# TRANSCRIPT OF PROCEEDINGS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRAITON

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

TECHNICAL ELECTRONIC PRODUCT RADIATION

SAFETY STANDARDS COMMITTEE

TWENTY-FIFTH MEETING

VOLUME I I



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AT



DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

# TECHNICAL ELECTRONIC PRODUCT RADIATION SAFETY STANDARDS COMMITTEE

## TWENTY-FIFTH MEETING

**Volume I**

Thursday, September 24, 1998

8:30 a.m.

Gaithersburg Hilton
260 Perry Parkway
Gaithersburg, Maryland

MILLER REPORTING COMPANY, INC.
507 C Street, N.E.
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at

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C O N T E N T S

P R O C E E D I N G S

**Chairperson's Opening Remarks**

MR. FLETCHER: Good morning. Welcome to the second session of the 25th meeting of TEPRSSC. We have a very, very busy agenda today and we will do all that we can to adhere to the times that are posted.

I would like to take a moment on behalf of the committee to express our appreciation to Dr. Orhan Suleiman, Dr. Rick Kaczmarek, Dr. Jacobson and all of those who have worked so diligently to put this agenda together and to coordinate all of the things that are needed to be done to insure that this meeting was held and has been a success. So we do thank you very much for all of the work that you are doing.

At this point, I would like to begin the agenda so that we may gain a little bit of time. It would, perhaps, be to our advantage to go ahead and get into the initial presentation even though we are, perhaps, running a little ahead of schedule.

Dr. Jacobson, would you like to open up.

**Electronic Article Surveillance Systems**

**FDA Introduction**

DR. JACOBSON: Good morning. I would like to personally thank the committee for the careful attention that you have paid to such a wide variety of topics these

couple of days.

[Slide.]

Today, you are going to hear about a different kind of security device from the one you heard yesterday. Today's systems don't use ionizing radiation but, rather, they use the non-ionizing part of the electromagnetic spectrum from ELF up through the microwaves.

EAS systems are sometimes called anti-theft systems and they provide the security that you see in retail stores and libraries, in supermarkets, the pillars that you so often see and if you take an item through that you shouldn't, an alarm goes off. You will hear more about them in specific from the manufacturers today.

Metal detectors, of course, are used to scan for metal weapons in a variety of places--airports, government buildings, schools, prisons. The reason for today's session is that both of these types of systems have the potential for interfering with the normal operation of certain kinds of implanted medical devices; for example, pacemakers, implantable defibrillators, and neurostimulators.

You are all familiar with the phenomenon of interference. If, like me, you tend to keep your radio too close to your microwave oven, or if you sit on the plane and get nervous when the pilot says, "Please turn off all your cellular telephones," and you are hoping that the guy next

to you really turned his off.

You will hear a lot more about the individual EAS systems and metal detectors later on today, so I am not going to go into them. We will also be talking a lot about electromagnetic compatibility. Obviously, that is the opposite of electromagnetic interference.

The goals for products are to be compatible and to function normally even when they are used near each other.

[Slide.]

To put today's discussion in perspective, though, let me say, up front, that we do not think that we have a major public-health problem at this time. But we would like it to stay that way, especially since both the medical-device industry and the EAS and metal-detector industries provide products that are really important for the lives of the American public.

There are some trends in each of these industries that point to increasing potentials for interactions of the electromagnetic fields that are produced by the security systems with the electronics of medical devices. We want to be sure that we know that we understand that and that we are allowing for it.

The trends in the device industry are fairly obvious. There is more and more use of implantables using more and more sophisticated microcircuitry. And there is

more and more use of EAS systems in metal detectors for security purposes. Some of these are being hidden in architectural features of the store so that they are not so obvious, for example.

This makes the store entrance looks nicer and a little more discrete but it also means that people don't know they are there.

[Slide.]

Electromagnetic compatibility issues are not new. They have really been around as long as people have been playing around with electromagnetic radiation. Over the past ten years or so, we have seen--I have just listed a few examples; apnea monitors interfered with by FM signals, wheelchairs misbehaving around mobile radio sources like those in ambulances and police cars.

Pacers have had a couple of incidences of interference, once in the '60's where they were sensitive to microwave ovens and then, in the '90's with interactions to the new digital cellular telephones.

In each of these cases--I am not going to mention the last one right now because you have a separate session on that this afternoon, but in each of these cases we use different approaches to solve the problem. An apnea monitor that was extremely sensitive to interference was recalled by the manufacturer.

With motorized wheelchairs, we notified patients and their physicians. We did a fair amount of in-house lab work and then we used that lab work in support of a voluntary-standards activity.

The early pacer problem with microwave ovens was quickly resolved with changes in both the pacer design and the oven design. In the '90's, the cell-phone industry sponsored several large clinical studies to get a handle on the types of interactions that were happening and were able to demonstrate what was happening and what to do about it.

The bottom line, I think, to this is that electromagnetic compatibility issues are fundamentally engineering problems. They have the added complication that we are talking about engineering issues that cross industries that may not necessarily be talking to one another all the time.

Often the approach to solving these kinds of problems has to be case-by-case based on the type of device, the type of environment it is going to be used in. And it requires consideration of design both by the product emitting the radiation in question and the product that is seeing the radiation and receiving it.

[Slide.]

Given the array of devices that can be interfered with is so broad and that the number of potential

interfering sources is so large, given the gadget-happy culture that we are in, we, at FDA, have taken a pretty active educational approach in approaching the whole issue.

In 1995, we sponsored a conference with the Association for the Advancement of Medical Instrumentation. We had a lot of interest in that conference and lots of cosponsors; HIMA, the American Medical Association, U.S. Pharmacopoeia, ANSI, a number of cosponsors. Our approach there was to lay out the problems as we see them and to try to facilitate discussions across groups that don't ordinarily deal with each other but who should.

We have had a couple of follow-up conferences since then. I think the bottom line, as it is on this slide, is to share information and ideas. That is sometimes quite difficult when companies, of necessity, feel they need to protect their proprietary interests in their products and they don't want to talk a lot about design and design considerations.

[Slide.]

Our concern about interference with medical devices from EAS and metal detectors stems from three lines of evidence. The first one is that we have a small number of reports--and we are going to be talking to you about each one of these lines of evidence this morning--but we have a small number of reports that have been made to us in our

medical-device reporting system, 46 reports in all, of which 44 were related to the three specific devices I talked about earlier; pacers, implantable defibrillators and neurostimulators, and the patients experienced interference with the proper functioning of their device.

There is also a small literature of clinical studies that show the same kinds of interactions, the so-called in vivo studies, and we have some in vitro laboratory work that demonstrates that you can see these same kinds of interactions in the laboratory. Again, as I said, you will hear more about these in a second.

[Slide.]

Last October, given this kind of information, we sent a letter to all of the EAS and metal detector manufacturers and asked them what they knew about interferences with medical devices and we learned that the companies, not surprisingly, varied in terms of how much attention they had been paying to the issue.

Several EAS manufacturers have actually been doing testing of their system with devices and the metal detector manufacturers have been involved in an effort to develop test methods by working through the American Society for Testing and Materials, so there has been some attention being paid.

The EAS firms knew of some instances of EMI, of

interference. The metal detector firms did not report any additional incidence. Most manufacturers are not including anything in their materials or their literature about this issue.

In the interest of making today's discussion as productive as possible for everybody, we did meet with all of the manufacturers. There was an invitation to meet with us before the TEPRSSC session so that we could sort of walk them through what we were going to say and what our concerns were.

[Slide.]

What we would like to do today for the committee is to lead off the discussion with sort of a broad-brush view of what we know from our lab and other lab data. Jon Casamento will present that. Then we will describe the adverse-event reports we have received. Stu Portnoy will be doing that for you. And then we will review the studies that have been done in vivo with patients. Mitch Shein will do that.

I will then wrap up our section with a number of suggestions we have of what actions might be appropriate in this area and then each of the industries will present their perspective. HIMA, the Health Industry Manufacturers Association, will represent the device industry, the International EAS Manufacturers Association and the two

largest EAS companies will speak for that industry.

The Chair of ASTM's Consensus Standard Group will give the metal detector perspective since there is no trade association for that industry.

After time for public comment, we will then look to your general discussion and get your general input and advice on the suggestions that we have for moving forward.

Thank you.

MR. FLETCHER: Thank you very much.

MR. CASAMENTO: Good morning.

[Slide.]

My name is Jon Casamento. I am a researcher in the CDRH laboratories. I have been looking at the technical aspect of the magnetic fields emitted from electronic article surveillance systems. I took a look at the in vitro studies that have been published to date.

[Slide.]

We will review the magnetic-field measurements that I have made, discuss results and I will show you a brief summary of the current in vitro studies.

[Slide.]

One thing to do is to describe an EAS system, electronic article surveillance system, for those of you that are not that familiar. They consist of one or more pylons that you see around a store or entrance or exit. One

or more of those pylons may be a transmitter. There are designs where both pylons actually transmit.

There may be systems where a single pylon is both the transmitter and receiver. The separation distances between the pylons varies with the technologies incorporated.

[Slide.]

We collected eight electronic article surveillance systems comprising three of the four general areas used in the electronic article surveillance technologies. The very low-frequency systems, which I am using the NTI definition that I found for VLF, is below 30 kilohertz, there were two systems we looked at low. They are primarily, although they are not always, CW or some sort of intermixed modulation fields.

The second technology was the pulse-magnetic technology. They live somewhere between 30 kilohertz to 300 kilohertz. Many of those are pulsed magnetic technology. Then we looked at radiofrequency systems which operate from medium frequency to high-frequency RF spectrum from 300 kilohertz to 30 megahertz.

The microwave systems we did not look at because we don't have any reports recently of interactions with those systems.

Measurements were made with electric-field

shielded single-axis coils for the VLF systems and we used commercial isotropic magnetic-field survey instruments for the other systems.

[Slide.]

I mapped the fields using three orthogonal planes in order to characterize the field-strength distribution from the electronic article surveillance systems.

[Slide.]

As an example of what some of these maps looked like, the magnetic-field maps, this is a field map using protocol A in which it is a vertical plane normal to the face of the electronic article surveillance system. The saddleback that you see in this slide indicates that we have two transmitters here.

I want you to note the relatively high field strength in the center of the saddleback which someone passing through the center of the gate would experience. These are peak measurements. The data you see is not smoothed. It is raw data as I collected it.

[Slide.]

Here is another picture of the same unit with two transmitters. You can see it is taken in the horizontal plane as one would encounter the plane as one moves through the electronic article surveillance system. Of course, the higher fields are as you get closer to the transmitters

themselves. You will note the relatively high field strength in the center of this particular design. This is the very low-frequency system.

[Slide.]

One of the scans I took was very close, as close as my probes would let me, about 6 centimeters from the face of the electronic article surveillance system. In pictures like that, you can actually see some of the structure of how the system functions.

[Slide.]

The low-frequency pulse-magnetic system. Here, it was taken in another horizontal view as you would encounter the field as you would walk through it. With a single-transmitter system, the fields, although they are very strong, also fall off very rapidly with distance. That is something to be noted with this system.

[Slide.]

This is a summary of the measurements that I made for stability sake of data. I list the field strengths I made at 34 centimeters from the transmitter pylon. That is the last column. In the center, I describe the sorts of modulation that you will encounter with the various systems.

You will note, if you look at the VLF systems on the right-hand column, that the VLF system fields tend to be fairly high. The pulse magnetic systems are a little lower

or about the same range, and the swept RF field strengths are less.

[Slide.]

I plotted this on a semi-log graph here to compare the various technologies. The very low frequency here shows as being stronger. The point where the line levels out there indicates that we have two transmitters in that data. The other systems all have a single transmitter and you can tell by more or less the constant slope of the line.

But the VLF and low-frequency systems have considerably higher field than some of the other technologies.

[Slide.]

I looked at the peak-induced voltages and unloaded a 200 $cm^2$ loop. That is within the range that a pacemaker loop would be within the body. I have seen data ranging from 45 $cm^2$ to better than 300 $cm^2$. I chose 200 $cm^2$ since that has been used in some of the literature and compared--this is to look at the degree of threat that a device would encounter.

You can see that the low-frequency pulse-magnetic systems provide a higher degree of threat here. The RF systems, surprisingly enough, come in second. And then the VLF lower. For comparison's sake, I have a sensing threshold marked in the bottom of the graph. That is the

most sensitive that a pacemaker can be set although some of the literature suggests that that line can be drawn more nominally around 3 millivolts which would be up in the next scale up from the 0.01. Up above the top of the word "sensing threshold," would be more or less in the nominal range for a pacemaker setting.

But the field strengths, apparently, from this with an unloaded coil under ideal circumstances would provide interference within that range as well.

[Slide.]

