2 -and he put them through his phantom, saline phantom, in a
3 fixed-rate pacing. As he exposed them to the EAS system,
4 the CW system, 52 percent of the pacemakers that he looked
5 at interacted; 95 with the pulse magnetic systems; and none
6 with the swept magnetic.

7 He was concerned. 14 percent of the pacers
8 reduced their rate of pacing when they went before the CW
9 EAS system and 38 percent experienced a reduced pacing rate
10 when they were exposed to the pulse-magnetic systems.

11 Now, he was concerned that these may have clinical
12 consequences. That is the author's concern in paper. I
13 haven't seen any data other than a summary.

14 Then he took the pacers and he stimulated them
15 with a simulated EKG signal and he tested them. Again, he
16 saw 52 percent of the pacers in the CW EAS system interacted
17 and 95 percent in the pulse-magnetic system.

18 The distances of interaction were different here.
19 With the CW system, he saw interactions 18 centimeters from
20 the transmitter gate and, in the pulse-magnetic system, he
21 saw interactions as far as 34 centimeters away. He noted
22 there were no interactions if the pacers were carried
23 straight through the EAS system. So these were pacers that
24 remained exposed to the EAS system for longer than two
25 seconds.

1 He did a similar study with the walkthrough metal
2 detectors. The exact conditions were not as well defined in
3 the summary. He saw 15 percent of the pacers interacted
4 with the CW metal detectors and 31 percent interacted with
5 the pulse-magnetic metal detectors, and 0 with the hand-held
6 metal detectors. The exact conditions, whether they were
7 fixed-rate pacing or stimulated at the time of the test were
8 not specified in the summary that I saw.

9 Dr. Tan works with Health Canada. He presented
10 this at URSI in Toronto last month.

11 Data from studies, be they clinical or in vitro
12 studies, should be supportive of standards development.
13 They should include distances of interaction. They should
14 document exposure required to cause interactions. They
15 should document patient or device orientation with the
16 security systems when interactions occur and include a
17 complete representative sample of the security systems and
18 medical-device technologies in use currently.

19 [Slide.]

20 FDA activities; the AAMI Pacemaker Committee EMC
21 Task Force has a draft of their document, PC69, Active
22 Implantable Medical Devices Electromagnetic Compatibility
23 Test Protocol for Implanted Cardiac Pacemakers and
24 Implantable Cardiodefibrillators.

25 They have just finished the section looking at

1 compatibility with cell phones and PCS. That committee is
2 chaired by Mitchell Shein, our next speaker. As of this
3 July, the committee kicked off work of the 0 to 30 megahertz
4 section of that standard which includes security systems,
5 metal detectors and EAS systems.

6 [Slide.]

7 We had personnel chair two sessions at the AAMI
8 conference in Boston in July concerned with EMC and EAS
9 systems. We had an FDA person co-chair a session at URSI,
10 part of which was addressed earlier in Toronto. We have
11 joined the ASTM F12 Security Systems Committee and CDRH sent
12 a letter to the EASS, electronic article surveillance system
13 and the metal-detector industry encouraging research.

14 [Slide.]

15 We also, shortly after the meeting last year, sent
16 a "Dear Doctor" letter to cardiologists, neurologists,
17 cardiovascular surgeons, neurosurgeons, emergency-room
18 physicians making them aware of the potential of
19 interactions with EAS systems and metal detectors.

20 We outlined three things that patients should be
21 aware of. One is not an immediate health risk but there are
22 some things that can they can take to mediate that risk.
23 They can be aware that electronic article surveillance
24 systems are hidden, could be hidden in entranceways of
25 stores and that they shouldn't remain near them.

1 They should not stay near the EASS or metal
2 detector earlier than necessary and do not lean against the
3 pylons and, for security systems when they are being scanned
4 by the hand wands, make the security personnel that they
5 have got a medical device and that they shouldn't linger
6 with the security wand near that metal detector longer than
7 is absolutely necessary or request an alternative form of
8 search.

9 [Slide.]

10 We have had a number of publications. Don
11 Witters, who spoke earlier, has a publication ready to come
12 country in MDDI, Medical Device Diagnostic Industry
13 publication, FDA concerns about medical devices,
14 electromagnetic compatibility interference with electronic
15 security systems.

16 [Slide.]

17 One of our sister organizations, the Winchester
18 Electronic Engineering Analytical Center in Boston, has done
19 a study with electronic article surveillance systems. It is
20 in press with Health Physics. They went out into the
21 greater Boston area and measured eight different EAS systems
22 in the Boston area and reported their findings.

23 [Slide.]

24 I have taken the liberty of plotting some of their
25 peak measurements here as a summary of the field strengths

1 that they say in the--this is plotted in amps per meter and
2 it is the peak field strengths that they saw in commercially
3 installed systems in the field.

4 I took that data and I plotted against the
5 performance standards of the current standard EN 5061A1
6 which is the current standard many manufacturers build their
7 devices to. I have got two lines on the graph. In the
8 presence of interference, here, is an upper performance
9 limit for the standard where the device is not supposed to
10 emit current in the presence of EMI above a certain limit if
11 the EMI is of this level.

12 The second performance standard line here, the red
13 line, is the limit below which the pacemaker should act
14 normally and should be able to discriminate physiological
15 signals from background noise and perform normally. In
16 between the two lines, the unit is supposed to behave in
17 some predictable fashion, version-to-noise mode being an
18 example for pacemakers.

19 These plots, in all fairness, are worst-case
20 coupling conditions. A patient going through and EAS
21 system, unless they happen to orient themselves perfectly,
22 would experience interference of levels considerable less
23 than these. But I wanted to look worst-case coupling that a
24 patient would see.

25 [Slide.]

1 I have taken the data that I presented last year
2 before this committee on measurements of fields emitted by
3 electronic article surveillance systems. This is a summary
4 of my data. I looked at eight systems, two of which were
5 identical, and plotted data similar to what you just saw
6 with the WEEAC data.

7 Also, I have looked at it in the same way here.
8 In both cases, you can see that it is possible, at least
9 over here, to see that if a patient were to perfectly orient
10 themselves and remain in the field, they could see some
11 interactions up to nearly 30 centimeters away from these
12 gates. That is supported by the Tan study and some other
13 information.

14 So there is an environmental threat to devices
15 that may not be exactly addressed by the standard.

16 [Slide.]

17 We are entering into an arrangement, an agreement,
18 with FAA, NIST and Food and Drug Administration to work
19 together to analyze metal-detector interactions with medical
20 devices. We are going to look at walk-through metal
21 detectors, hand-held metal detectors, and we are going to do
22 electromagnetic-field measurements and characterization and
23 work on developing standardized test methods for certain
24 medical devices.

25 [Slide.]

1 Conclusion; while it still appears that ambulatory
2 medical-device EMI from security systems does not post a
3 major public-health issue at this time, FDA continues to be
4 concerned about the potential for adverse patient
5 interactions. FDA continues to believe that a comprehensive
6 study of the public-health risk of medical-device EMI with
7 security systems is still needed and that such a study must
8 include fully representative samples of security systems and
9 ambulatory medical devices.

10 [Slide.]

11 Data from the study should be supportive of
12 standards development, include distances of interaction,
13 document exposure required to cause interactions--

14 [Slide.]

15 --document patient or device orientation with the
16 security system when interactions occur and include a
17 complete representative sample of the security systems and
18 medical-device technologies in use.

19 That concludes my presentation.

20 MR. FLETCHER: I am going to ask Mitch Shein to
21 come on and complete before we open for questions.

22 MS. SHEIN: Good afternoon. I am Mitchell Shein.
23 I am a senior reviewer in ODE.

24 [Slide.]

25 I am here this afternoon to give you an update on

1 what has gone on in the last twelve months regarding our
2 activities on the interaction between medical devices and
3 security systems.

4 [Slide.]

5 Our objectives this afternoon are to provide you
6 with some background on some of the standard development
7 activities that we are pursuing as well as some other
8 cooperative efforts between FDA and the affected industries.
9 I would also like to touch on what we believe is the
10 continued need for comprehensive development of in vitro and
11 in vivo studies.

12 [Slide.]

13 With that in mind, I think it is important to note
14 here that FDA continues to believe that we do not have a
15 major public-health issue here at this time. However, we
16 would like to make sure that it stays that way.

17 I think what I would like to do now is, for the
18 benefit of those who are new to the panel who were not here
19 with us last year when we presented this, is to kind of
20 review the information that we have at our disposal and
21 warrants continued monitoring.

22 [Slide.]

23 We have seen industry trends that we think
24 indicate the continued, if not increasing, potential for the
25 interaction medical devices and security systems. In

1 particular, we have seen the increased use of implantable
2 medical devices as well as their increased use of
3 sophisticated circuitry.