I am going to look at the in vitro studies for EAS interactions. We went through the published in vitro studies to date. I will show you those studies in a minute that we looked at. This shows the number of interactions for devices studied versus the technologies used.

[Slide.]

These were the studies that we used to collect the data for the summary. I think device immunity is related to the amount of energy that the system, electronic system, is presented with and then its ability to resist that energy through whatever means the manufacturer designs into the device, be it, in this case, it may be some sort of filtration system or other electronic means to counter any interactions.

That concludes my remarks. Any questions?

MR. FLETCHER: Thank you very much.

MS. KAUFMAN: Is he taking questions now?

MR. FLETCHER: I will take one or two, but I want to limit the questions as much as possible.

MS. KAUFMAN: If you could go back to slide 11 and you notice the most sensitive setting, the sensing threshold, that was the most sensitive setting for a pacemaker, where are they normally set? Could you show us on that graph where they are normally set?

[Slide.]

MR. CASAMENTO: They are set at 3 millivolts, right about where the pencil is.

MS. KAUFMAN: Thank you.

MR. CASAMENTO: Any other questions?

DR. CARDELLA: The sensing threshold that you are talking about is the pacemaker's ability to sense electrical impulses from the heart, internal, or are those sensing thresholds from external, when they try to reset the pacemaker from the outside?

MR. CASAMENTO: Oh; those are internal to the heart, signal levels that the pacemaker is designed to respond to because it is monitoring the cardiac activity and I am sure there are some physicians who are going to talk in the public session that will describe that in very good detail.

MR. FLETCHER: Thank you.

Let me just say to the panel, the only reason that I am limiting questions at this time is these presentations are tied together and we will have periods of time where we can address questions. Perhaps, one presentation might answer a question that you may already have, and we have a full schedule.

DR. PORTNOY: Hi. My name is Stuart Portnoy. I am a physician at the Food and Drug Administration where I review manufacturer's marketing applications for cardiac devices including pacemakers.

[Slide.]

In this prescription, I am going to explain to you how I assessed and classified the adverse-event data reported to the FDA concerning interactions between security systems, including metal detectors and anti-theft systems, with medical devices, such as pacemakers, implantable cardioverter defibrillators and spinal-cord stimulators.

A copy of this presentation was provided to the TEPRSSC panel members in your panel pack labeled MDR Analysis, tab K. Please note that my presentation today reflects an update of the MDR database which now includes 46 reported adverse interactions as opposed to the 30 MDRs summarized in your panel pack.

[Slide.]

The medical device reporting system, or MDR, is a database of reports to the FDA of medical device adverse events. During the past ten years, there have been 46 adverse events reported to the FDA of interactions between security systems and medical devices.

To better understand the nature and severity of these adverse events, I recently reviewed each MDR report assessing the level of severity of the interaction according to the criteria shown in this overhead slide. These criteria are a modified version of the parameters used by the FDA to assess MDR reports for medical device adverse events reported by physicians and hospitals.

Severe interactions included those that were fatal or life-threatening, resulted in permanent or significant impairment, required surgical intervention or required patient hospitalization. Moderate adverse events were those that resulted in patient discomfort but no significant impairment or interactions in which the medical device was reprogrammed, for example, if an implantable cardioverter defibrillator, or ICD, was reprogrammed to the inactive mode.

Under these circumstances, if the patient had a life-threatening arrhythmia, the ICD would not have been able to deliver appropriate therapy.

A mild adverse event was one which resulted in a

detectable device interaction except that the patient didn't actually feel any symptoms, for example, if a patient's pacemaker went into the stat VVI pacing mode. Under these circumstances, the patient would not have recognized that this was happening. However, the patient's physician, during pacemaker follow up, would detect a reversion to the stat VVI mode during routine interrogation of the patient's pacemaker.

Finally, I also assessed the credibility of each MDR report. If a patient's physician detected that the patient's ICD was reprogrammed, for example, but the patient only remembered going through an anti-theft system one month prior to his or her visit with the doctor, then that report was considered less credible than, for example, a patient reporting having actually experienced physician symptoms while going through an anti-theft system.

So what I did with these reports, if there was a questionable credibility, I lowered them one level of severity.

[Slide.]

This is the most important slide of my presentation. This table shows all 46 MDR reports. The adverse interactions are arranged in columns from left to right in order--excuse me; from right to left--in order of increasing number of occurrences. For example, there were

more MDRs reported for pacemakers than there were for spinal stimulators or ICDs.

The security and anti-theft systems are shown in the left-most column. They are loosely arranged from the bottom to the top in order of increasing level of severity and they are arranged in groups according to which device you see in each column.

It is important to note that many of the MDR reports did not include a great level of detail. For example, some MDRs stated that a security system was involved but it did not specify whether it was a metal detector or an anti-theft systems.

Therefore, this table represents a summary of the MDR adverse events only to the level of detail as reflected in the MDR reports. No other sources of information were used to further assess these adverse interactions.

The data in this table suggest several findings. First, most of the MDR reports reported interactions involving pacemakers, spinal stimulators and ICDs. There was only one reported MDR for an interaction with a hearing aid and another for an IV-infusion pump.

Second, two-thirds of the severe adverse interactions occurred between metal detectors and medical devices, most of them pacemakers. In addition, most of the ICD interactions occurred with metal detectors.

The MDR data for spinal stimulators suggest a different mechanism of interaction as compared to cardiac devices. All of these spinal stimulators were implanted for the relief of chronic pain. Most of the MDR reports simply describe the adverse interaction as "overstimulation." Many of these interactions were very painful and patients even reported being jolted or thrown to the floor.

Because all of these reports simply specified that a security system was involved, it is not clear whether these interactions were with metal detectors or anti-theft systems.

The proposed mechanism of interaction with spinal stimulators is the induction of electrical current into the patient's lead system resulting in the sensation of pain. It is possible that patients with spinal stimulators are more susceptible to interactions with security systems than patients with cardiac implants because spinal stimulators usually use longer electrodes which may actually act as antennas that pick up the strong electromagnetic field generated by some security systems.

In addition, spinal-stimulator electrodes are wired directly into the patient's nervous system potentially lowering the physiological threshold for adverse interactions.

It is important to recognize that the MDR data

summarized in this table is qualitative and not quantitative. For example, the FDA believes that there may be significant underreporting of adverse interactions between security systems and medical devices. In addition, this table summarizes MDR data grouped by the number of reports of each type of medical device but not the incidence of interactions.

Since there are approximately 1 million pacemaker patients and far fewer ICD and spinal-stimulator patients, it is difficult to draw firm conclusions regarding the actual incidence of adverse interactions.

In conclusion, the MDR reports summarized in this table can best be used to provide us with some information about the frequency and severity of interactions between medical devices and security systems which can help us in estimating the clinical significance of these adverse interactions.

Before I turn over the microphone to Mitchell Shein, who is going to summarize several studies reported in the medical literature regarding these interactions, I will try to answer any questions regarding my presentation as time allows.

MR. FLETCHER: Are there any questions at this time?

MR. TUROCY: The MDR reports you indicated were

filed by physicians in hospitals?

DR. PORTNOY: That's correct.

MR. TUROCY: What feedback have you received from the manufacturer of those medical devices on their failure investigation?

DR. PORTNOY: We have met with the EAS manufacturers and we have also met with HIMA which is the trade association for the pacemaker and defibrillator spinal industry. Many of these manufacturers are aware of these MDR reports. Some of them have performed their own investigations. As you will hear later on, many of these manufacturers have also performed their own in vitro and in vivo studies.

So they are, as well, trying to understand better the nature of these interactions. But we haven't had much direct contact to discuss the MDR reports, themselves. Basically, once they are received by the FDA, then we use those as a kind of independent source of information.

MR. TUROCY: Thank you.

DR. CARDELLA: As a follow up to that question; these 46 events are physician or hospital reported and, basically, you are saying you have zero industrial reported events. Is that fair?

DR. PORTNOY: There is a formal process for filing an MDR report. Once that is done, the manufacturer does not

have any responsibility to the FDA to provide further information. The information is collected by the hospital, by the physician and there is a formal process how that is done.

I am not sure of what the responsibility is of the manufacturer at that point. I think, really, they have no responsibility at that point.

DR. LIPOTI: You mentioned that there is probably a significant underreporting of incidents. Can you give us any indication of how much underreporting? I know it is like the preacher asking the folks who are here why they are here, but we really are interested especially because there was one severe reaction with the infusion pump and no other reported cases. It puzzled me why there would only be one reported incident.

DR. PORTNOY: You know, your guess is as good as mine. What I believe is that probably the likelihood of that type of interaction is very, very low. If you look at this table and you see there are a lot of pacemakers, a lot of spinal stimulators, defibrillators, so I think that it is possible that that device is much more immune to this type of electromagnetic interaction. That would be my guess.

DR. JACOBSON: I would just like to add, too, we have to make sure that we understand which manufacturing community we are talking about because the security-system

manufacturers would have not have an obligation to come in and report that.

It is not always clear that everybody knows that it is happening or that they attribute it to the right thing. So medical-device manufacturers may not hear about it. Physicians may see something but not realize what it is or what the cause is and, therefore, not report it.

So it is difficult to do much more with this kind of information than just say, okay; this seems to be an early warning system, a flag, that we need to look at this issue a little bit further.

MR. SAVIC: I would imagine there are a certain number of cases of reported activities such as this even in the absence of some of these security devices. What type of validation did you undertake to verify that, indeed, these were caused by the particular surveillance?

DR. PORTNOY: That is an excellent question. We don't have a way to validate the credibility of these reports beyond the text that is provided. In other words, in your packet, there was a table. What was in there, showing you of the MDR reports, is that is all the information that we have describing at adverse events.

Here is an example. This is the first page of 46 adverse events. You can see the adverse-event column. That is a summary. In some cases, it is exactly the text that

was included in the MDR report. I tried to edit this as little as possible for your purposes.

So if a patient says that they felt whatever the symptoms were while they were in the AS gate, then we have to trust, at that point, that that is something related to the presence of the AS or of the metal detector and it is not something that the patient might otherwise experience.

As you point out, some pacemakers don't always work properly. Some of them eventually have to be recalled. So there are adverse events that we know about. There are hundreds of adverse events that are reported each year for these devices that have nothing to do with the AS systems.

But when we see that the patient is in the gate and they are detecting something unusual at that moment, then we can't rule out, at that point, that the AS system was involved and it suggests highly that, in fact, that was what caused the interaction. That is how we are looking at this data.

MR. FLETCHER: Thank you very much.

MR. SHEIN: Good morning. I am Mitchell Shein. I am the Center senior pacemaker reviewer. This morning, I am going to be presenting a brief overview of the in vivo literature studies regarding interaction of medical devices in EAS and metal-detector systems.

Before I get to that, I would like to address Mrs.

Lipoti's question regarding underreporting. In 1990, SMDA was passed and they had a requirement for postmarket surveillance. I worked with the studies with pacemakers. The requirement for those studies was recently alleviated by FDA in the last year, but the initial reports of those studies suggest that the number of reports coming back to the company might be underreported at rates of 40 to 50 percent, actually.

Now, this is going to be dependent upon the tracking systems that the individual company uses. I can't say that that is industrywide. Those are a couple of the reports that we saw. None of those were conclusive, but there is a fair amount of underreporting.

With that, I would like to have the first slide.

[Slide.]

Forgetting the literature, itself, I would like to talk for a minute about pacemaker response to electromagnetic interference. The way pacemakers are designed these days, they might have any one of the responses to an electromagnetic field that they enter.

They might oversense the field and that might result in the inhibition of the delivery of the pacing stimuli. They could, also, if they are in a dual-chamber device, if you have atrial oversensing, you might get ventricular pacing at the frequency of the interference or

atrial-track pacing.

You might also get, if the device is so designed, a reversion to an asynchronous mode which devices are often referred to as a noise-reversion mode. This is a design mode that the devices lapse into in the presence of a field with the intent of putting the patient in a safe pacing mode until they move out of the assaulting field.

The clinical significance of any of these is dependent on the individual. The inhibition of the delivery of therapy for a pacemaker-dependent patient, of course, can be quite problematic. Atrial-track pacing at high rates might be not well tolerated for some patients.

Asynchronous pacing, itself, while done frequently for things such as transtelephonic monitoring, carries a small risk of pace-on T phenomena and could be proarrhythmic. It could result in ventricular fibrillation. The odds of that happening are very small, but there is a discrete possibility.

It also bears noting that there is bench testing that we have seen in house that is characterizational testing that shows pacemakers goes through a transition zone as they move into the field between their normal behavior and their noise-reversion mode. During that period of time, there may be random pacing and there may be high-rate pacing. It is relatively not well characterizable.

Additionally, there is the possibility, as Dr. Portnoy suggested, that the pacing leads or neurostimulator leads, themselves, could act as antenna and when they enter these fields, there could be a current induced. The effect of that current is going to depend on its magnitude and, if it is of sufficient magnitude, it may result in a response by the end organ.

As Dr. Portnoy suggested, it could be pain in patients who have neurostimulators. For pacing patients, that could result in a cardiac cycle. But with stimulation thresholds on the order of a volt in cardiac pacers for pacing patients, we expect it would be far less likely to occur.

[Slide.]

As can be seen, the literature is not terribly rich with a number of studies in this area. This list might not be exhaustive. However, we don't believe there are many other reports in the peer-reviewed literature.

I would like to take a moment, now, to work through these chronologically.

[Slide.]

In 1988, Copperman, et al., evaluated 103 pacemaker patients presenting for follow up. These patients were attached to ECG monitors and asked to pass through a single metal-detector gate in both directions at least three

times. Copperman reported no incidence of interaction with any of these systems.

[Slide.]

In January, 1993, Dodinot, et al., reported on 32 patients who were exposed to three simulated types of EAS technologies including radiofrequency, a continuous signal at 2 to 10 megahertz, a post-electrode magnetic field at 132 kilohertz field modulated at 15 hertz and two magnetic fields, one at 300 and one at 10,000 kilohertz.

No interaction was reported for the RF or pulse technologies. However, for the magnetic technology, seven of the 32 patients responded in the 10 kilohertz field, six of 32 in the 300 hertz field. Dodinot also reported on an instance acceleration in the 300 hertz field but characterization of this patient's particular response was not provided beyond that.

Finally, this paper does not specify how patients were exposed but makes brief mention that inhibitions occurred when patients stood in regions of relatively low as well as high intensity and that pacing resumes as soon as the patient leaves the field or the field is turned off.

[Slide.]

In 1997, in the French journal Simucouer and, subsequently, at last year's annual meeting of the North American Society of Pacing and Electrophysiology in San

Diego, Mugica, et al., reported on 178 patients exposed to two Sensormatic systems, the Ultramax, which is an acoustomagnetic system using a 58 kilohertz field which Mr. Casamento previously referred to as an LF-pulse magnetic system, and the Sensormatic AisleKeeper which uses a non-modulated 73 hertz field which he previously referred to as a very low frequency system.

As shown, a total of 29 interactions occurred, 17 in the Ultramax, 10 in the AisleKeeper, two in both. Among the responses included were three instances of atrial oversensing resulting in maximum ventricular-rate pacing, one patient who responded with what was described as the DDD rapid-stimulation mode, although I am not familiar with what the specifics were.

There were also three patients classified as "other," whose ECGs were too difficult to troubleshoot and figure out precisely what happened.

[Slide.]

In the most recent issue of PACE, Wilke, et al, reported on 53 patients who were asked to walk through four systems of unspecified technologies operating at different field strengths. They included two security systems, an anti-theft device and an electromagnetic access device.

Seven pacemaker dysfunctions, all with unipolar sensing configurations, were observed with the higher

powered security system, five inhibitions and two cases of ventricular pacing secondary to atrial oversensing. Only two inhibitions were seen in the security system with lower field strength. No anomalous behavior was observed in either a anti-theft or electromagnetic-access system or with any system in a bipolar configuration.

[Slide.]

In an article which is currently in press for publication in PACE and with previously granted permission from the author, I would like to turn my attention now to what we believe is the single most comprehensive study on the issue.

McIvor, et al, evaluated the response of 25 ICD patients and 50 pacemaker patients who were asked to perform four exposures to three types of EAS systems, six actual devices in all. Those systems included two magnetic audiofrequency systems listed, three swept radiofrequency systems, and the acoustomagnetic system listed at the bottom.

[Slide.]

No interactions were observed in any of the ICD patients or two of the telectronic pacemaker patients reported. No interactions were reported for exposure to the swept RF systems and that is why they are not listed on this slide, or for the remaining 48 pacemakers, all exhibited

responses of the type I have mentioned earlier.

I would note here, the EAS-induced pacing are the first reports we have actually seen of this type and they warrant further evaluation.

[Slide.]

In addition to its broad investigation of the interactions between pacers and EAS systems, McIvor, et al., also presents this table which merits consideration through today's discussions. Specifically, while there are clearly fewer interactions for the patient walking through the system which is represented as protocol A as well as standing in the middle of the system at the central point, which is protocol B, there were clearly interactions happening here.

[Slide.]

I would like to close by looking at some case studies. While these case studies don't represent large studies on the whole, they are illustrative of the types of interactions that we might see. They include the report from McIvor as well as from Mathew, et al., which were inappropriate discharges of an ICD and an EAS system and also the one from Eisenberg, et al., which is listed at the top which was a spinal-cord-stimulator patient who, walking through the system, suffered significant sequelae and ended up with long-term disability.

I guess, in conclusion, what I would like to say is that there is no single, comprehensive or conclusive in vitro or in vivo study nor is there any way for either device community to predict the advances of the other as they develop their next generations of devices.

In short, a commitment to communication and cooperation appears vital. Some of this will occur under the auspices of the ongoing drafting of voluntary standards. A direct communication between the two communities is vital.

In closing, I would like to say that there is clearly more work that needs to be done in this area.

MR. FLETCHER: Are there any questions at this time?

Dr. Jacobson?

DR. JACOBSON: So our question, then, is what do to.

[Slide.]

We have enough evidence, we think, to warrant some actions and that is why we are talking with you today. We really value your advice on these suggestions as I go through them during the discussion period. It will probably be particularly helpful after you have heard the presentations from the industry's perspective as well.

The one thing I would like everybody to keep in mind is that we really have two very different situations to

consider, too, in terms of the future, and that is things to think about for the installed base of products, things that are already out there, and also designs for future products.

[Slide.]

I think for the already existing products out there, both the medical and the security type, industry can develop safety recommendations for use. This could be labeling for users on the device or to their customers, retailers, for example. It could be some kind of signage on EAS systems and metal detectors so that device users would be aware that they are being used.

Additional in vivo testing, clinical-type testing, of patients would be very helpful to follow up on some of the things that you have seen, sort of tantalizing clues but it is hard to pin down some of the things, to help identify problematic combinations and also the information from such studies could be useful in designing future products.

The manufacturers would have to cooperate here. There is precedence for that in the clinical studies I mentioned that were done sponsored by the cell-phone industry for pacer interactions with cell phones that was paid for by the cell-phone industry and that was published last year in The New England Journal of Medicine.

In the course of these studies, in vitro work could be done simultaneously and then that in vitro work

could be used to correlate lab effects with those seen in the clinic and maybe allow the development of some good bench test, good surrogates for clinical testing so we wouldn't always have to go into the field to do this type of testing.

And, of course, we need to continue monitoring and reporting of adverse events.

[Slide.]

For our part, we can get the word out to physicians and patients. In your package, we included a draft advisory that we have done, intending that to go out to physicians, to cardiologists, neurologists, emergency physicians and others, to alert them to the issue so they can counsel their patients.

We are holding off mailing that until after this meeting to see what kinds of feedback we get here. We have also solicited comments and gotten quite a few from manufacturers and clinicians on that draft advisory.

One of our recommendations that is causing some problems to some of the physicians and EAS manufacturers is the one that suggests that patients may want to ask for alternate forms of entry or exit. We would be interested in your advice on that.

Another was our recommendation, "Don't stay near the device longer than necessary." There was a request to

change that to, "Walk through at a normal pace." We would be interested to explore that a little bit.

We also need to continue to urge physicians to report to us. Again, we use these reports as an early-warning system but, even in the last couple of days, we have gotten some information from physicians once they heard about this meeting, and, "Oh; I have a report; wouldn't you be interested in it?"

So we need to continue to get the word out.

We also could target information to special groups. We are starting to think that, given what we have seen, at least in the MDR that we have got in house, that maybe the neurostimulator patients--there aren't very many of them--they may be a special subset of patients that need some additional information, given the design of their product. We could target messages to individual groups.

And, of course, we need to continue our laboratory assessments and to do as much there as we can and to evaluate what is happening with some of these systems. If these voluntary efforts fail and if it looks like we have a public-health problem brewing, then we will have to evaluate our regulatory actions.

We would be looking both at the options we have under the medical-device law and under the rad-health statute.

[Slide.]

I think new products raise different kinds of issues. We have been stressing all of the session increased communication. We think that is really an important thing. Increased communication across the industries can be very powerful here in terms of each product manufacturer knowing the environment that their product is going to operating in and what products will be exposed to that environment and being able to design to that.

Device manufacturers will need to include electromagnetic interference as a design consideration under our quality-standards reg. We don't have a similar provision in the rad-health act unless there is a mandatory performance standard in place but, obviously, a good design is simply good practice so I don't think that really should be a problem.

We are also going to be looking at our premarket applications for medical devices to be sure that electromagnetic-interference issues are addressed both in terms of performance and in terms of labeling.

Again, we need to monitor what is happening out there and evaluate whether we need to do more and, if so, what.

[Slide.]

As I mentioned earlier, we have had quite a lot of

success in helping to work related issues through technical forums. Perhaps we should encourage a workshop or workshops for these products or some other kind of formal scientific exchange. I think the value of such an exchange could be realized if we, then, could take the information generated there and use it in good standards-writing efforts, going into the consensus standard-setting communication.

The metal-detector communication, as I mentioned before, has already started this. We, at FDA, have always been staunch supporters of the voluntary consensus standards process. The U.S. runs on voluntary consensus standards from setting fire codes to film speeds to heart-valve testing.

Very recently, last year, we were given authority by Congress to officially recognize voluntary consensus standards. They realized the magnitude of the job we have if we were expected to write mandatory performance standards for all medical devices. It simply isn't possible. So the idea of recognizing voluntary consensus standards is an incredibly powerful tool that we have now.

We are very excited about using it. We have already recognized this summer close to 400 voluntary standards that we would like to use. One of those is the EIC's standard on electromagnetic compatibility which would be very useful here.

So, I think buying into the consensus standard process is really a very viable option and would be a win-win for everybody.

MR. FLETCHER: Thank you, Dr. Jacobson.

Are there any questions from the panel?

MS. KAUFMAN: Do we have any data from countries outside the U.S. on incidence and any kind of actions that other countries have taken on this issue?

DR. JACOBSON: We probably have some anecdotal incidents, but most countries don't collect information or they are just starting to collect postmarket information in a consistent way.

MR. WILSON: On your MDRs, when was that information requested for this report?

DR. JACOBSON: When was the information requested of whom?

MR. WILSON: For the collection of all of this data. What I notice is that a number of these reports go back as far as 1988. A lot of them are old reports.

DR. JACOBSON: Right. There really is no formal request for this. This is a standing obligation that the device manufacturers and the user facilities have to supply this information to the agency. When we looked at the database, we just went back and looked at whatever was in there, however old it is.

So some of it may be on older products, for example, which may be where you were going.

MR. SAVIC: I noticed on your advisory that you don't have the infusion pumps listed in there even though there was one incident involving those. Is that a deliberate decision?

DR. JACOBSON: Yes. I think in the advisory, you will notice that we talk about--that we are really orienting this one towards the cardiologists and the neurologists. We are not sure and we are still considering, so we would be interested in your opinion as to whether it would be necessary to go out with something on infusion pumps. I think, now, there isn't really enough to warrant that. We have only one report.

MR. ELDER: Relative to that draft notice that you are sending out, I was just struck by the title of it being important information on anti-theft devices and so on and so forth. If most folks in the room are like me, they get mail all the time that says, "Important. Dated. Open immediately."

What I am saying is the word "important" is not so important anymore. I am going to suggest a title change, and it is just a suggestion. But why don't you hit them between the eyes with saying, "FDA recommendations for minimizing any adverse effects on pacemakers, ICDs, spinal-

cord stimulators by electromagnetic anti-theft devices."

DR. JACOBSON: We certainly will take your suggestion into consideration. These public-health advisories are a standard format that we use where we have different color ink on the front of the document. Hospitals and physician groups are relatively used to receiving them.

We had a recent one that you will hear about this afternoon on the medical-telemetry systems and actually went back and did an evaluation of the impact of that alert. Very high percentages of people remembered seeing it, remembered what the message was. So I hear you. We always struggle with that.

The thing is, we want to put this in context in terms of--the recommendations we have in there, as you will see, are fairly benign. Again, one of the reasons we are here today is to kind of feel our way along in terms of how much of a concern is this. We don't want to raise a lot of unnecessary fears among patients on the one hand. On the other hand, we want to make sure they have the information, like a very, very important message.

MS. EHRGOTT: Is this the correct time to be parsing this statement here, or do you want to defer that until later? I guess my concern is what was brought up before about alternate exits and entrances. Does that mean a similar information sheet has to be delivered to every

establishment that employs these monitors and is that problematic?