4 From the detector side, the security system side,
5 of the house, there is an increased use of these devices for
6 security purposes. You see them cropping up in stores and
7 in increased locations all around. There is also the
8 possibility that the technology seems to moving toward, or
9 will allow for, if nothing else, incorporation into the
10 actual architecture of the door frames so that your casual
11 passer-by won't even know that the systems are in place.

12 Again, we have seen no change in these trends but
13 they still exist and we continue to monitor.

14 [Slide.]

15 Our actual sources for concern, the harder data
16 that we were acting on, relate to three primary sources.
17 First, is our medical-device reporting database as well the
18 information we have found in the peer-reviewed literature
19 and, lastly, the information that Mr. Casamento related, or
20 laboratory studies.

21 [Slide.]

22 I would like to turn now to the information that
23 we have in our medical-device reporting database. A recent
24 review of that system turned up 61 total records of medical
25 device interaction with security systems. This is fifteen

1 more new reports than we had last time when we spoke to you.
2 All but two of those 61 were seen with pacemakers,
3 implantable defibrillators or nerve stimulators.

4 [Slide.]

5 All of these reports have been reviewed
6 individually. Dr. Stuart Portnoy of our office did the
7 reviews. They were assessed for their level of severity
8 where we tried to assign them to a category of either a
9 severe, moderate or a mild interaction. Severe interactions
10 were limited to those that were fatal or life-threatening or
11 those that resulted in permanent or significant impairment
12 to the patient.

13 In addition to assessing the severity of the
14 interaction, we tried to assess the credibility of the
15 report. These reports were analyzed based on the
16 information that was submitted alone. In other words, there
17 is no additional research or information sought on the
18 individual reports.

19 So, in the cases where the credibility was high,
20 we allowed these reports to be scored as they were. For
21 those that the credibility was not as reliable--for example,
22 a pacemaker patient who felt, when he reports to his doctor
23 a month later, "Oh; I had a syncopal episode about a month
24 and I think I was walking into a store at the time," where
25 the association could not be tied closely.

1 For those, Dr. Portnoy lowered the level of
2 severity one level.

3 I would like to put an overhead up. Can everybody
4 read that? It is on your handout, but, for the benefit of
5 the audience, let me put it up on overhead.

6 [Overhead.] This is actually a compilation of all
7 61 reports. The way they are arranged is they are arranged
8 across the top by the type of medical device that it was
9 interacting with. In the left column, they are arranged by
10 which of the security systems they were attributed to.

11 Within each of those security systems, there is a
12 gradation of the severity of the episodes that were related.
13 You see some very thin green dots. I wasn't able to go in
14 with the business of the slide and actually highlight the
15 new reports, but that is what those dots represent.

16 So, with that in mind, obviously, we are seeing
17 continued response. We have seen an increase in the number
18 of responses, certainly for spinal-cord stimulators. Again,
19 we are not seeing it at any greater rate, we think, that
20 what we had seen before but we are seeing that this
21 situation certainly requires continued monitoring.

22 [Slide.]

23 I would like to turn now to what we have in the
24 way of the peer-reviewed literature. These references may
25 not be an exhaustive list of everything that was out there,

1 but we think it is fairly comprehensive. The Copperman, et
2 al., paper was presented. It looked at 103 patients in
3 metal-detector systems. For those 103 patients, there were
4 absolutely no interactions reported.

5 Dodinal, et al., looked at 32 patients in four
6 simulated EAS systems and he only saw some responses in two
7 of the magnetic systems. Mugica, et al., reported on 178
8 patients exposed to two SensorMatic systems. He identified
9 29 interactions including dual-chamber rapid stimulation and
10 three of those 29 were ECGs that were too complex for
11 somebody to decipher to determine exactly what had
12 transpired.

13 Wilke, et al., reported on 53 patients and he saw
14 nine responses to security systems. The McIvor, et al.,
15 paper is the paper that I reported last year as about to be
16 published. It has since come out. It came out in October
17 of last year.

18 [Slide.]

19 He looked at 75 patients, 25 defibrillator
20 patients and 50 pacemaker patients, and exposed them to
21 three different types of EAS technologies, six systems in
22 all. All but two of the responses that he reported were in
23 response to the Acustomagnetic system.

24 What he had the patients do, in the four protocols
25 and exposures that he used--in protocol A, he had the

1 patients transit straight through the center of gate. In
2 protocol B, he had the patient--you can't see it, but they
3 were actually asked to rotate in the center of the field.
4 Protocol C is with the patient rotating adjusted to the side
5 of the field and then the last protocol dealt with the
6 patient leaning up against the gate, basically hugging it.

7 What was of note in that paper is one, it was kind
8 of a representational sample of the EAS systems that were
9 out there. He didn't quite have a large enough population
10 to have a truly representative sample of either
11 defibrillators or pacemakers. Another interesting finding
12 was that, although the most frequent responders were to
13 protocol D, there was a fair number of responses to protocol
14 A and that would represent a patient casually walking
15 through the system.

16 [Slide.]

17 The newest paper out in this area was published by
18 Groh et al. You will hear in detail, in a moment, from Dr.
19 Zipes on that. What Groh looked at was 169 defibrillator
20 patients. They had them exposed to three SensorMatic EAS
21 systems. They reported no interactions in patients taking a
22 ten- to fifteen-second leisurely walk through the gate but
23 they did, however, see nineteen responses during patients
24 who were exposed for two-minute periods of time in close
25 proximity to the gate.

1 Of those nineteen responses, they noted that three
2 were likely to have resulted in an inappropriate discharge
3 of the defibrillator and four that possibly could have
4 resulted in the inappropriate discharge.

5 [Slide.]

6 In addition to those literature studies, there are
7 several case reports out there. The first that you see up
8 here is just with the spinal-cord stimulator and the latter
9 three are all ICD events. The reason I put these up is that
10 they are indicative of what is going on in actual field
11 usage, so these events do happen. They don't happen
12 frequently, as is seen by the number of MDRs. We don't have
13 a huge number there, but they do happen and they can happen
14 and they are being reported.

15 [Slide.]

16 So where do we go from here? Last year, when Dr.
17 Jacobson presented to this panel as part of this discussion,
18 she broke this issue down into two components, specifically
19 into a installed base of product--that is, those that are
20 implanted in patients or already existing in the environment
21 and those concerning designs for future products.

22 [Slide.]

23 Regarding the installed base of products, last
24 year, we reported that industry could do several things to
25 address this issue. They could develop safety

1 recommendations, and it is my understanding that the HIMA
2 Pacemaker Task Force has gotten together with many
3 representatives of the security-system community and they
4 have gone out and have been working together to develop
5 labeling for the medical devices so that there is a
6 consistency in presentation in these manuals from one
7 manufacturer to the next.

8 Although we haven't seen that actual label, I am
9 told that it is still under review and we look forward to
10 having the opportunity to comment on the information that is
11 provided.

12 From the security-system side of the house, I
13 understand that they are looking at labeling to be put up so
14 that patients can better identify when these systems are in
15 place, particularly for those systems such as I mentioned
16 before that could be built into the architecture.

17 Looking, in terms of what we had asked for last
18 year with respect to a comprehensive in vivo study, to our
19 understanding, nobody has taken a step to accomplish that at
20 this point and we still think that there is a need to assess
21 the true public-health risk with a comprehensive evaluation
22 of the systems that are out there.

23 With regard to developing a surrogate, no work on
24 that has taken place yet but there are standards efforts
25 that are under way that Mr. Casamento alluded to that I

1 think, certainly, will help to address that. We may not
2 have a surrogate, but we certainly will have testing in
3 place to evaluate the interaction of these systems.

4 [Slide.]

5 From what we discussed last year on what FDA can
6 do regarding the installed base, we talked in terms of
7 issuing an advisory to physicians. Mr. Casamento put up the
8 public-health advisory that we sent out shortly after the
9 panel convened last.

10 We also talked in terms of the potential to target
11 special-interest groups; for example, the neurostimulator
12 patients whom we believe may not be experiencing a
13 disruption of the device behavior but, rather, the energy
14 put out by these systems may be coupled in their leads and
15 they may be having events due to an induced current,
16 perhaps. So we might have to address that.

17 We continue to monitor the adverse-event reports
18 although they are not many. Our laboratory efforts are
19 ongoing and will continue, certainly, through the standards
20 development process and we continue to consider whatever
21 regulatory options we might have to take to address the
22 issue.

23 [Slide.]

24 On the flip side, news products raise different
25 kinds of issues, efforts that we spoke of last year

1 regarding what industry might do to increase their
2 communication between one another. It is very important for
3 those making emitters and those who have devices that might
4 be susceptible that they have a very clear understanding of
5 what the areas of vulnerability may be so that these devices
6 can live out in the environment together quite well.