DR. JACOBSON: Yes. That is one of the concerns. In fact, the question was how do we go about getting this information to the retailers, for example, or to other users of these systems so that they would understand when people approach them and is it even technically possible to turn off these systems once they are in use.

Those are the kinds of issues I know that the manufacturers are very anxious to address.

DR. CARDELLA: I pass through these devices frequently, I'm sure, but I really haven't paid that much attention to it. Are they currently labeled as producing electromagnetic fields or is there labeling that advises pacemaker patients about it now? Are they unlabeled at this point?

DR. JACOBSON: The manufacturers actually can address that better than I, but, in terms of safety information about potential interactions of medical devices, most companies do not have anything like that in their labeling. Most stores, that I have seen, at least, might have the brand name but they don't have anything in addition.

Or they might say, "Protected by such and such." But it doesn't mention the fact that there is

electromagnetic radiation, as far as I know.

MR. FLETCHER: Thank you very much.

As you may note, we are slightly ahead of schedule. But if Jim Putzke is prepared, we will continue to move forward.

**Medical Device Industry Perspective**

MR. PUTZKE: Good morning. I am Jim Putzke. I am here this morning representing the Health Industry Manufacturers Association.

[Slide.]

I would just like to make one point initially and that is that our industry has a very important role to play in the filing of MDRs. In fact, I believe most of the MDRs are filed by the industry because we are obligated to report adverse events that we get from physicians or any healthcare professional, or anyone, for that matter, about our devices.

It was in a very specific time period so I think that you will find that most of the MDRs that are filed are filed by the industry as opposed--they may be initiated by healthcare professionals by calling the industry, but we are obligated to funnel those calls to a central location so that decisions can be made according to very specific criteria on whether this is an "MDRable" event or not.

I have tried to summarize a little bit what we know about the interactions although we have had some new

information this morning. But my overheads go back to a meeting that we had at HIMA with the FDA in the middle of July. So you will see the 30 number again later on.

And then I address the characteristics of implantable electronic medical devices. I don't mean to include prostheses of any type, knees, hips, heart valves, anything like that.

And I address the characteristics of these devices to see whether the adverse events make sense given what we know about the characteristics of the devices and then talk about a couple of applicable--I picked out three standards out of the CENELEC centers that our devices perform to to talk a little bit about the limitations that standards impose with respect to addressing these issues.

And then, I have some general conclusions and future plans. I have concentrated primarily on electronic article surveillance systems since patients come in contact with them more frequently and metal detectors encompass such a wide range of technologies. But, presumably, some of the same comments apply to both.

For each of the points, I will try to address pacemaker and defibrillators separately from neurostimulation devices because the incident rate is different. The designs are quite different. The clinical significance of the interaction is different and, of course,

the labeling which we provide with products, which I have included copies of in the handout, is also quite different.

[Slide.]

With respect to pacemakers and defibrillators, then, as of the 7-15 meeting, of the reported incidents, about 50 percent of them are related to pacemakers and defibrillators, nine of which involved EAS systems. One can only speculate as to the number of opportunities for interactions--that is, the number of times that our patients pass through these gates.

But a representative worldwide number is approximately 2.5 million active implants that are passing through EAS systems on a regular basis. I would say conservatively about half of those are in the United States.

The reported problems have, for the most part, involved either prolonged and/or close--what I mean is typically, patients leaning or standing in the immediate vicinity of the gate as opposed to passing through the EAS systems at a normal pace. Although most of the interactions involve low-frequency magnetic fields, interactions have also occurred on the so-called swept RF systems, on that technology.

Interaction is not some mysterious thing, interaction between the RF and the electronics in the device but rather it is the development of voltage on the leads

that connect our devices to the heart or to the nerves in case of neurostimulators--but develop voltages that are high enough due to the strong magnetic fields that it causes oversensing.

[Slide.]

With respect to neurostimulation systems, in terms of what is known, first of all, although most of the reports are on spinal-cord stimulators, this is a rapidly growing area and neurostimulators are being used for a wide variety of applications, for the control of Parkinson's disease, tremors, peripheral nerves, deep-brain stimulations, urinary incontinence, stimulating the movement of food through the digestive system. Almost everything that you can possibly imagine you could stimulate is certainly being experimented with.

As opposed to pacemakers, neurostimulators, at least today, do not include sense amplifiers. They are not trying to sense anything and it is strictly a pulse generator. But it is reasonable to assume that, in the near future, manufacturers will try to close the loop on neurostimulators--that is, try to sense myopotentials or nervous-system signals and provide additional benefit to patients.

It is also reasonable to assume that the sensitivities of these devices will probably need to be

higher than the current sensitivity with pacemakers and defibrillators.

In the case of neurostimulators, prolonged and close exposure--oh; I would mention that there are about 50,000 active implants worldwide passing through these systems regularly. Again, they account for about half of the MDRs, or at least they did at that point in time.

In this case, prolonged and close exposure is not a prerequisite to patient discomfort. Even momentary exposure can be painful to patients, although, significantly, a single EAS technology is involved in the majority of the incidents--that being in the magnetic systems, the low-frequency magnetic systems--and interaction in this case, as reported by the FDA, is a result of developing sufficient voltage on the leads to support current flow that will directly stimulate wherever the lead is attached.

Really, the pulse generator would not even have to be in the body. Just putting the lead in the body by itself, the pulse generator doesn't really participate in that. So voltages that are developed in the lead system directly stimulates the heart. I am talking about the neurostimulation systems. It directly stimulates the nerves, not the heart, in the case of the neurostimulation systems.

[Slide.]

I thought we would talk a little bit about EMI protection that our devices contain today. Implantable medical devices are among the most resistant to EMI of all medical devices and are subjected already to rather extensive EMI testing although most of that testing does involve higher frequencies which are the characteristics of known intentional emitters; radio, t.v., radars, microwave ovens, cell phones, et cetera.

The titanium can, itself, is a very effective RF shield but not so effective at lower frequencies. In fact, as you will see on a later slide, we use about 30 kilohertz to about 200 kilohertz as the telemetry link for bidirectional communication between programmers and implantable medical devices. So the titanium can is pretty much not there in those frequency ranges.

All the lead systems which connect the device to the area of stimulation can act as antennas being surrounded by the body's conducting medium makes them a very poor antenna at high frequencies.

Then there must be, of course, a hole in the titanium can through which the leads pass. We use integrated-feature filters in that area to screen off RFI right at that point so that very little energy gets into the can.

But, after all, we must sense physiologic signals. We have band-pass filters that are centered in the area of 25 to 100 hertz which are followed by switch-cap filters

But, after all, we must sense physiologic signals. We have band-pass filters that are centered in the area of 25 to 100 hertz which are followed by switch-cap filters that further steepen the skirts on band pass. The sensitivities on these devices range from in the hundreds of microvolts--I would say 100 microvolt--to about 5 millivolts which is a very wide range. But keep in mind that we must not only sense the normal intracardiac electrograms but we also must sense the signals that are associated with abnormal activity like fibrillation which is a much lower amplitude signal.

So that is why most of the defibrillators have some sort of automatic gain control to drive the sensitivity down when there is not normal rhythm present.

As already mentioned, the presence of noise has been anticipated by pacemaker designers since day 1, essentially. The mode of operation that was chosen, or a feature of pacemakers, is that if they are confused by a rapid pulse rate, they revert to asynchronous mode which means they start pacing believing that is the safest thing to do if you are confused; start pacing.

And they will pace until the interference goes away. The frequency at which that begins varies from manufacturer to manufacturer but it is generally in the range of, say, 12 to 25 hertz or so as the lower end of that

and then up to a higher frequency.

The thought is that, certainly, at frequencies of 12, 25 and 60 hertz, that cannot be a physiologic signal. It must be noise. Therefore, I am going to do something which I know is safe and that is pace.

[Slide.]

This was already covered mostly so we can go through this quickly. But telemetry--I have already mentioned that we use the range of 30 to 200 kilohertz for bidirectional telemetry with our implantable devices. RF reprogramming is just simply not a problem with modern products because of the extensive coding and error checking that goes on in that communication link.

Now, with respect to pacemakers and defibrillators only, oversensing, which is a result of the voltages developed on the lead, can cause the inhibition of the pacing output, reversion to asynchronous pacing. In the case of dual-chambered devices which are designed to sense in the atria and then pace in the ventricle, generally the sensitivity in the atria is set to a lower value than that in the ventricle so, as you approach a noise source, it is logical to assume that you would sense on the atrial lead first.

The pacemaker's response to that is, then, to pace in the ventricle. That has been called tracking. It is

important to point out, though, that when that does occur and we talk about high-rate pacing in these cases, it is always within the range that has been preset by the physician as being physiologically safe for that patient; that is, there is no mechanism that will cause the rate to go to some dangerously high rate.

So with a dual-chamber product, the physician must program a maximum tracking rate and it is usually in the range of 125 to 170 beats per minute, something in that range. So, in the presence of EMI, it will not do anything other than pace within that range.

Then, with rate-adaptive products--many of our new products include rate-adaptive features to help people that have a dysfunctional SA node. And so we need some way to know that the patient needs more perfusion. This is done with either accelerometers internal to the device inside the titanium can and, therefore, not susceptible at all to MI or measuring other things.

One thing that I think stands a chance of being impacted by these devices and has been demonstrated; there are devices that measure transfer of impedance by simply measuring the impedance between two points in the chest and use that to derive respiration rates so as you start to exercise or walk or whatever and you start to increase respiration, the pacemaker picks up its rate.

Again, with rate-adaptive products, the physician must program a maximum rate, what is called a "maximum sensor rate," and EMI or voltage picked up on those leads will not cause the rate to go outside of that range.

The unpublished report cited said, I am not aware of any instance of direct stimulation of the heart as a result of EMI on the leads. There is a good reason for that with pacemakers and defibrillators. At all times except when stimulation is the desired outcome, they present a rather high impedance to the lead system and, therefore, it is difficult to get a lot of current to flow in that lead system and to cause direct stimulation. So I think that report needs to be looked at.

Now, concentrating just on neurostimulators, again, and this has been said several times, direct stimulation is the issue with those devices. And, again, it is just due to the voltage that has developed on the lead system.

[Slide.]

I chose just these three sections out of the rather lengthy CENELEC standard that is a draft standard that we are working to. The first one is designed to limit the amount of current that can flow in the lead system as a result of EMI. All three of these tests are done with the signal generator directly connected to the pulse generator.

These are not radiated tests.

The pulse generator is directly connected to a signal source through an interface circuit and the frequencies vary. There are different limits, depending on the frequencies. But, in the first case, it basically limits the current that can flow to 50 microamps down in the lower frequencies and goes on up linearly, then, to about 20 milliamps at the high frequencies.

The reason this is important here is that this really effectively limits the capacitance that one can select for the integrated feature filters because if those filters are too large a value, then more current will flow in the system at high frequency than is allowed by this standard and pretty much effectively limits the integrated feed-through filters to about the 2 nanofarad range.

The second one is talking about protection--the word "malfunction" is in the standard so I use that, but I want to explain. Here we apply, again, directly, frequencies from 20 hertz to 500 kilohertz at a voltage amplitude of 1 volt peak-to-peak CW.

The requirement is that the pacemaker--it can sense, it can inhibit, it can track, it can revert to asynchronous pacing. It just should do those things in an orderly manner and transition between those things in an orderly fashion.

I want to talk about the malfunction because it is almost inconceivable for me to imagine some EMI source that could possibly damage a pulse generator after it is implanted in the body. When you think of the tremendous energies that are associated with electrocautery in the hospital. You can defibrillate across the patient's chest with an implantable medical device.

Now, not counting things that are inside the hospital like radiation therapy, perhaps, or diathermy or something like that where you can heat up the generator because it is metal, EMI just is not going to damage pulse generators no matter what the magnitude, within reason. They will return to normal operation once the EMI is gone.

Then the other one is the protection from sensing. That is kind of, again, directly connected. It covers a wide range of frequencies and the differential voltage that is applied varies from about 200 microvolts peak-to-peak in the lower frequency ranges to about 1.5 volts peak-to-peak in the higher frequency ranges, in the 730 hertz modulation The requirement here is that the devices not sense.

Clearly, certainly, EAS technologies can generate voltages in excess of these limits on pacemaker and defibrillators in close proximity to the gates. Calculations which have been done by many--Mr. Casamento, this morning--show that assuming a 200 $m^2$ loop, which is not

large, show voltages that are significantly over 1 volt peak-to-peak are possible.

[Slide.]

Starting with conclusions, obviously, both the EAS system providers and the pacemaker/defibrillator providers are meeting all standards imposed on their industry. However, the standards do not preclude interaction.