7 I don't think you are going to see the absence of
8 security systems anytime soon and, certainly, pacemaker
9 patients, there are a couple million of those currently in
10 the United States. They are not going to go by the wayside
11 anytime soon, either.

12 As far as what the FDA might do, we continue to
13 evaluate the information submitted in premarket submissions,
14 both PMAs and 510(k)s, to make sure that, where appropriate,
15 testing supports that these devices are not interacting in a
16 deleterious effect. We also continue to closely watch the
17 information that is coming in under the MDR system so that
18 should there be a blip or an item of concern that we can
19 respond accordingly.

20 [Slide.]

21 We talked in terms of joint efforts between
22 industry and FDA, in terms of sharing scientific and
23 engineering information and, certainly, that has gone on.
24 There was a session at AAMI, a workshop, on EAS and medical
25 devices last June that many of the people in the room

1 presented at.

2 The other possibility, and where there has been
3 considerable effort, is in the standards arena. I chair a
4 working group that has been charged by the AAMI Pacemaker
5 Committee to develop an EMC testing standard for pacemakers
6 and defibrillators.

7 We have broken the spectrum down into four
8 components. The first component was pretty much the
9 cellular communications band, 450 megahertz to 3 gigahertz.
10 We are about complete on that section of the spectrum. We
11 have just kicked off, as John noted, in July, work on the 0
12 to 30 megahertz band width. In fact, we are convening on
13 Monday and Tuesday next week to continue this work.

14 I imagine that it is going to be not a near-term
15 project. Hopefully, we will be able to complete it in a
16 couple of years which is what it took us to complete the
17 first section of the spectrum. There are also standards
18 efforts going on in Europe that are competing interests
19 which, I think, will help to spur this along.

20 So there is a lot of collaboration between the
21 agency as well as the affected parties.

22 [Slide.]

23 I guess, in conclusion, I would just like to
24 reiterate that we don't see any existing comprehensive study
25 to truly quantify the real public-health risk at hand.

1 While we don't want to raise fears in the patient community,
2 we certainly want to see this issue addressed with
3 scientific rigor. Until such a study comes out, we will
4 continue to monitor what is going on out there.

5 Thank you.

6 MR. FLETCHER: Thank you.

7 We have time for a few questions.

8 MS. KAUFMAN: In the report that you just handed
9 out, you mentioned, I think, that there were 15 additional
10 reports compared to last year.

11 MS. SHEIN: Yes.

12 MS. KAUFMAN: It looked like at least three of
13 those were rated as severe, of the new reports.

14 MS. SHEIN: Yes.

15 MS. KAUFMAN: But then, when you look at the
16 infection from SensorMatic, and they are talking about some
17 newspaper articles and television programs, it seems like,
18 more recently, someone has come out with some kind of report
19 saying that things are okay; "anti-theft devices, no shock
20 to the heart," ABC News, "healthy hearts at the store."

21 MS. SHEIN: I think those reports that you are
22 responding to and what you are alluding to are comments that
23 came out in response to the Groh, et al., paper that was
24 published in Circulation on July 29 this year. Dr. Zipes is
25 going to speak to that.

1 I saw some sidebars in the media relating to those
2 statements. I don't know what else they considered other
3 than the information they read in the report so I don't know
4 the context, specifically, that those comments were made in.

5 MS. KAUFMAN: Which report was that?

6 MS. SHEIN: The Groh, et al., paper that I put up
7 there, the last reference. Dr. Zipes, who is in the room
8 and worked with Dr. Groh, is an author of that paper as well
9 and he will be presenting that in detail, I understand,
10 during the public session.

11 MS. KAUFMAN: Okay.

12 MS. SHEIN: Oh; it is in the book. I'm sorry.

13 MR. WILSON: On that same item, is there any cause
14 for concern when, according to the numbers and they don't
15 seem to quite agree--this shows 46 or 45--over a ten-year
16 period of MDRs, in less than a year time frame, we had
17 sixteen.

18 MS. SHEIN: I think if you look at that, nine of
19 those were neurostimulators. I think one, with the
20 publicity that was associated with this last year, has
21 certainly made people more cognizant and more likely to
22 think in terms that that might be a source for an adverse
23 event.

24 Two, you are starting to see more neurostimulators
25 come out in the environment and be used for other purposes.

1 The way they run the leads in those situations may
2 contribute to that. I don't have a way to validate that. I
3 can only make guesses and that certainly warrants further
4 research.

5 DR. LIPOTI: Exactly to that point, I don't see
6 any new research that is being done on the spinal-cord
7 stimulators. I only see research that is being done on the
8 pacemakers and the defibrillators. It seems to me that when
9 I look at what is causing the problem, the unconscious,
10 severe injuries, shocking, jolting, discomfort is all
11 spinal-cord stimulators.

12 Are you working with that industry as well?

13 MS. SHEIN: I will have to turn to Jon to allow
14 him to address that. He is in the Office of Science and
15 Technology. That is our research arm and I don't know what,
16 if any, efforts are ongoing.

17 Do you want to comment on that, Jon?

18 MR. CASAMENTO: We haven't done anything with the
19 spinal-cord stimulators yet. They are still on our site but
20 we haven't gotten any in. Certainly, with our systems in
21 the laboratory now, we will be able to look at them in the
22 future. But the larger population at hand was the pacemaker
23 community. A lot of work and publications have been done in
24 that area so, right now, we haven't gone with the spinal-
25 cord stimulators.

1 DR. LIPOTI: How about the infusion pumps?

2 MR. CASAMENTO: No; we haven't done that one yet.
3 That was, what, one case, two cases?

4 DR. LIPOTI: One case is all you have got here.

5 MR. CASAMENTO: But we are aware of that and that
6 is also on our list of items to look at.

7 MS. SHEIN: I think also part of our approach with
8 respect to that is that the standards efforts that are going
9 on and the techniques that we will be using for testing
10 pacemakers and the like will give us a lot of information on
11 how to pursue those other avenues.

12 MR. CASAMENTO: I think the test techniques that
13 we are developing for the pacemakers will couple very well
14 to the spinal-cord stimulators. So I don't look at both
15 things being mutually exclusive.

16 MR. FLETCHER: I thank you both very much for your
17 presentations.

18 **Open Public Hearing**

19 MR. FLETCHER: At this point, we are going into
20 our period of open public hearing. We have two presenters,
21 Dr. Doug Zipes and Dr. Geraint Davies. I guess Doug Zipes
22 will be first, ten minutes each.

23 DR. ZIPES: Thank you. I am Doug Zipes. I am
24 Distinguished Professor and Director of Cardiology and the
25 Crannate Institute of Cardiology at Indiana University. I

1 have been asked to start with a very brief biography.

2 I am Past President of the North American Society
3 of Pacing and Electrophysiology, the largest group of heart-
4 rhythm experts. I am Vice President of the American College
5 of Cardiology, 25,000 cardiologists. I am editor of an
6 electrophysiology journal, co-editor of what has become the
7 standard reference for cardiac electrophysiology textbook,
8 and Past Chair of the Electrophysiology Boards of the
9 American Board of Internal Medicine. We write the
10 examination for electrophysiologists.

11 I had the honor of being able to present to you a
12 year ago and, since that time, we have conducted a study on
13 implanted cardioverter defibrillators. The study was
14 supported, in part, by SensorMatic. However, I and my
15 associates wrote the protocol, reviewed the data and
16 published the manuscript that you have in Circulation in
17 July.

18 [Slide.]

19 Dr. Groh is first author of the paper. The study
20 was conducted at Indiana University Methodist Hospital and
21 Southwest Florida Heart Group in Fort Myers, Florida.

22 [Slide.]

23 The purpose was to assess the potential for
24 interactions between electronic article surveillance systems
25 and the implantable cardioverter defibrillator in a

1 controlled setting. We chose the SensorMatic system because
2 roughly 60 percent of those installed systems are
3 SensorMatic. Two of the three case reports purporting to
4 show triggering of the ICD were with the SensorMatic device
5 and several of the other studies suggested that there might
6 be a problem with the SensorMatic system.

7 [Slide.]

8 We did the study over a four-month period and we
9 tested all available implantable cardioverter defibrillator
10 models and lead systems that were available at these three
11 separate sites. We tested three SensorMatic systems; the
12 Ultra-Max, The Aislekeeper and the P-Magnetic system.

13 [Slide.]

14 We studied 170 patients, 169 of which were able to
15 complete the protocol. We studied these patients during a
16 routine walk through the system during extreme exposure and
17 during extreme exposure and pacing. I will come back to
18 those in just a moment.

19 We studied all available to us at the time ICD
20 manufacturers which included 33 CPI defibrillators, 6
21 Inermedics, 103 Medtronic, 1 Telectronic and 26 Ventritex.
22 Very, very importantly, 51 of these patients had abdominal
23 implants of their defibrillator. Now, we don't do that any
24 more and they were implanted at that time--because of the
25 size of the device, it could not fit in a subcostal

1 position, subclavicular position, in the chest. However, no
2 one is--or almost no one is--implanting abdominal devices
3 anymore and they are all pectoral. As you will see, the
4 only significant interactions we had were with abdominal
5 implants which is a system no longer used.

6 We tested three sensing circuits that were
7 available; endocardial tip-to-ring, which is a true bipolar
8 system; endocardial tip-to-coil, which is a somewhat
9 compromised bipolar system, and epicardial in two patients.

10 [Slide.]

11 During a routine exposure, patients strolled
12 through the EAS system at ten- to fifteen-second duration.
13 This is far longer than one of our patients who was on a
14 walker walked through the system. This is extremely slowly
15 and far longer than what an ordinary individual would do
16 walking through the system.

17 During extreme exposure, the patient stayed two
18 minutes within the testing system within six inches of the
19 transmitting port. During extreme and pacing, in 126
20 patients, we turned on the pacing component of their
21 defibrillator to test whether the pacing might be influenced
22 as well as the defibrillator, itself.

23 Therapy from the defibrillator was deactivated.
24 Thus, if the device spuriously saw what might be a fast
25 heart rhythm and would have delivered a shock, that part was

1 deactivated and, therefore, patients were at no risk.

2 We had continuous ECG monitoring and we
3 interrogated the device before and after each walk through.
4 We evaluated any alteration in the normal function of the
5 ICD and we considered that clinically relevant that might
6 possibly lead to a spurious ICD delivery of therapy.

7 [Slide.]

8 This and the next slide show the testing system.
9 This patient is walking through, slowly, over a ten- to
10 fifteen-second period--

11 [Slide.]

12 --while this patient is standing with his
13 implanted device within six inches of the transmitting gate
14 for a period of two minutes during the extreme exposure.

15 [Slide.]

16 This shows the data. During routine exposure at
17 ten- to fifteen-seconds walk through, there was no
18 interaction whatsoever between any of the implanted ICDs and
19 the EAS system. During extreme exposure, two minutes within
20 six inches of the port, three patients had what would have
21 been inappropriate ventricular fibrillation detection and
22 very probably would have caused the device to deliver a
23 shock in response to spurious VF.

24 Those three occurred with the Ultra-Max and what
25 the device saw was continuous noise during that exposure,

1 endocardial-tip ring in one and endocardial-tip coil in two.
2 One of those three was a Medtronic 7219 which is an older
3 device and the other two a CPI 1746, also an older device.

4 During extreme and pacing--now, this is, again, a
5 two-minute exposure, but we turned the pacemaker function on
6 in these patients at a rate fast enough to overdrive their
7 own spontaneous rhythm, there were nineteen interactions.
8 Twelve of these interactions were merely a delay of the
9 pacing stimulus of, generally, parts of a second or a second
10 or so. And we did not consider them clinically relevant.

11 Seven, however, we felt were clinically relevant.
12 In five of these seven, there was complete pacing inhibition
13 and prolonged pacing inhibition in two. Three occurred in
14 the Ultramax and four in the Aislekeeper, endocardial tip
15 ring in two, tip coil in three and epicardial in two. ICDs
16 was the 7219, Medtronic, the 1746 in CPI. These are the
17 same that showed what would have triggered ICD discharge
18 with apparent ventricular fibrillation detection. And then
19 there were four occurring with older Ventritex systems, the
20 110 and the 100.

21 Twelve of these patients, as I said, had
22 insignificant delay of pacing. Four of these patients had
23 very old units in which they had both a defibrillator and a
24 pacemaker separate. Since we did those things, we have
25 combined them into one single unit. So these represent very

1 old units and these patients had no problems at all.

2 [Slide.]

3 This shows the results and interactions during
4 routine exposure, ten- to fifteen seconds pass-through, no
5 interactions at all. During extreme exposure, three
6 interactions and we considered them clinically relevant
7 because they probably would have triggered a device
8 discharge.

9 During extreme exposure plus pacing, 19 of 26
10 interactions, we considered only seven of those 126 to be
11 clinically relevant, three with total inhibition, four with
12 long inhibition of pacing. Three of those were these three
13 during the extreme exposure.

14 [Slide.]

15 This is an example showing the noise picked up on
16 the scaler ECG. This is the patient's QRS complex. The
17 device, then, saw the noise as a very rapid heart beat and
18 would have led to a shock. This was an abdominal implant.

19 [Slide.]

20 This slide shows a mild delay in pacing. This is
21 the pacing stimulus. The next stimulus should have occurred
22 here and, as you see, it is delayed very slightly and we did
23 not consider that significant.

24 [Slide.]

25 Very importantly, there was a correlation with the

1 abdominal location. This shows any interaction at all of
2 the seventeen. You can see clearly the majority occurred
3 with the abdominal location. This was clinically relevant.
4 Those seven patients with clinically relevant interactions
5 all were abdominal in location.

6 [Slide.]

7 This shows the time since implant with any
8 interaction at all. Those who had no interaction, you see
9 there was just three years since implant, while those with
10 any interaction, four and a half years or so of implant, and
11 a similar difference between relevant interactions. Thus,
12 the older devices interacted much more than any of the
13 current devices.

14 [Slide.]

15 In addition, there was a correlation with R-wave
16 amplitude. The better the amplitude, the less likely the
17 interaction because these devices automatically adjust for
18 R-wave amplitude and change the sensitivity.

19 [Slide.]

20 So, in summary, no interactions between
21 defibrillators and the theft-detector devices were observed
22 during a slow, mid-gait routine exposure. Interactions were
23 observed between the defibrillators and the sensing system
24 with extreme exposure and extreme exposure with pacing,
25 insignificant in twelve, clinically relevant in seven. With

1 extreme exposure plus-or-minus pacing, the likelihood of any
2 and a clinically relevant interaction increased with older
3 ICDs, abdominal implants and decreased R-wave amplitude.

4 Our conclusion is that it is safe for patients
5 with ICDs to slowly walk through electronic article
6 surveillance systems. Extreme exposure may rarely lead to
7 an inappropriate ICD discharge. This minimal risk should
8 diminish further as older abdominal ICDs are replaced.

9 Thank you very much.

10 MR. FLETCHER: Thank you.

11 I am going to ask Dr. Davies to give his
12 presentation and then we may proceed with questions.

13 DR. DAVIES: Good afternoon. My name is Dr.
14 Geraint Davies. I am a Ph.D. physicist and I have been
15 working on the interactions between the EAS systems and
16 pacemakers for around seven years. I am a member of several
17 international committees dealing with safety issues related
18 to magnetic fields including some pacemaker committees in
19 Europe.

20 Today, I am actually representing a speaker from
21 Sensormatic. My affiliation is with the International
22 Electronic Article Surveillance Manufacturers Association,
23 which is tongue-twistingly known as IEASMA. The speaker was
24 meant to be from Sensormatic today and I will give his
25 presentation. He was unavoidably detained by weather

1 conditions in Florida, I'm afraid. So you get me instead.

2 [Slide.]

3 First of all, let me give you a brief summary of
4 what EAS is as is shown in this first slide. Shoplifting
5 affects each and every one of us. It is a black-market, a
6 black industry, which amounts to around \$13.5 billion in the
7 U.S. alone. This means that it costs, on average, \$150 a
8 year per household.

9 The retailers' solution to this program is
10 electronic article surveillance. It is a very effective
11 solution because, around the world now, there are close to a
12 million systems installed in over 100,000 stores. So EAS
13 systems are really part of the landscape.

14 [Slide.]

15 I would like to just share with you some of the
16 data which I presented in my talk last year, just one page
17 of it and then I will moving on, some of the key data which
18 shows that there is a long track record of safe operation of
19 these systems together.

20 EAS and medical-device systems have been around
21 for over 30 years together and growing up in the same
22 environment. One can estimate that, during that time, there
23 have been over 2 billion passages of a defibrillator system
24 or a pacemaker user through and EAS system. Nowadays, that
25 amounts to roughly 200 million exposures every year in the

1 U.S. for implant wearers.

2 The number that I am giving here, the 45 MDRs,
3 relates only to EAS and security systems. I have taken off
4 the number that relates to metal detectors. So, in the last
5 eleven years, there are only 45 MDRs that relate to EAS and
6 security systems. So, in roughly 2 billion passages, that
7 is a very small number indicating that the prevalence of any
8 interactions is extremely low.