The second point speaks to relevance. It is true that interference between these devices can be demonstrated and has been reported. The question is with the current level of awareness provided by manufacturers and healthcare providers and in the patient's normal daily interactions with these devices, is a clinically significant event likely.

There is a small number of complaints compared with a large number of daily interactions I believe strongly suggests that the answer is no.

The third, in considering any possible action that would affect the lifestyle of patients, the risk associated with the action should far outweigh the benefits. These are elderly patients, for the most part, that are already suffering from being more dependent on others. The pacemaker is, fortunately, one of these things that you don't need anybody's help to use. It creates a great deal of independence for a patient.

Some of the things that have been proposed--seeking an alternative entrance, for example--bothers me a great deal because that means you have to take somebody with you. Otherwise, who goes in to ask to seek an alternative entrance. Once you are in the store, if there is some type of emergency that you need to evacuate, what do you do? Do you ask somebody for an alternative exit? So I think that is putting the risks out of perspective.

[Slide.]

With respect to neurostimulators, again, both the EAS system providers and the neurostimulators are meeting their standards, the same statement, that these don't preclude interaction under certain conditions. The reported rate is about 50 times higher than that between pacemakers and defibrillators and the EAS systems.

In this case, one particular EAS technology, that magnetic technology, if not one manufacturer, accounts for the majority of the reported interactions. The neurostimulator labeling which I have examples of later contain stronger cautionary recommendations than current pacemaker/defibrillator labeling and that may be warranted by the higher rate of reported events.

Of course, in this case, patients may feel and occasionally experience painful stimulation from the peak voltages induced by EAS fields.

at

[Slide.]

I won't bore you with reading that whole thing but this is basically the labeling that is included by most manufacturers but only, again, predominantly for the last year, year and a half, with our submissions. It basically advises people that these devices exist and that they should not linger in the area of the entrances and exits of store and to proceed through these things at a normal pace.

[Slide.]

With respect to the neurostimulator labeling, I would mention, is a little more aggressive, the same thing, advising people that these things exist in libraries, stores, et cetera. They suggest using care as you approach these devices. If you feel unwanted stimulation, you might ask for assistance to bypass the device.

[Slide.]

I think, to summarize, lines of communication between the Health Industry Manufacturer Association and the IEASMA representatives are, certainly, already in place. I won't rule out possible changes in implantable medical devices that would help to minimize the interaction although, in view of the strong magnetic fields, I doubt whether total elimination, no matter how close you get is possible. But I never say "never."

Also I think there might possibly be changes that

could be made on the EAS side to help control the potential for interaction. But, again, you get into, as Dr. Jacobson explained--if the solution existed today, I think it would probably take, since our devices last six to ten years and development life cycles are two to three years, it would take ten or twelve years before you would purge the system even if a solution existed today.

I do think one thing is that EAS providers should avoid placing systems where people are required, in the normal conduct of business to linger, and that is at the counter. You must stand there while you are being checked out. I would prefer at the entrance and exits where you are expected to pass at a normal rate.

We need to develop means for communicating the characteristics of implantable electronic medical devices so that whenever technology permits, interactions can be avoided. It seems like standards committees and regulatory bodies mainly consider two points when they are licensing intentional emitters. One is they limit the emissions to prevent the interference with other licensed emitters. That makes sense.

Two, they limit the emissions to the biohazards which are defined by the ANSI 95.1. I would just like to suggest that there is one other consideration and that is the extent to which these devices might interfere with

implantable electronic medical devices which are enhancing the quality of life for millions of people worldwide.

Perhaps a section for the ANSI standard could be developed dealing with the characteristics of these devices and steps taken that could minimize, if not eliminate, the potential for interference.

Thank you very much.

MR. FLETCHER: Thank you.

Questions from the panel?

MR. THOMAS: In your conclusions and also when you showed us the applicable standards, whose standards are those? Are those HIMA, FDA?

MR. PUTZKE: No. Those are CENELEC standards although, as you probably know, Mitch is working with a group, EMC committee of AMI that is working on standards that AMI will produce. Those are CENELEC, the international standards.

MR. THOMAS: Then, a follow-on to that; in the neurostimulators, you provided applicable standards for the pacemakers and defibrillators but there were no standards that you gave us for the neurostimulators.

MR. PUTZKE: I believe that is a hole in the system today. I am not aware of standards which--

MR. THOMAS: So there are no standards for neurostimulator?

MR. PUTZKE: That I am aware of.

MR. THOMAS: So, therefore, the conclusion is incorrect that they are meeting all standards because there are no standards to meet.

MR. PUTZKE: Yes. I think you have a good point there. I am not aware. Now, somebody else might address that later.

DR. LIPOTI: One of the points that you made is that you are concerned about the strong language in the draft warning that would go out to physicians who were implanting these devices in their patients. Yet when I read what kind of warning is already in the patient labeling for spinal-cord stimulators, it really is quite comprehensive.

This is under tab L of our handouts. The patient labeling goes on to say, "The devices listed below have magnetic energy to cause painful increases in stimulation if you are near them. Where possible, it is best to avoid theft detectors and airport security devices. The devices listed below have enough magnetic energy to turn your IPG on or off if you are near them. Approach these devices carefully; large stereo speakers with magnets, MRI equipment, manufacturer and heavy industrial equipment, electric-arc welding equipment, electric induction heaters, electric steel furnaces, power lines and electrical substations and power generators."

Would you comment on that? That was written by industry; right?

MR. PUTZKE: Right. I think, in general, our labeling usually includes most everything that we can think of that could potentially interfere. I guess what I am primarily concerned about is the notion that, in conducting their normal, everyday activities like shopping, for example, which is something which would be considered, I think, a normal, everyday activity, that people would be more dependent on others as a result of having an implanted medical device.

Anecdotally, when we are with the cell phone--I happen to have a relative with a pacemaker. We went through the cell-phone stuff and it turned out to basically be a non-issue unless the antenna was held directly over the implant site, within several centimeters, basically.

But, to this day, that relative will not use a cell phone. I think that is very unfortunate because that can be a lifesaving device of its own type if you need to get a hold of somebody. So I think that, since these people are generally older, anything that you do that makes them concerned and reminds them that they are being supported or their life is being enhanced with an artificial device is the wrong thing to do unless there is a significant risk.

DR. LIPOTI: I have one more question. I am not

really aware of what all these spinal-cord stimulators do. You mention they are used in Parkinson's, urinary incontinence and to move food through a digestive system. What might passage through and EAS system do to somebody who had one of these implanted for those reasons?

MR. PUTZKE: Certainly, you would probably want to get somebody up to--I don't happen to represent that particular manufacturer very well. It is pretty much a single manufacturer doing those implanted devices these days. But I believe that mostly these devices--it causes a sensation or a feeling of pain. I don't really know in the case of Parkinson's or tremors or some of the--I believe it would be the same. They would have possibly a sensation of pain. It was reported in one of the MDRs that the patient actually fell down. I don't know to what extent you can validate that that was attributable to that, but it was certainly reported.

I think these other things are slower moving things that you ordinarily--one stimulation that you would get passing through gates, although there is pain, isn't going to cause any other situation.

MR. TUROCY: The MDR reportable requirements, as far as I understand, involve three categories; death, serious injury and serious illness, or malfunctions that would cause those two conditions. Do you have a frequency

or a breakdown from the medical device manufacturers that fall into either of those three categories?

MR. PUTZKE: I don't. Perhaps somebody from the FDA could comment on that since I only represent pacemakers. I don't know. Certainly, death would be very uncommon. In fact, I am having a hard time remembering one in my 20-some years of experience. But serious injury categories would be an unwanted shock from the defibrillator as a result of the MI. I believe we have had several of those that have been reported. Actually, in both those cases, going back to that same setting and trying to replicate that was unsuccessful. But, nonetheless, it is undeniable that it occurred.

MR. TUROCY: To the best of your knowledge, then, there is no death.

MR. PUTZKE: To the best of my knowledge.

MR. TUROCY: And serious injury is possible?

MR. PUTZKE: That, of course, wasn't reported in any of these. That would certainly be reported.

MR. TUROCY: Thank you.

MS. EHRGOTT: Just one more. When you say 50,000 active implants passing through EAS systems regularly, the 50,000 applies to the total implants in the United States and then regularly it could be one or more times a week?

MR. PUTZKE: That's correct.

MS. EHRGOTT: So we are talking about the

multiplier of that as events--

MR. PUTZKE: It might be a worldwide number. I am quite sure that it is.

MS. EHRGOTT: That is a worldwide number.

MR. PUTZKE: Right.

MS. KAUFMAN: You said something in your opening statement that confused me about who is making the reports, the medical-device reports. It sounded to me like you were saying that it is the medical-device folks that are making that report?

MR. PUTZKE: That is what I believe. I know that we turn in thousands.

MS. KAUFMAN: And you said something about if that were the case that it is the medical device representative who is making the decision as to whether or not it is reportable?

MR. PUTZKE: Yes, according to criteria that have been agreed to by FDA and the medical-device industry.

MS. KAUFMAN: Lastly, my question is, on pacemakers, you had mentioned that the devices always returned to their normal function in their own? I just wanted to clarify that. Then never require any intercession by anyone. The way that they are designed, they always return to their normal function?

MR. PUTZKE: Yes; that's correct. These are all

temporary things.

DR. CARDELLA: My question was similar to Cass's. As these devices get more and more clever in terms of the algorithms and situations that they can attempt to address, how confident are you that, (a), it makes the right decision--in other words, it may not be as smart as everybody leads it to believe. It probably just goes to a default position.

In other words, if it is confused, it paces. My concern is that the device may get stuck in that mode. We don't know the reliability with which it converts back, at least I don't. That is issue No. 1. And, if a device defaults to a position such as the defibrillator being turned off, is there a provision that that turns itself back on eventually or does it require, by happenstance, the patient goes to the physician and finds out, "Oh, jeez; my defibrillator has been turned off for six weeks and I didn't know it." Question No. 2.

Question No. 3 is what is the incidence of spuriously defaulted functionality of these devices. How often do you go to the physician and say, "Gee; the defibrillator is turned off. It must be that the battery is weak," and those types of issues. What is the incidence of that occurring?

MR. PUTZKE: Very, very, very low with respect to

the last one. With respect to the defibrillators being turned off, some of those devices have been designed so that the application of a magnet for a period of time, 30 seconds is typical, will revert them back and forth between modes.

So it is more likely in the cases of devices being turned off that the patient came in contact with some form of permanent magnet. True, they may have remembered going through an EAS gate but everybody goes shopping. I certainly suspect that those instances were the result of coming in contact with a permanent magnet someplace.

I'm sorry; the first question?

DR. CARDELLA: Is there a provision for the device to come out of the default position?

MR. PUTZKE: The way reversion is done, it isn't like the device internally sets a register or something and says, "I'm going to revert," and, therefore, you might be concerned about it getting locked up there. The reversion is a function of sense events occurring at a certain interval. As long as they occur at that interval, it is like a retriggerable flip-flop. As long as they occur at that interval, then the output of the sense amp is ignored for purposes of resetting the timing.

But, as soon as they go away, then normal operation continues. I am not aware of anything ever being locked up in that mode. Now, there can always be failures,

of course.

DR. CARDELLA: So, typically, in the case of a pacemaker, the reversion to asynchronous pacing is an active process and not a default process. In other words, it converts to that on purpose and, given its d'ruthers, it will revert back to demand pacing, let's say.

MR. PUTZKE: Absolutely.

DR. MARX: I had one comment and follow up of what you said. My experience has been, as a person who does put in implantable devices, when we report an adverse event to industry representatives that we work with, they are obligated to report that to FDA.

MS. KAUFMAN: So the manufacturer is not making the decision. It is the physician who is making the decision? I am a little bit confused on that.

DR. MARX: There may be more than one decision. First I have to decide that I am going to say something about it to you and then you have to decide that you are going to report it to the government. But I have not had an experience where something I thought was significant did not get reported.

MR. PUTZKE: We have been really careful about making sure that phone calls that might even smell like a complaint get routed to the right people in the company so that MDRs can be filed if that is the decision.

MR. FLETCHER: This will have to be the absolute last comment.

MR. TUROCY: The decision to file that MDR report is made upon whether the event falls into three categories; death, serious injury or serious illness, or a malfunction that would cause those two events. So the manufacturer has that obligation to investigate and determine whether the event has contributed to either one of those three categories.

MR. FLETCHER: I would ask the committee at this point to hold your remaining comments until we get to the committee discussion portion. We have arrived at the point--I think I thank you for getting us back on schedule, but we have arrived at a point where we are scheduled to take a break. So please be back for the next presentation scheduled for 10:30.

I would ask that those people signed up for the public hearing please come forward and see Dr. Suleiman at this time.

[Break.]

MR. FLETCHER: Let me do two things before you begin. First of all, I want to take a moment to recognize, just in case we get too busy in the future, the members of this committee that will be rotating off. They will be Betty Sisler, Joe Elder, Stanley Savic, Bob Turocy and Jane

Ehrgott.

We want to say thank you for your service and for your comments and for sticking through for the last four years. We have really appreciated you. We will miss you and we encourage you to keep in touch with the activities of the TEPRSSC committee. So thank you very much.

Second, I would like to call Nancy Presley to give a very brief explanation on a portion of one of the questions that came up regarding MDRs this morning.

MS. PRESLEY: I am Nancy Presley. I am in the CDRH's Office of Surveillance and Biometrics. I was just asked to give you a little introduction or a little background on the MDR medical-device reporting since there was some questions about that this morning. I will let you know this is totally unprepared and off-the-cuff.

There are different reporting requirements depending on who you are and where you are. We have reporting requirements for manufacturers. There is also mandatory reporting for user facilities. Under the user facility reporting requirements which came from the Safe Medical Devices Act back in 1990, it requires user facilities, which would be hospitals, nursing homes, long-term care facilities, pretty much anybody other than a private doctor's office, to report deaths and serious injuries, or injuries, or illnesses, back to the

manufacturer when they occur, when they have these adverse events.

They have to report deaths not only to the manufacturer but also directly to the FDA. So if a death report happens, it goes to both the FDA and the manufacturer. If it is a serious injury or serious illness, they are reported only to the manufacturer.

They are not required to report malfunctions. They can voluntarily report malfunctions under the voluntary reporting but it is not a requirement. Manufacturers, on the other hand, are required to report deaths, serious illnesses and injuries, and malfunctions to the FDA. Many of the reports that the manufacturers get come through the user facilities and the user facilities formal reporting to them, but they also get notified about reportable events in other ways, either from private physicians who are not required to report, sometime from consumers.

There can be any number of ways that they get information about an event that is reportable, not only from the user facility. So their requirements are slightly different. The manufacturers do have to report malfunctions if it could lead to a serious illness, serious injury, or death.

That is the basics of it. Are there any questions?

MS. KAUFMAN: Could there be any question on the part of a manufacturer as to whether these incidents that we are discussing today would have been considered a malfunction?

MS. PRESLEY: Yes. What you are asking is if there room in there for interpretation that they wouldn't be reportable? I think a case could be made for that, that these would not be malfunctions that would lead to serious injury or death. So they could be considered non-reportable.

MR. FLETCHER: Thank you very much.

Our next presenters, and let me advise that, from this point on, we will be operating on a timer basis so that we can get everybody in because we have got a lot of presentations. The lighting system is before you. I believe the way it works is it is green until you get to the last two minutes and then you get a yellow and a red. At red, I will stop you.

I was told I needed a gavel. I have been provided with--now, what you don't understand is I am a Marylander. I do eat crabs. I know how to use this.

Please proceed.

**EAS Industry Perspective.**

MR. KLEIN: In fear of that gavel, I am Rudolph Klein, known as Bud to most people. I am recently retired

Vice President of Monarch Marking Systems. Now, I am consulting with Monarch and several other companies including Sensormatic. I was one of the founding members of IEASMA, the EAS trade association over ten years ago and I have been the president of this organism for the last three years.

IEASMA membership represents most, but not all, of the EAS major systems companies. It represents Knogo, Meto and Sensormatic but does not represent 3-M or CheckPoint at this time.

For today's presentation of the portion of the position of the EAS industry that we do represent, I would like to introduce a key member of our technical committee, the IEASMA technical committee, Dr. Geraint Davies. Dr. Davies has a Ph.D. from Cambridge in the United Kingdom where he taught physics for several years and then joined a consulting group where he develops electronic and medical products and works in EAS as a consultant to Meto, the third-largest EAS company.

Dr. Davies?

DR. DAVIES: Thank you very much.

It is a great privilege to be here today. Thank you very much. I am particularly glad that we have had such good presentations before which have made a lot of the important points to be made and also some very perceptive

questions as well which I will try to address in this talk.

[Slide.]

On the first slide, I show you the overview of what I will be talking about today. I would like to discuss anti-theft in a little more detail to give you a bit of background of what it is like and place it in its social context. I would also like to talk about the relationship between EAS and implantable devices.

As the FDA has described, at the moment, we have no public-health problem with that relationship. What I would like to talk about is how we can keep that going into the future through the way we communicate with patients and also through the activities of the various industries involved.

[Slide.]

So a little bit about the EAS industry. First of all, there are around a million systems worldwide and the EAS systems are used by the vast majority of major U.S. retailers. There are also various trends in retailing which mean that EAS is set to grow even more in the future.

Now, theft by employees and by members of the public is a significant problem. It is around a $20 billion problem in the U.S. That works out at around $500 per household. This is kept in check by EAS technology. So EAS lowers prices for everybody. It saves job for people in the

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retail trade. And, of course, it improves the shopping experience.

[Slide.]

I won't go through all the details here. There are several different EAS technologies and, as people have described, they suit different retailer needs. So there is microwave technology, there is swept-RF technology, acoustomagnetic and electromagnetic technology.

It is important to recognize, these technologies have been around for a long time. Ten years is the youngest technology. The frequency ranges which are covered go all the way from very low frequencies to very high frequencies, as has been described. And I have also listed some of the key advantages. There are many other factors that come into a retailers choice about which system to use, but I have listed some of the key ones there.

I would like to go into the physics of why all these different systems have different frequencies, and so on, but I am afraid I don't have time. Trust me, there are real good physics reasons why the different systems have different frequencies for the different needs of the retailer.

It is worth noting that there have been no new anti-theft technologies in seven years. It is a very stable platform and, indeed, in each installation, a system will be

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installed for typically over ten years.

[Slide.]

So, first of all, as an industry, I should point out that many of the companies which are involved in our industry have many different technologies. They offer different technologies. In particular, nearly all of the companies offer RF technology. So, as an industry, we have a good overview of the types of interactions which come from all of the different technologies.

On the other hand, the consumer really can't tell the difference between different systems. So if you try to advise them to behave differently with respect to one system or another, they wouldn't really know how to respond.

[Slide.]

If I refer to the MDRs which the FDA has and, also, case reports and anecdotal reports, you will find that all types of EAS systems create interactions with implantable defibrillators. So the technologies which induce interactions include electromagnetic, acoustomagnetic, and, indeed, swept-RF technology.

This, in published peer-review studies, we find that all of these technologies can affect implantable devices.

[Slide.]

You might wonder why, for example, RF technology

at

which has very high frequency would cause any interaction with pacemakers. If I might try to explain this curve here; this is a typical pacemaker behavior curve where you have sensitivity up this axis and frequency along here.

Of course, it is trying to sense low-frequency signals from the body, so it has a filter which rejects high-frequency signals. It would typically not have any interaction to a high-frequency signal up here at about 10 megahertz, for example, with RF technology.

[Slide.]

However, what you might find--in fact, what you do find--in practice is that, for example, the RF signal has a sweeping frequency. That can cause modulation in its intensity or, indeed, the person may be swinging around inside the system which is also producing a modulation in the signal intensity.

Because of the input electronics of the pacemaker, it can easily demodulate that signal into one of a very low frequency and, although the intensity of that demodulated signal is much lower than the intensity of high-frequency signal, it is within the interaction sensitivity of the pacemaker. So that is one of the reasons why they can all interact.

[Slide.]

You have heard a lot this morning about

interactions and various types of medical conditions and it can be quite scary. So let's consider why we can, on the one hand, talk about all these interactions and, on the other hand, say that we have no public-health problem.

There are two reasons for this. One has to do with the infrequency of the interactions and the other one has to do with the lack of severity of the interactions. I will talk about both of these.

First of all, we have seen that, in the last ten years, there are 21 MDRs associated with EAS. I have split those out. You find that, in that period of time, there are 83,000 MDRs associated with pacemakers and only nine of those are associated with EAS. So that is around 1 in 10,000.

There are several implications about that. One of them might be we consider, when we are making pacemaking manufacturers to respond to the situation, how careful do we have to be about telling them to focus on this 1 in 1,000, 1 in 10,000, events compared to all the other things that they are supposed to be dealing with. I think there were some very pertinent questions in that regard earlier on.

If we look at defibrillators, in that period of time, there were around 3,000 MDRs and only two of those were associated with EAS. So that is under one in 1,000. Of course, as the point was made earlier, during this

period, there have been well over a million implants and these people with implants are going through EAS systems all the time.

You can work it out. It is probably about a billion times that these systems have been tested, these implants have been tested in EAS systems. We are coming out with very low numbers that you can count in the fingers of your hand.

So this is a tiny piece of the implant story and it is not a public-health problem.

[Slide.]

This is also supported by clinical research. There are historical studies which, I believe, the next speaker is going to talk about. I won't go into those in any great detail, but looking at 100,000 patients historically, there are no instances reported of interactions or clinical symptoms.

In in vivo studies--that is, trials on real patients, over 600 patients--we have found various types of interaction noted during these trials. But I think the most significant thing is the comments that the physicians who are running these trials. These are the physicians who are making these comments about the interactions, and you see the types of comments they say. "These are not serious." "They are benign." "They are not clinically significant,"

and, "They do not represent a danger."

These people have the patients' welfare at heart. They are not going to be lying to us about what they think the effects of these interactions are.

[Slide.]

There are some details here. For example, when you hear some people talk about interactions and they are worried about them, it is important to know that asynchronous pacing, for example, as we have heard, is a planned electromagnetic interference strategy. It is planned by the pacemaker manufacturer.

In addition, in some tests that you might see, there are some protocols about hugging the pedestals, twisting inside the gate for a long period of time. These are, in general, not found in the real world. They are very, very extreme circumstances that are being tested there and it is simply not typical. Typical behavior is people that will pass through an anti-theft system in a few seconds.

It is also worth noting that the fields that we have here are inductive fields so they fall off very rapidly with distance. It is cube of distance, so you only have to go a very small distance away from the pedestal before the field has fallen significantly.

Of course, as we have just heard from the implant

community, implant EMI designs are improving all the time.

[Slide.]

So our practical advice to pacemaker patients is walk through the systems at a normal pace, don't linger, don't lean. This is endorsed by the clinicians that we have talked to and it is also supported by the labeling which is in pacemaker and ICD devices. It comes with them.

Now, people can conform to this because, first of all, the systems are normally in plain view. We prefer to deter people from shoplifting rather than catch them, so we like to make them in as plain view as possible. Very often, the systems are labeled to encourage this.

We have heard about concealed systems and some concerns about that. First of all, I should say that concealed systems have the same field strength as non-concealed systems. There is no additional field to get through brick walls or anything like that. It is the same field strength.

But we do recognize that patients wouldn't be able to know where they are and what we are suggesting is voluntary signage throughout the industry of these concealed systems which says that EAS systems are in use.

We have also heard concerns about aisle systems. There are technical things such as the zone of potential interaction with the aisle systems which are the narrow

systems in checkouts. First of all, those are usually quite narrow because the field intensity is low.

Secondly, you don't queue up for goods once you have paid for them. Whenever you are queuing up, you haven't paid for the goods and you can't catch somebody for stealing stuff before they have had the opportunity to pay for it. So, typically, there are no queues, no lineups, inside the systems.

Finally, we have heard about walkaround as a possible route to solving these problems. We don't believe that that is practical. We have heard several arguments about what might happen in the wrong type of situation. It is also important to recognize that there are no on-off switches on these systems. The retailers don't want them because the employees could switch the system off and let their cousins go through and so on, and also the guards to operate these systems would be very costly for them.

Indeed, there are usually no unprotected exits either because you also protect the exits the employees can go through because they can steal things, too.

[Slide.]

I will pass very quickly over the next slide. I think the important thing to recognize about this is that you have to balance any physical risk that you might assume with the psychological risk to the patients of unnecessarily

causing anxiety for them. That is a delicate balance which needs to be considered at all times and is in the minds of the clinicians when they give us the advice about what to do about anti-theft systems, to reassure patients, not harm them.

[Slide.]

I won't talk in any great detail about this slide. As an industry, we have had a lot of track record with talking to the pacemaker community and the implant community. We have talked to medical experts. We have been talking to the implant community for over eight years and I, personally, have been at conferences in Europe where we have given papers on this topic.

It is well-known to both industries. We have also set up a research facility which, I think, is important. We have set up a research facility which is an independent facility in Georgia Tech which allows these confidentiality issues of manufacturers to be overcome because manufacturers of both pacemakers and anti-theft systems can test the interactions in confidentiality.

[Slide.]