9 There have also been studies each carried out on
10 around about 50,000 patients--surveys, rather. One was in
11 the U.S. with the Department of Veterans Affairs and one was
12 in the U.K. with the National Pacing Registry. Each of
13 those surveys showed no reports of EAS interactions.

14 As the FDA has just said, the prevalence of this
15 is so low that it is not seen as a major health problem
16 today. Exactly as the FDA has just been saying, how do we
17 stay ahead of the curve?

18 [Slide.]

19 So I would like to talk about some of the key
20 areas that were identified in last year's meeting and
21 describe how a lot has been going on in each of these areas
22 and I will also talk about what will continue to go on after
23 this meeting.

24 We recognize, as with all electronic products, the
25 potential for interactions is there and medical devices are

1 becoming more complex. I think the consensus at the moment
2 is that what is happening at the moment with devices is
3 reasonably well understood. There have been a number of
4 studies, in vivo studies, which amount to roughly a thousand
5 patients studied over recent years.

6 Those types of interactions, which are similar to
7 the ones that were described in the recent studies, in fact,
8 are dealt with by the sorts of procedures that I will be
9 talking about later. What is really important to understand
10 is how we can make sure that, in future, this level of
11 protection is continued and, in fact, improved.

12 Some of the things that we have been doing. Our
13 focus at the moment, rather than on looking at a very broad
14 patient study which, in aggregate, probably has already been
15 performed through a number of different studies, is to look
16 at how we can use in vitro modeling to protect future
17 developments, to improve future developments, of devices.

18 We have been working with implant manufacturers,
19 now, for over seven years and that collaboration continues.
20 In fact, SensorMatic has installed equipment in the R&D labs
21 of all the major implant manufacturers.

22 We have also, you may recall, set up a test
23 facility at the George Tech Research Institute. This uses
24 in vitro tests of implants, in general. This is a very
25 well-used facility and I will describe a little bit more

1 about that later on. This may be a very good place to try
2 to use validated in vitro modeling to really understand in
3 vivo effects and to give device manufacturers a very good
4 predictor of the performance of their systems.

5 We have already heard from Dr. Zipes about his
6 study. I would like to talk also about communications that
7 have been going on between various groups to improve
8 understanding and patient education. I will do that in my
9 next slide.

10 [Slide.]

11 First, let me talk a little bit about standards.
12 The role of standards will be maintain and improve product
13 compatibility. The FDA has already described how they have
14 been sharing a multi-industry committee of AAMI on which the
15 EAS Manufacturers Association is participating.

16 There is also a joint committee with HIMA with our
17 association which has been set to work with FDA to answer
18 FDA's questions and also to work on the action items
19 identified by this committee last year. Also, we have been
20 participating in, and we are participating in, standard
21 setting activities in Europe within the body of CENELEC. In
22 fact, in under twelve hours, I have to be in London sitting
23 on a CENELEC pacemaker committee so you will forgive me if I
24 don't have a lot of time to hang around for questions
25 afterwards. I have a plane to catch later on.

1 Also, of course, product design and design of
2 future products. The EAS manufacturers have been working
3 with implant manufacturers to discuss improved filtering
4 designs for medical devices. There are good reasons to feel
5 that there will be progress soon in this area with the
6 device manufacturers.

7 I have mentioned Georgia Tech Research Institute.
8 This is a very good place for premarket testing of devices.
9 Over 260 medical devices have been tested in a huge variety
10 of EAS systems up to now. Our feeling is that this is a
11 good place to spend research dollars to improve the
12 performance of future devices.

13 So much has already been done and much more is
14 underway. I will talk about the promised communications.

15 [Slide.]

16 So, one thing is that joint committees both here,
17 with HIMA in the USA and in Europe with the IAPM, have been
18 working to develop a standardized language. I would say,
19 actually, that this meeting last year and the involvement of
20 FDA has been instrumental in catalyzing all of this signage
21 and also the education programs which are underway.

22 I will talk about the education programs briefly
23 in a second, but let me just describe some of the signage
24 programs that are underway in the EAS industry.
25 SensorMatic, in particular, has issued decals for indicating

1 that anti-theft systems are present where there are visible
2 systems and also for indicating that there are EAS systems
3 in use where the systems are not visible.

4 All of this activity has actually resulted in
5 widespread media coverage. There have been over 500 media
6 stories in the past year so this is a very well aired topic
7 now. There have been physician advisories by the FDA, by
8 overseas regulators and by physician groups. The particular
9 message which has been communicated for patients to observe
10 in order to give them complete safety is, "Don't linger,
11 don't lean; pass straight through the systems."

12 [Slide.]

13 Here are few examples. I won't go through them in
14 detail in order to be short on time. This one is from the
15 American Heart Association, taken from their website, in
16 fact. Here, in order that individuals should not be unduly
17 concerned, the Association is being sensitive here to the
18 psychological needs of the patients. What it says is it
19 agrees with the recommendations issued by the FDA which
20 particularly include, "Do not linger, don't lean."

21 [Slide.]

22 If I go on, this message has also spread to Europe
23 so we have the European Society of Cardiology. This excerpt
24 is taken from their newsletter. Here, again, you see
25 specific instructions are given; "Don't linger, don't lean.

1 Pass straight through the system." The committee recommends
2 that you follow these recommendations.

3 [Slide.]

4 Finally, since I am British, I will put this one
5 up. The Medical Devices agency in the United Kingdom, once
6 again, has given the advice, "Don't linger, don't lean.
7 Walk straight through."

8 [Slide.]

9 I suppose, in summary, I would say that there are
10 many positive things that have happened since last year and
11 there are many positive things still in process. With the
12 help of FDA's clear stance on this, there has been a
13 consensus developed about practical patient advice. That is
14 really helpful, to be practically helpful to patients. This
15 advice is, "Don't linger, don't lean." It is now becoming a
16 worldwide accepted communicated message.

17 Also, the huge amount of media focus that has
18 brought attention to this topic has confirmed that the
19 number of symptomatic interaction remains extremely low. So
20 it is still not a public-health problem. But we are looking
21 toward the future so there are a lot of interindustry
22 efforts with the device manufacturers and the EAS
23 manufacturers to enhance EMC, electromagnetic compatibility.

24 Included in this is standards development efforts
25 to take account of EAS systems. In fact, I will be,

1 tomorrow in London, presenting exactly the sort of data that
2 the FDA was presenting today about what the EAS systems can
3 produce to make sure that the device manufacturers and the
4 standards authorities are fully aware of EAS systems.

5 So, in summary, then, I think everybody is working
6 very hard to ensure that we have a continued excellent
7 product safety record. Thank you very much.

8 MR. FLETCHER: Thank you.

9 Do we have any questions on these presentations?

10 DR. LIPOTI: I have a question for you, Dr.

11 Davies. I see a lot of work where you are dealing with
12 pacemaker manufacturers and defibrillator manufacturers and
13 not one single instance of where you are working with
14 someone who manufactures spinal-cord stimulators.

15 I also see a lot of press coverage of what happens
16 with pacemakers and defibrillators and not one single press
17 coverage of spinal-cord stimulators. And I see some very
18 severe reactions with spinal-cord stimulators.

19 What do you intend to do tomorrow, in London, and
20 for the rest of the year to correct that deficiency?

21 DR. DAVIES: Thank you. That is very well
22 observed. In fact, it is important to know that many of the
23 manufacturers of the stimulators are the same manufacturers
24 as the defibrillators and the pacemakers. So, in fact, in
25 our discussions, we are talking to them also about those

1 devices.

2 As you correctly point out, there are a large
3 number of instances in recent MDRs. So we are also trying
4 to understand why this is and trying to locate the right
5 experts to understand what is going on. So that is from the
6 point of view of the industry.

7 You are asking what are we doing about standards.
8 The standard I am dealing with tomorrow is about
9 defibrillators but, later on in the series will be neural
10 implants and spinal-implant standards and I will be
11 certainly be raising that issue there.

12 DR. LIPOTI: It seems to me much more urgent that
13 you deal with the spinal-cord stimulators. The
14 defibrillators and the pacemakers are not any more implanted
15 abdominally. But I think the spinal-cord stimulators, it
16 would be rare if it was in a subclavicular position. So I
17 think it is much more important that you reverse your
18 emphasis and that you work with spinal-cord stimulators.

19 DR. DAVIES: That is certainly something where we
20 are now focusing an increasing area. I think that is a good
21 observation.

22 MS. FAHY-ELWOOD: I had a quick question for Dr.
23 Zipes and that was I was curious about the total percentage
24 of patients now with implanted devices that have them
25 implanted in the abdomen and how long before you think all

1 of those types of implants would be out of commission,
2 replaced.