So I come to my recommendations, finally, and thank you very much for your tolerance. I think these are pretty much in line with what we have heard so far. We continue to share data. We emphasize the use of the Georgia

Tech Research Institute. We allow manufacturers to continue to improve their EMI designs and, as the anti-theft community, we continue to obey the global standards, conform to the global standards, with which we already conform.

How to stay ahead of the curve as systems develop? We have heard discussions of establishing in vitro models that can be validated that allow testing to be made more simple and more predictable.

MR. FLETCHER: I am going to have to cut you off.

DR. DAVIES: Okay. Thank you very much.

MR. FLETCHER: Thank you.

Let me point out, first of all, for the next two presenters, it was not our guidance and instructions that someone besides the person listed give the presentation. However, since that has occurred once, we will allow that for these presentations if you already have someone to do so.

MR. GILES: Good morning. My name is Olin Giles. I am Senior Vice President and Chief Technical Officer of Sensormatic Electronics Corporation. We are located in Boca Raton, Florida and, while it is nice to be here today, I have one eye on the Hurricane Georges situation and am hoping to, perhaps, get back before we get an untimely visit from Hurricane Georges.

[Slide.]

Sensormatic is really a leader in the area of electronic security and, in particular, electronic article surveillance, having been one of the founding companies in this industry some 30 years ago, introducing to retailers EAS. A majority of top retailers around the world use our systems and we are very proud of the fact that we have a global presence and that we have 445,000 systems installed and that we are really part of the landscape.

It is really hard to avoid passing through an EAS system as some of the earlier speakers have covered.

[Slide.]

It is important for you to understand that there are a number of different types of EAS technologies. You have heard reference to those. You have seen breakdowns and you will see others. We are unique in the industry in that we offer all of the EAS technologies. These technologies started 25 years ago with our microwave system.

Microwave has some unique advantages. It occurred during the time America was having malls built all around the country. It was the only technology that would cover the wide entrances in a shopping mall. But, like most things in life, it is not a perfect technology. It had shielding problems, some false alarms and limitations.

Another technology which Sensormatic and others offer in industry is swept-RF. It is a great technology.

It has low cost, inexpensive tags, a terrific scan deactivation approach, but it has limitations in terms of exit width.

I should point out that electromagnetic technology came along not to far in time after, some 20 years ago. It was initially used in libraries because it had the advantage of being able to be turned on and turned off as you brought books back. But it had disadvantages in terms of the opening width and the fact that it, too, also had false alarms.

Finally, the most recent technology, and yet it is ten years old, is acoustomagnetic. It offers wide openings, not as wide as microwave, very high detection rate, not false alarms, small label size, but it, too, has limitations.

So, in summary, we have a technology for different retailers and it really isn't feasible for one technology to cover all of the market.

[Slide.]

We are here to talk about whether or not there is a public-health issue. It has been noted already, but just to quickly summarize, EAS is not new and medical-implant devices are not new. In fact, they both go back about the same length of time, 25 to 30 years. Like other electronic products, there are interactions but interactions that are

safe for the most part. And that is important to us as a major supplier of security systems, that these products be safe.

To assure that, we have been working with the medical-implant industry for a number of years. We are very knowledgeable of all the manufacturers. We know the key players by name in these companies and we have been carrying on a dialogue for some time that I will tell you more about in the future.

So you might say that it is not by accident that this occurred but by plan. As a matter of fact, I can tell you, in the case of Sensormatic, on more than one occasion, we have changed our product to improve the compatibility to some degree, which we thought was significant.

So the result is we have over a billion passages, as has been reported earlier, through EAS systems, we feel, without a public-health hazard and, as has been said earlier, few adverse events.

[Slide.]

But as Dr. Jacobson covered at the outset, the past is the past. We want to keep it this way. We want, in the future, to be able to continue to insure this as medical devices become more complex.

I saw recently the article in the back of The New York Times with all the electronic apparatus that, in the

future, is going to be part of our body or, perhaps, our body, so it is something to keep in mind. These devices are being developed now.

I can tell you, as we read about any new medical device, we write a letter to that manufacturer and say, "Hey; think about this as you design the product." And EAS will become more widespread.

[Slide.]

This chart has been reviewed, the MDR chart, in several different ways but a little different summary here. I have broken it down by EAS technology across here. Sensormatic offers the Acoustomagnetic, the Swept-RF, the Electromagnetic No. 1. The Electromagnetic No. 2 is a subset of electromagnetic and you will see why that is in a few minutes. We do not offer that.

You will note, as Dr. Davies described earlier, that there are nine MDRs associated with pacemakers and MDRs. 83,000 MDRs are essentially for every 10,000 reported MDRs on pacemakers, only one adverse event. For ICDs, also a very low rate. For spinal stimulators, a little higher--spinal stimulators a much higher rate.

I think, for that reason, we understand why perhaps, with a different audiences, different physicians, a small population, perhaps a tailored message to that audience might be appropriate. I should point out that all

EAS technologies are located on this chart, similar levels of MDR count; the Acoustomagnetic, the Swept-RF, the EM No. 1. You will see that they are virtually the same in terms of reported MDRs.

So we think that representation--perhaps, it is underreported. We understand that. Whether it is 40 or 50 percent, as was acknowledged earlier, we believe these are relatively low numbers for the overall MDR count of 85,000 or so.

[Slide.]

Some observational studies, in addition to the MDRs. We are aware that there are two major databases associated with pacemakers, one in the U.K., some 59,000 patients. These are prospective databases. By that, at the time of any adverse event, you try to understand what it is so that you can go back and do a database search as opposed to downstream, someday, saying, "Well, let's try to figure out what happened there."

We had that database searched and there were no adverse events attributable to EAS.

Another large database closer to home here, the Department of Veterans Administration or Affairs, 43,000 patients covering, I think, fifteen years. We surveyed that database and only one adverse event was there for airport detectors, none for EAS. So these observational studies, we

feel, add to the MDR because they are databases that are maintained very actively and we believe that they are at least a piece of information and data for your consideration.

[Slide.]

Our company and others have sponsored clinical studies in addition to our other activities that we described earlier. Some 450 patients have been studied to date. These are in vivo studies. To quickly summarize. It has already been covered. Dr. Mugica in Stimulcoeur, a peer-reviewed paper, in 1997, 200-plus patients. Dr. Botella in Spain, some 60 pacemaker patients. A paper is in process there, not yet published.

Dr. Frank in France did a study for a major retailer in France and that retailer had heard some questions and had a study done. Dr. Dodinot has been reported earlier, actually two published articles by Dr. Dodinot in PACE in 1993 and 1997. Dr. McIvor, who is here today to speak, will tell you about his 50 pacemaker patients and 25 ICD patients.

And Dr. Douglas Zipes is here today and will tell you about his study which is still ongoing, about half finished, and he can give you his update on that.

All of these studies find that acoustomagnetic and electromagnetic interact. The interactions are brief and

not of consequence. Walking through at a normal pace really would insure safety as a result of any of the observations observed here.

[Slide.]

We have covered acoustomagnetic and electromagnetic. Our company also manufacturers swept-RF technology. Separately, we have looked at the literature here and some of the studies. I think this has been covered earlier, a recent study, in fact, just published in PACE by Dr. Wilke in Germany. He studied in vitro interactions and noted interactions in a number of pacemakers tested.

Lucas and Dodinot in PACE in articles also noted some in vitro interactions. I pointed out earlier that there are two MDRs on that summary which showed that there are MDRs on all technologies. Two of those came from swept-RF. And we are aware of some anecdotal reports of other adverse events, four of them, I think it is, associated with that.

Finally, there is a study going on at Johns Hopkins which you will hear more about in a few minutes. So, fundamentally, they all interact. Our company offers all the technologies. But we believe the interactions are, for the most part, virtually always safe.

[Slide.]

So, as Dr. Jacobson said at the outset, the key

here is to work for the future to insure that a relatively good safety record stays intact as devices become more complex, as EAS systems proliferate. So we strongly support and want to be involved in the voluntary standards committees that are addressing issues of these types.

We already are active on the AMI committee that Mitchell Shein talked about earlier. We also support additional research in this area. We are willing to fund some of that research. We believe the FDA should play a proactive role in that research. And so we are interested in having discussions to talk about whether something along the lines of the recent cell-phone study that was independently set up or some other way to insure that the right level of data and the right integrity is brought to bear on this particular issue.

We believe as an industry, the Georgia Tech facility which has been on line now two to three years, is one that all of us should try to use because, in that facility are most of the typical EAS systems that are available and it allows medical-implant manufacturers or EAS manufacturers to go in and test their products to be sure that the compatibility is there.

Again, I can tell you that we have done that on every product that we have introduced for the past ten years and, on more than one occasion, made some minor changes to

make that compatibility really compatible.

Lastly, working with device manufacturers to improve device compatibility is important going forward. As Mr. Putzke described in his earlier comments, he believes, an we believe, that improvements can be had. We are aware of devices, as a result of our own testing, that are virtually immune to interaction and we believe, as these devices are understood and more emphasis placed on that, that they can be further improved, better filters, better linearity.

We are confident that progress can be had in that area.

[Slide.]

So, in summary, I would leave you with these five major points. Adverse events are rare. I think that point has been made by several of the speakers. They are not non-existent but they are certainly rare. I think it is clear from the clinical studies, from the in vitro studies, from the MDRs, that all EAS technologies have some form of interaction--not unsafe, but some form of interaction.

This is the result from a lot of cooperation between our industries that we can accelerate by working more effectively together. We believe it is fair to state, as Dr. Jacobson did at the outset, that there really isn't a public-health problem today. And we want to keep it that

technologies. The EAS industry in the U.S., for the most part, consists of two major companies using completely different technologies. RF is available from both companies while acoustomagnetic, the other major technology, EAS technology, is exclusively available from a competitor.

[Slide.]

Electromagnetic, or EM, systems sold by both companies has faded from major use in the U.S. retail markets but is still used widely internationally. Checkpoint has only 200 such systems primarily serving libraries. Microwave also appears to be slowing dramatically in the U.S. as well.

The discussion today should not focus on any one company but rather on the specific technologies offered. The work being undertaken by this committee must reflect the characteristics of those individual technologies.

[Slide.]

To fail to do so would be akin to grouping a propane engine that may burn clean with a diesel engine that may not with the pollution of motor vehicles. To analogize with FDA-regulated products, the agency regulates medical devices by placing them into one of three classes, depending on such factors as the risk to the patient.

Similarly, the committee should take into account the different levels of risks presented by the varying

technologies used in EAS products. As I will discuss, RF systems have been shown, in all studies that we are aware of, to be the best performing major technology for the avoidance of interactions.

Any proposed action should not paint the whole industry with the same brush. Checkpoint sells and services radiofrequency systems that operate at 8.2 megahertz. We have seen them described by the FDA this morning. For over 25 years, Checkpoint has cooperated fully and openly with the largest manufacturers of implant devices dating back to and including such companies as Arco and Cordis, Siemans, of course, now St. Jude and Medtronic, by providing our RF equipment to the manufacturers and letting them do the testing.

Checkpoint has even gone so far as to sponsor testing with groups such as the Montefiore Medical Center, St. Francis Hospital and the Heart Institute of St. Petersburg. Our funding of such products was without preconditions or interference regarding methodology. We have never reinterpreted nor interfered with the publication or presentation of the results.

Checkpoint fully expects to fully cooperate with manufacturers of implant devices in an effort to learn more about the issues discussed today. We will continue to support ongoing research in this area.

[Slide.]

We have noticed articles written by medical professionals who conclude that there is no clinical significance to magnetic-system interactions with cardiac pacemakers and, consistently, we see the safety claims, as long as you don't hesitate when going between the systems, or as long as people walk at normal speed or as long as patients use good judgement passing through the systems without stopping.

[Slide.]

The reality is that it may be naive to expect elderly pacemaker patients, on their own, to avoid pausing in an EAS system. How can a patient avoid an in-aisle system which is typical in supermarkets, during checkout at a wholesale club as the receipt is examined, or at a mall as people stand near the system pondering a coat purchase or pause at the entrance of a store front, perhaps in a mall, to talk to a friend. The systems are designed to be unobtrusive.

[Slide.]

A study of EAS systems in pacemakers conducted by the Heart Institute of St. Petersburg that was sponsored by both of the leading EAS companies is the only in vivo study conducted in the U.S. so far as we are aware. Checkpoint, it turns out, was asked for a larger grant than the other

company which also sponsored the study.

We look back at our acceptance and, believe me, wish the grants were more equal. However, the study speaks for itself. The study protocol was reviewed by the institutional review board and was presented for peer review twice at NASPE and EuroPACE. The findings of the study are clear and convincing: radiofrequency EAS technology had no interactions with pacemakers in this in vivo study.