3 DR. ZIPES: There are virtually no abdominal
4 implants today. The only time one would do that would be a
5 very rare exception. We did one, actually, several months
6 ago, an extremely thin young woman who didn't want any bulge
7 at all in her chest area and we implanted the device
8 abdominally. That is extremely uncommon.

9 Most of these patients who do have device
10 expiration because of the ease of the surgery of just
11 popping the one out and putting another one in may still
12 have their abdominal implant. So it is very difficult to
13 say when the last ones of those will die, essentially.

14 MS. FAHY-ELWOOD: Do you have any idea of the
15 total percentage, though, of implanted devices that are
16 currently in the abdomen?

17 DR. ZIPES: I would have to guess, but my guess
18 would be less than 10 percent, maybe even less than 5
19 percent.

20 MS. FAHY-ELWOOD: These MDRs that we talked about,
21 do you know what percentage of those might have been
22 abdominally implanted? Is that what we call them, MDRs?

23 DR. ZIPES: I don't know what an MDR is.

24 MS. FAHY-ELWOOD: Medical-device reports where
25 people report, I guess, to the FDA about these?

1 DR. ZIPES: I have no idea. I do know that, of
2 the three apparent defibrillator discharges due to an EAS
3 system, I was able to track down two and both of those were
4 abdominal implants--not in my study, but as published as
5 separate case reports.

6 DR. LOTZ: Related to that, I noticed you
7 commented that, at least initially, the abdominal-implant
8 devices were larger and an older technology. Can you tell
9 whether the problem with the abdominal implants being
10 affected is due to the older technology or due to the
11 abdominal location?

12 DR. ZIPES: Good question and we have not studied
13 that. That would be a very relevant thing to do. The
14 patients in our study had older implants, as I showed the
15 correlation with date of implant as well. But that would be
16 a very good thing to look at.

17 DR. LOTZ: That might be particularly relevant to
18 the question about the spinal-cord stimulators.

19 DR. ZIPES: Exactly right. I think that is a very
20 relevant question. Thank you.

21 MR. FLETCHER: Is there any other discussion from
22 the committee?

23 We would like to thank all of the presenters for
24 the information they provided and we are now ready to go
25 into our committee discussion on those subjects of the

1 presentations this afternoon.

2 **Committee Discussion**

3 MR. FLETCHER: Any questions, comments or
4 suggested guidance to the FDA based upon those
5 presentations?

6 MS. KAUFMAN: It appears that the letter that FDA
7 sent out a year ago stimulated some reports back to them
8 that they may not have been receiving in the past. So it
9 seems that, perhaps, that was a prudent thing to do and that
10 they ought to continue to gather the information.

11 MR. WILSON: I had a question for Don Witters.
12 Concerning the wireless medical-telemetry devices, are there
13 any EMI design considerations for those devices, emission or
14 immunity?

15 MR. WITTERS: There is. It is, in some cases,
16 relatively minimal because the existing standards for
17 medical devices allow exemptions for some of the devices
18 that have transmitters in them, and it is extremely
19 difficult to do testing right at the frequency that you are
20 actually transmitting or trying to receive.

21 I may not have made it clear, but much of the
22 technology that is used for these systems is very old. It
23 is basically fm radio technology developed 50 years ago.
24 The rules by which they were developed and continue to be
25 used in many cases go back even further than that. So they

1 can be quite susceptible which is what we have seen.

2 On the good hand, much improvement has been made
3 in these devices. Today, you can certainly get devices that
4 are programmable and allow you to see and, in some cases,
5 program rejection of interference at certain levels. But
6 they do have improvements to be made.

7 DR. CARDELLA: In regards to the wireless medical
8 telemetry, there seems to be some controversy in the
9 information provided in terms of over what period of time
10 grandfathering of existing telemetry systems would be
11 allowed to run on for. What are your thoughts about that,
12 the two-year versus the five-year grandfathering period.

13 Also, if you could address a little bit of the
14 financial impact to institutions because the healthcare
15 dollars are getting tighter and tighter for these small
16 hospitals to upgrade \$100,000 or \$200,000 system is a non-
17 trivial task.

18 MR. WITTERS: Let me say that our consideration
19 within the American Hospital Association had much discussion
20 on that. I think our position at FDA is probably more
21 neutral about the financial impact. That certainly is a
22 concern but not the primary concern that we are involved
23 with.

24 The transition period that was proposed by FCC is
25 much shorter than the AHA proposed. The AHA is much closer

1 to the financial burdens and impacts that this makes. That
2 was based partially on a survey that AHA performed through
3 its American Society of Healthcare Engineers of
4 approximately 6,000 hospitals with something like 1500 or so
5 reporting back that their equipment is anywhere between
6 relatively new up to ten years or more old. An average life
7 figure of about seven years is what they thought.

8 Balance that against what the FCC typically deals
9 with. Their transition period would possibly have been
10 seven months. They figure that you want the use of that
11 service, you are going to out and buy new equipment and that
12 is how you are going to get it. Two years is a relatively
13 short end of the compromise, but still something much better
14 than you would typically get from FCC on their transition
15 period.

16 Manufacturers have said in the meetings that they
17 could have equipment out when they have a final notice in a
18 year or perhaps eighteen months. It would take a period of
19 time after that to get anything in large numbers, of course.
20 It is not clear if we would want to support a longer period
21 of time because that does, again, put patients, perhaps, at
22 increased risk that might not be if we were to try to do
23 this a little bit quicker.

24 It is difficult to balance that off.

25 MR. WILSON: I want to keep Don on the hot seat

1 here. In the proposed rule, it talks about all television
2 stations are required to commence d.t.v no later than May 1
3 of 2003. So are we headed towards a major problem with
4 these devices before that time frame?

5 MR. WITTERS: We think that the coordination with
6 FCC, the National Association of Broadcasters--all t.v.
7 stations are members of that--and the extra effort that the
8 FCC is requiring the broadcasters to do before they even
9 think about doing their testing which comes before actual
10 transmission will cover most of this.

11 Up until July, this seemed to be working well.
12 The incident I mentioned in July was mainly one within the
13 hospital, itself, or the hospitals, in this case, not the
14 broadcasters or FCC. They made the effort and, actually, in
15 that case, made an extreme effort to contact the people.

16 The hospitals, on the other hand, AHA recognizes
17 they have to educate their people better to understand that
18 they need to get that information to the right people and
19 understand what they have to deal with.

20 Most of the large markets, the urban areas, have
21 d.t.v. now. Washington does. New York, Dallas, L.A.,
22 Chicago. They already have it up. They had it up last
23 year. The next step down included smaller areas like Miami
24 and other areas and the smaller, even less populous areas,
25 are the ones that you are referring to that are going to be

1 on by 2003. Most of them are coming on, like, now, a larger
2 group of them.

3 The next big deadline is the 2009 deadline to shut
4 down analogue signals. But, at that point, digital will
5 close up and the extra channels that will be freed up will
6 be made available to other transmissions, four of which are
7 set aside for emergency broadcast, hospitals, ambulances,
8 that sort of thing, which was put in by the FCC to take up
9 some of that extra room.

10 But, as I said, the competition is very, very
11 fierce for this. We think that this is an extremely big
12 step to get something for a relatively small community but
13 we are also a community that has consequences that are
14 extremely serious for patients directly.

15 DR. MCKETTY: The recommendations for the spectrum
16 need indicates that the assumption is 500 concurrently
17 operating telemetric transmitters. How did they come up
18 with this number?

19 MR. WITTERS: If you read through the
20 recommendation of the AHA group that looked at that, you
21 will see that that is based on two things, a survey of a
22 dozen or so hospitals in this area and elsewhere and on the
23 experience of some of the people in the AHA group who do
24 work at rather large facilities. Typically cardiac-care
25 units are the ones that heavy users of this.

1 That was how that number came about. The
2 assumption was at least to sort of double that in the next
3 ten years to get the next portion of that. So the 12 to
4 14 megahertz that is requested and made it into the proposed
5 rulemaking, if this all goes through, will become--the
6 medical-telemetry service is based on that information.

7 MR. FLETCHER: Any additional questions, comments?
8 Cass had mentioned earlier that, since there seemed to be a
9 response to the letter that was sent out last year, the FDA
10 should be encouraged to do that. I think we should, in our
11 deliberations and our proposals, at least make some comment
12 about what they are currently doing and the direction we
13 think they should be going in.

14 If we do that in the form of a motion, at least
15 they will have something specific to gear future actions.

16 MS. KAUFMAN: It seems to me that one of our
17 concerns last year was that incidents may be occurring that
18 FDA didn't know about because the public might now know to
19 report it. So now they do and FDA is starting to get some
20 results back to that.

21 It is encouraging that they have only gotten
22 sixteen reports out of I think the 2 million folks who have
23 had implants. So I think it sounds like fairly good news
24 and I would like to make a motion that FDA simply continue
25 to collect those reports and encourage that they be

1 submitted.

2 MR. FLETCHER: Is there a second to that motion?

3 DR. LOTZ: I second.

4 MR. FLETCHER: It has been moved and seconded that
5 FDA continue to collect information regarding these
6 incidents. I would like to amend it slightly; as additional
7 information becomes available, expand their investigations
8 as needed into these devices, if you will accept that.

9 MS. KAUFMAN: Yes. I do. I don't see anything at
10 this point that warrants an expansion, but if something came
11 to their attention, then, certainly.

12 DR. LIPOTI: I disagree vehemently. I think that
13 the spinal-cord stimulator, the number of incidents that
14 came in, is really remarkable. Of the sixteen, I think
15 twelve or so were spinal-cord stimulators.

16 So, although I support the motion to continue to
17 collect data, I will be making a much stronger motion after
18 this one.

19 MR. FLETCHER: Any other comments? All those in
20 favor, raise your hands.

21 [Show of hands.]

22 MR. FLETCHER: Opposed?

23 [No response.]

24 MR. FLETCHER: The motion carries.

25 Dr. Lipoti?

1 DR. LIPOTI: I move that we recommend FDA
2 immediately begin work with neurologists and neurosurgeons
3 to raise their level of concern about the number of
4 incidents regarding spinal-cord stimulators and its
5 interaction with these surveillance devices.

6 That is the end of the motion. I would like to
7 find a Dr. Zipes of the neurologist community that would be
8 willing to do similar kinds of research.

9 MR. FLETCHER: Let me get a second for your
10 motion, first. Is there a second for the motion?

11 DR. CARDELLA: Second.

12 MR. FLETCHER: The motion was that the FDA be
13 encouraged to immediately get in contact with neurosurgeons
14 and neurologists to further investigate the incidence of
15 spinal-cord stimulator injuries.

16 Any further questions or discussion? All if
17 favor, raise your hands.

18 [Show of hands.]

19 MR. FLETCHER: Opposed?

20 [No response.]

21 MR. FLETCHER: Motion carries.

22 Now, if you wanted to put a capper on it.

23 DR. LIPOTI: I really want to compliment the
24 cardiologists for responding very quickly and for conducting
25 research. I think that, with the additional information

1 that has come in over the last year, that it has really
2 gotten my attention and I hope it gets FDA's attention that
3 spinal-cord stimulators have a similar problem.

4 MR. THOMAS: I would like to make just a comment.
5 Dr. Zipes, that work that you folks did was incredible. I
6 want to compliment you for, first of all, the active
7 participation of the American College of Cardiology with the
8 FDA and also the manufacturers work. Looking at this the
9 second year in a row, I am very impressed with the work that
10 has happened over the last year.

11 DR. ZIPES: Thank you.

12 DR. CARDELLA: I had another comment. For these
13 devices, and I don't report to be an engineer, but is it
14 possible to engineer pacemakers or implantable
15 defibrillators or spinal-cord stimulators; is it possible to
16 engineer those to be shielded against--we are in the midst
17 of installing a magnetic-resonance imaging scanner at our
18 place, and you have to put up elaborate radiofrequency
19 insulation and, in some cases, magnetic-field-strength
20 shielding.

21 Is that an achievable engineering project or is
22 that nontrivial?

23 DR. ZIPES: The MR issue is very difficult, I
24 think, although I know that some of the pacemaker ICD
25 manufacturers are working on that at the present time. The

1 other kinds of shielding of other EMI I think has progressed
2 extremely effectively.

3 Unfortunately, the public still worries about
4 microwave ovens and the things of years ago. I tell my
5 patient, the only way a microwave oven is going to hurt you
6 is if you crawl inside it. It really is not going to do
7 anything.

8 And none of these other things really have
9 significant impact as well. The MR, though, I think is a
10 more formidable issue yet is being addressed. Not being an
11 engineer, I can't carry the discussion any further than
12 that.

13 MS. SHEIN: I think, in looking at the devices,
14 particularly the cardiovascular devices, the ICDs and the
15 pacemakers, those devices are among the more robust devices
16 in protection against the EMI in their design. But you also
17 have to remember that these devices are intended to detect
18 cardiac signals and monitor what the heart is doing, itself.
19 And there is a certain amount of overlap in the frequency
20 between the systems that emit and these devices.

21 That is one of the particular problems with some
22 of the security systems is that there is not a set of
23 discrete frequencies that these devices operate at. They
24 are all over the board in contradistinction, for example, to
25 the cellular telephones that are more tightly circumscribed.

1 Again, with cell phones, as I offered last year,
2 those are discretionary devices. A patient may choose
3 whether they want to use them or not or how close in
4 proximity they come to them. With the number of security
5 gates that are used and the prevalence in the U.S., and
6 particularly at this point in time, those are not what I
7 would consider to be discretionary devices.

8 So, while there are efforts to see what you can do
9 to make these devices more hearty against the EMI assault, I
10 don't know that we will ever be able to say that you can
11 eliminate that as a risk.

12 MR. WITTERS: I would just add to that. You were
13 concerned about the spinal-cord stimulators. As John
14 mentioned, we are not so clear about the mechanism that that
15 might occur in. You can do so much in filtering. You can
16 do so much in software. But if it is, and it turns out to
17 be, something that is directly induced on the leads, that is
18 much more difficult to deal with and is not so clear.

19 The body is a conductor and the leads are going to
20 very sensitive neural pathways in the body. It is very
21 difficult to understand exactly what might be going on there
22 and then deal with it. It may not be a filter. It may not
23 be a control. It may be just the way that they are in the
24 body and these signals and how they are coupling. We don't
25 know.

1 DR. LOTZ: I had one kind of related question and
2 that is do you have any reports of incidents with
3 implantable devices being affected by powerline-frequency
4 devices. I have had a couple of engineers with the Electric
5 Power Research Institute tell me, but I don't know any
6 specifics, that one of their biggest concerns is workers who
7 are going back into work, say, in a power plant and places
8 like that with devices like this that are potentially
9 subject to interference from 60-hertz fields.

10 MS. SHEIN: I think 60 hertz clearly falls into
11 the range that you have to monitor for signals. Dr. Zipes,
12 how do you advise your patients who go into those
13 environments?

14 DR. ZIPES: That was an issue years ago and does
15 not appear to be today, unless they are extremely close to
16 the power source. For example, a mechanic working on a car,
17 unless he gets his device within six inches of the spark
18 plugs, it is not going to create a problem. Similarly, with
19 power tools and so on. That is what we advise our patients.

20 DR. LOTZ: That would relate, also, to the
21 situation where they are concerned about people going back
22 into the work force where they might otherwise--

23 DR. ZIPES: If we have a patient who, indeed,
24 deals with some sort of source of EMI, we actually expose
25 them under a controlled situation and see whether it does

1 have any impact.

2 If I may, could I make two comments.

3 MR. FLETCHER: Go ahead.

4 DR. ZIPES: First of all, I think you are right on
5 with the spinal-cord stimulator for a couple of reasons.
6 First of all, its location may be close to what we saw with
7 the abdominal implants. But, secondly, I, too, am disturbed
8 by the relatively small number of reports but a very small
9 number of implants.

10 We are not talking about the ICD pacemaker volume.
11 We are talking about a handful, basically, at the present
12 time. And seeing even twelve, I agree with you. I would be
13 very concerned. That area is going to blossom more. There
14 are preliminary data to suggest that spinal-cord implants
15 help patients with angina, coronary-artery problems, and we
16 are actually starting a study with one of the pacemaker
17 companies to look at that.

18 So that could burgeon even more and I think you
19 are right on with that.

20 At the risk of upsetting my good friend Mitch, I
21 would not be excited about a large multicenter pacemaker ICD
22 trial for a couple of reasons. First of all, although we
23 only studied 169 patients, it was a wide variety of
24 defibrillators that we investigated. It wasn't just a
25 narrow group.

1 I think if we did a thousand of the patients, we
2 would see the same kinds of data only times ten. The other
3 issue is that the pacemaker ICD companies are rolling out
4 new devices every two years. So, if you start a study now
5 and study these for the next two years, two years from now,
6 there is going to be a whole new array, generation, of ICD
7 pacemakers and you are going to start to study them as well.

8 So I would not be enthusiastic based on the data
9 that we have, the millions of interactions that have to
10 happen daily in the United States with the EAS systems and
11 the implanted device community. With the minuscule numbers
12 of reports, I would not be very excited.

13 What I would be excited about would be to get to
14 the manufacturers and establish testing procedures up front.
15 As they develop their new device, look for a whole array of
16 things that you all could put in place to be certain that
17 the new devices would not have the capability for this kind
18 of spurious interaction.

19 Thank you.

20 MR. FLETCHER: Thank you. I actually agree with
21 your last statement quite a bit, that if they are developing
22 new devices every couple of years, it is a little after the
23 fact to be trying to find out what they do once they hit the
24 market.

25 Do we have any additional discussion that we would

1 like to make at this time?

2 MS. KAUFMAN: On the telemetry, does this
3 committee need to have any kind of a recommendation or is it
4 proceeding as is without our offering any guidance? Do we
5 need to do anything relative to that?

6 MR. FLETCHER: If they are continuing to proceed,
7 perhaps they can, if they want to request something from the
8 committee.

9 MR. WITTERS: No; we are continuing to proceed
10 with that and interact with the FCC and the AHA, the
11 manufacturers and everybody that we can.

12 MS. KAUFMAN: So you don't need anything from this
13 committee relative to that issue?

14 MR. WITTERS: At this point, my presentation was
15 informative. If there are comments, they are gladly
16 accepted.

17 I just wanted to finish one point. I was talking
18 to Jon and there are some systems, I believe, that do work
19 on the EAS at some of the powerline frequencies; is that not
20 correct, Jon?

21 MR. CASAMENTO: There is one model out there that
22 works at 73 hertz.

23 MR. WITTERS: Which is close to the 60 hertz. So
24 that is something that we are certainly going to be actively
25 looking at.

1 MR. CASAMENTO: I would like to mention that, with
2 pacemakers and stuff, on the front end, there is some room
3 for improvement on input filtering and balancing the diode.
4 There is some room to move, from an engineering standpoint,
5 to harden pacemakers a little bit. Pretty soon, they are
6 going to reach the functional limits of their ability.

7 And then there is how they are used. There is the
8 biphasic units which stimulate from tip to ring, and there
9 is a monophasic, unipolar leads that to tip to can. Those
10 would certainly be much more susceptible to interference.
11 The technology, I think, is going more away from that
12 unipolar lead more to the bipolar stuff. Is that correct,
13 Dr. Zipes?

14 I would expect to see a big improvement when that
15 happens. I think a similar thing is going on with the
16 spinal stims. The unipolar lead arrangement seems to be
17 much more susceptible to interference than the bipolar
18 arrangement as far as what I have been able to determine to
19 date.

20 There are reason clinicians choose one mode over
21 the other, but there certainly is room to look in that area.

22 MR. FLETCHER: Dr. Lipoti, you wanted to make a
23 comment?

24 DR. LIPOTI: Yes; I am very happy with all that
25 Dr. Witters is doing, working with FCC on the interference

1 issue. The only concern that I have is the concern about
2 cost. The changeover in medical telemetry equipment is
3 going to cost quite a bit to the hospital and if they have
4 to pay more for their band because it is available through
5 this auction business, I think it is going to be cost-
6 prohibitive. I think it is going to be very difficult.

7 So although you have assured me that this is
8 supposed to not be part of the auction in the Federal
9 Register, it says they are making no finding on whether the
10 band would have to be made available through auction.

11 So I would like this group to go on record as
12 saying that this should be exempt from the auction.

13 MS. KAUFMAN: Is that a motion?

14 DR. LIPOTI: It's a motion.

15 MS. KAUFMAN: I second it.

16 MR. FLETCHER: Any discussion? Everybody
17 understand the motion? All in favor raise your hands.

18 [Show of hands.]

19 MR. FLETCHER: Opposed?

20 [No response.]

21 MR. FLETCHER: The motion carries.

22 DR. CARDELLA: I have an additional motion for the
23 telemetry issue. I would like to see the conversion
24 recommended in a two- to three-year time frame, not a five-
25 to seven-year time frame.

1 MR. FLETCHER: That is a motion and we need a
2 second.

3 MS. KAUFMAN: I will second it.

4 MR. FLETCHER: It has been moved and seconded that
5 you would like to see the telemetry--give me everything
6 again.

7 MS. KAUFMAN: I would like to see the switchover
8 to the new frequencies occur in a two- to three-year time
9 frame rather than a seven-year time frame and the
10 grandfathering of old existing systems be allowed to run on
11 for two to three years, at most.

12 MR. FLETCHER: Does everyone understand the
13 motion? Questions? Comments?

14 MR. THOMAS: Will manufacturers be able to meet
15 that time line? Sometimes, that is too aggressive for the
16 manufacturing and development process.

17 MR. FLETCHER: Can someone respond to that?

18 DR. CARDELLA: I thought I understood that the
19 manufacturers would be prepared in twelve to eighteen months
20 to have enough systems on line to manage the conversion.

21 MR. WITTERS: What I said was that the
22 manufacturers have stated in the meeting that they think
23 that, within twelve to eighteen months after the final rule,
24 that they could have product available for purchase by
25 hospitals.

1 MR. THOMAS: My concern is is there going to be
2 enough product available to make that transition in that
3 time frame. We are talking a lot of stuff, and lots of
4 medical institutions. I am not sure that the motion, as
5 stated, is practical in the real world of manufacturing.

6 MR. SZEGLIN: I don't think they will be able to
7 do it in eighteen months. I really don't. I don't think
8 they will able to come out with the design and get through
9 all of the testing and development, all of the procedures,
10 all the GMP requirements, et cetera. I just don't that is
11 realistic at all.

12 DR. CARDELLA: I would be willing to entertain
13 amending it to a three- to four-year time frame, not five to
14 seven years. I think five to seven is too long. Would you
15 re-second that?

16 MS. KAUFMAN: I would like to change the amendment
17 to say, "assuming product is available or as soon as product
18 is available," rather than extend the time period.

19 MR. SZEGLIN: That could take ten or fifteen
20 years. As soon as it is available?

21 MR. FLETCHER: We need to focus on what the motion
22 is going to be so that we will know what we are voting on.
23 If you are going to change the time frame, could you restate
24 exactly what you want us to vote on?

25 DR. CARDELLA: I move that the conversion to the

1 new frequencies occur in a three- to four-year time frame
2 after the final rulemaking and that existing systems be
3 allowed to run on for that same three- to four-year period
4 of time.

5 MR. FLETCHER: Second?

6 MS. KAUFMAN: Yes.

7 MR. FLETCHER: Any further discussion? All in
8 favor, raise your hands.

9 [Show of hands.]

10 MR. FLETCHER: All opposed, raise your hands.

11 [No response.]

12 MR. FLETCHER: The motion carries. There is one
13 abstention.

14 Any further discussion? By the way, let me just
15 point out that when I raise my hand, I am just showing you
16 how. I only need to vote when there is a tie.

17 Let me take this opportunity to once again thank
18 our presenters. You have brought us some very good, well-
19 thought-out information and you have definitely demonstrated
20 that a lot of progress has been made from last year.

21 As we have demonstrated in our motions to you, we
22 encourage you to continue in the direction you are going and
23 to look at those areas that we have expressed concerns for.
24 I also want to thank the committee who, once again, has
25 conducted some stimulating discussions. I am sure tomorrow,

1 we may have to talk fast if that Floyd person gets here any
2 sooner.

3 But I am sure tomorrow's discussions will be just
4 as stimulating. So I thank you and I am going to turn the
5 meeting back over to Dr. Suleiman who has some comments.

6 DR. SULEIMAN: Somebody said why hadn't I spoken.
7 Because Roland is doing such a good job, I don't have to.
8 Let me tell you, there are two roles of this advisory
9 committee. One is that if FDA is proposing some regulatory
10 standards, we run the concept by you beforehand.

11 The other thing is for you to advise. And, as I
12 was telling Roland, we are sort of redefining the process
13 and so a lot of issues that are related to our regulatory
14 responsibilities, we are running by you. In some cases, we
15 are not proposing standards, necessarily, but we value your
16 opinion.

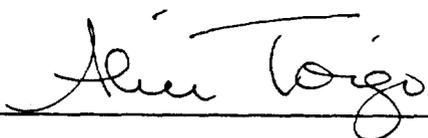
17 So some of these motions, they sort of say, it
18 sounds like you are doing the right thing, or, gee, we think
19 you are missing a point there, I think they are very, very
20 relevant and what you are saying is being listened to very
21 carefully by the Center. So we appreciate it.

22 We will see you tomorrow morning at, I believe,
23 8:30.

24 [Whereupon, the proceedings were recessed, to be
25 resumed at 8:30 a.m., Thursday, September 16, 1999.]

C E R T I F I C A T E

I, ALICE TOIGO, the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.



ALICE TOIGO