The other study which was acoustomagnetic had interactions as discussed earlier today with 96 percent of the patients. Based on this kind of study, it is critical to distinguish RF from other technologies.

Other studies confirm these results. Dr. Mugica recently did an in vivo study with acoustomagnetic technology in France that, in our view, was done in an unusual way but still showed interaction results. Apparently, patients were tested while in a metal bed, sitting on the bed, leaning up against the bed.

Our engineers tell us that a metal bed is likely to absorb much of the EAS energy. Even so, the magnetic systems still showed high levels of interactions with pacemakers thus confirming the Heart Institute St. Petersburg's conclusion.

Regarding the Wilke study published in PACE recently, none of the systems tested were from Checkpoint.

They were from a European manufacturer. Also, RF systems operating in Europe may have stronger emissions based on more relaxed FCC-type agency positions.

Even so, the in vivo studies conducted by this report showed no interactions for RF technology. And, in fairness, Checkpoint purchases components from this manufacturer and the components are customized to reflect the U.S. FCC requirements.

Georgia Tech Research Institute is often referred to in safety claims by other groups as an expert in EAS pacemaker testing. But Georgia Tech has never approached nor asked Checkpoint to participate in any projects nor have they shared any data.

They cite confidentiality. It strikes us odd that these studies are used as such a strong reference point for magnetic technologies yet all information remains hidden. To use secret studies to support safety claims is simply wrong. We are aware of significant non-RF interaction occurring with certain systems here in the U.S. that we believe will become public in case-history reports. And we also believe that there is great underreporting today.

[Slide.]

We believe that these interactions are severe enough to cause great scrutiny on the EAS industry in a very

public way. Checkpoint has even seen the press confuse pictures of our RF systems in their descriptions of other systems. What is particularly troubling and, perhaps, more frightening for the medical community and public-health officials are the attempts to intimidate the Heart Institute of St. Petersburg including what appears to us as legal threats regarding the full release of their study.

Scientific information by qualified experts and open to the review process cannot and should not be suppressed from public view. We have a peer-review process so that health experts may review data and draw their own conclusions free of commercial interest.

Even with these containment tactics by others, the FDA has indicated that they have received enough input on interactions to reach a point where they must make a more serious and probing inquiry into the pacemaker interaction issue. And we support this view.

Common sense suggests that pacemaker patients and their families be entitled to a warning when they enter a store with an EAS technology in use that it has a high degree of probability to cause an interaction particularly when the interaction could cause dizziness or worse. We agree with the options that advise patients not to linger near those EAS systems.

Conversely, RF-system technologies that have been

shown through in vivo studies to have low emissions using frequencies that do not produce interactions should not bear this burden. Again, grouping all technologies merely to address a potential problem with one is unfair.

To our knowledge, Checkpoint has never been shown to have an interaction with any in vivo testing which is the best basis for good data.

[Slide.]

It is important that the EAS industry be motivated by public-health authorities to develop technologies that reduce the potential for unwanted interactions. Avoiding a university requirement for warning signage will motivate EAS developers to use technologies and strategies that provide good performance without interference potential.

EAS technology providers should at least be able to show in scientific studies that a given technology will or will not cause interactions so that reasonable judgments can be made as to whether a given technology requires warning signage. Technology-specific signs may help patients make more informed choices about where they choose to shop based on their personal risk and, just as important, their well-being.

On another point, Checkpoint proposes that FDA consider taking a stronger role in guarding against misinformation, false statements, legal intimidation tactics

or paid-consultant medical influences that seek to prevent or delay valid studies or case histories about EAS pacemakers from being published.

We believe that there may be examples of such activities today directed at PACE and, possible, the New England Journal of Medicine. There are reports that medical consultants or lawyers have even attempted to influence doctors with patients who have experienced severe interactions not to publish case-history reports. These kinds of actions are clearly not in the interest of public safety.

One another point of clarification; IEASMA, the so-called EAS trade association, does not speak for Checkpoint and never has. In fact, one of the main reasons we never joined them was their position by its members that there should be no competition on the basis of health-device issues dating back to its formation in 1991.

Checkpoint believes in public safety, open testing of equipment and the free dissemination of information. The involvement of the FDA in these efforts is both welcome by Checkpoint and necessary to insure that unfair grouping of all technologies does not result. FDA involvement will also add the stature necessary to address the subject in an orderly, scientific manner without "the sky is falling" alarm but with differentiation among technologies.

In review, RF and magnetic technologies should be evaluated and judged separately because of their unique characteristics. We are advocates for assuring consumer safety through scientific study. Technologies that are designed in ways that avoid unwanted interactions should be encouraged.

Finally, legal intimidation and undue influence should give way to open disclosure, good communication and the peer-review process. Our final comment on today's proceedings; it may be important for any presenter, whether from an industry, academia, research or medical institution, to fully disclose his or her source of compensation including the primary manufacturers of EAS systems.

I believe that many of the doctors here today have an arrangement with a particular vested interest. Checkpoint is committed to assist this committee and the FDA in the continuing research and investigation of these matters.

Thank you.

MR. FLETCHER: Thank you very much.

Our next presenter will be Mr. Podhrasky.

**Metal Detector Industry Perspective**

MR. PODHRASKY: Good morning. First of all, I would like to thank everyone for the opportunity to be here today and speak. I think these are very important issues,

issues that have been close to my heart for quite some time and are consistent with the work that I have been doing.

[Slide.]

My name is Bob Podhrasky. I am Vice President and Director of Research and Development for Garrett Metal Detectors. This is just my resume there so you know who I am. I have been associated with metal detecting for 30 years. I have been working in product development for most of that time and I have contributed to eighteen patents.

I am a member of the ASTM and the AAMI. Through my ASTM work, I am able to interface with the other manufacturers, the other metal-detector manufacturers. In fact, I was able to speak to five other manufacturers to get their ideas, to include their ideas in today's talk.

[Slide.]

I have some concerns. First of all, there is no organized effort between the industries, which are metal detector and medical implant, et cetera, to assure safety. There are no guidelines or standards for us as an industry to fall back on and, in today's changing world, industries do present a potential to be moving targets to each other.

There is concern from the public and, to some degree, guilt by association. Reports on problems from electronic blankets to hairdryers, microwave ovens, cell phones, power lines, EAS systems, et cetera, increase the

public concern about all devices.

When reporting a problem, as you have seen in some of the reports, a person will often recall that they were exposed to a metal detector and totally be unaware that they were exposed to many, many other sources of influence. I do see a lack of understanding leading to misinformation, and this includes information from doctors, from writers, from security administrators, security guards and sometimes even their own manufacturers.

Quite often, when I read an article concerning the safety of metal detectors, I see at least some amount of incorrect technical information.

I want to let you know that I do get questions from my customers. On the average of once a week, I send a letter out to my customers regarding the safety of metal detectors. Those questions are split by about 50:50 concerning the safety with regard to pacemakers and safety with regard to pregnancies.

[Slide.]

Some of the observations that I have; manufacturers and their customers and the public are all concerned about safety. We know that metal-detecting equipment meets all known standards. These are examples of some of the standards. We have Canadian Health and Radiation Protection Bureau, an IEEE document, OSHA

documents, the old standard for metal detecting, the NILE CJ standard 601 and 602 which has put an energy limit for metal detectors on the table for over 20 years.

We have the Department of Commerce. I think most interesting and most current, though, are the European standards, ENV 50166 and also some other European standards.

[Slide.]

Other observations are the field strengths that we experience are not unusually large. They are within the levels normally experienced in the daily environment.

[Slide.]

Here is a slide showing some examples of magnetic-field strengths that you might experience in a typical day. Let me read across the bottom from left to right. EAS, ELF EAS devices. The next over--and these are in ammeters. The next over is 56 ammeters for a hair dryer. Next is from the AAMI Medical Journal which shows that operating rooms can have a magnetic field of 56 ammeters or more.

Going over next is low-frequency AS systems with 50 ammeters. The next is somewhat surprising; an electric shaver held at 6 inches from the body at 48. The next is a hand drill held at 6 inches from the body. That might be a pretty common occurrence. Then we go down to 15 ammeters which is a walk-through metal detector at 5 ammeters. That is turning sideways to the panel in the worst case and then

1.6 ammeters for a hand-held metal detector going down to 1.3 ammeters as you walk by your television set or 0.31 ammeters for a video-display terminal.

So you can see the metal detectors are certainly within the realm of energy levels that one might experience day in and day out.

[Slide.]

Our industry feels that 25 years of experience has shown that there have been few reports of interactions. Another thing you might like to know is that field strengths and wave shapes in the industry have not changed significantly over the years. We typically respect the guidelines set 20, 25 years ago by the NILEC and tend to stay within those levels.

[Slide.]

Other comments from the manufacturers are past efforts to enlist the assistance of the FDA and the medical-implant manufacturers have not been successful, particularly my conversations with implant manufacturers. They say, "Well, I cannot address every metal-detector manufacturer so if you come to me as a manufacturer and ask for testing or verification, I am not able to do that."

However, if you come to me as an industry, we will be able to work with you. Another element is there are several studies--most of the manufacturers have had some

sort of study made in a university or in a hospital. Typically, the conclusion is that metal detectors are safe.

[Slide.]

Here is an example on this next slide of the study. It is pretty much unreadable but the bottom line says, "The interference was observed from hand-held metal detectors and on 14 implantable cardiac pacemakers, no interference was observed." So, again, this is a typical test. They make a test and they say there is no interference observed.

How thorough the test was, what the conditions were and all that, these are something that, certainly, you should be concerned with. But I can tell you that when the metal-detector manufacturers go and ask that researchers do testing on the equipment, the answer is always, "There is no interference."

[Slide.]

Studies have been made and articles published promoting the use of metal detectors to assist medical diagnosis of ingested materials. That is more recent history, that we do have doctors and other researchers who are using metal detectors for other applications on the human body and, again, there have expressed no concerns concerning safety.

[Slide.]

Opinions? Metal detectors do no physiological damage to the body. That is important because people do ask, particularly ladies who are about to bear children, and people who work around metal detecting on a long-term basis are certainly concerned about whether these machines affect their body. Our opinion is no, they don't.

The next thing is metal detectors have no significant effect on know medical implants. You see that I am not saying they don't have effect on medical implants, but no significant effects.

There is a need to be better able to understand the safety of these products. I have been working very aggressively to establish some standards and guidelines to be able to demonstrate the safety. There is also a need to insure safety in the future. As times change, and as equipment changes, we need to have some guidelines, some understanding between the industries to fall back on to be sure that we are doing the right things.

[Slide.]

Some more observations; our industry is in a difficult position. Evidence indicates that the potential for interaction is too great to say metal detectors are totally safe. However, the perceived problem is not great enough to develop the necessary resources of others to determine the limits of safety.

So, yeah; everybody will say it is a problem, you should be concerned about it. But it is not a big enough problem to do anything about. That is a very difficult position for our industry. The FDA report referenced earlier today showed 15 interactions or 15 reports in the nine years of the studies.

My concern about the report is first there is no follow up to verify the cause. Was it the combination of the equipment? What was the use? What was the severity of the interaction? There was no notification sent to the metal-detector manufacturers to allow investigation into the cause of the problem.

If there is a problem, the manufacturers are very interested in learning those problems and working with the medical-implant manufacturers to understand causes and effects and incorporate those ideas into their new designs.

There was no determination of if the product was actually caused by a metal detector or if it was caused by another device. As I pointed out earlier, there are a lot of devices that you come in contact with during a day. Was it a transceiver? Was it EAS? Was it other electronic equipment or was it the metal detector?

The last is there was no the determination if the problem was really with the medical implant and not with, perhaps, the metal detector. If you will study the

information provided, you will find that 6 of 15 reports addressed one particular model of defibrillator. I think that is important to note.

I would say that if industry guidelines were set and if the medical-implant manufacturers had incorporated that information into their testing program, those six interactions probably would have never happened.

Concerning notifications and warnings, I find they are typically skewed toward the safety of the medical industry. There is nothing wrong with that, but I think we need to be aware. But they do not consider the need for comprehensive security measures and safety of the general public, as it was being discussed earlier, that you can't always walk around an EAS system.

There are some applications of security that consider only metal detecting to be the most comprehensive means of scanning a person. Hand searches don't do the job, so sometimes, if you are in a prison, sometimes if you are going to see a high official or sometimes if you are going into a courtroom, you may be denied access because you don't want to go through the metal detector.

The notifications combine metal detectors and EAS devices. I am concerned even hearing the conversations earlier on that the position of EAS--well, it could be a problem but, if you do the right thing, it won't be a

problem. I would like to not be included in that conversation. I would like to demonstrate that metal detectors are, in fact, safe.

Again, the notifications, I find, are often based on a lack of knowledge. This is even from the medical-implant manufacturers. I don't believe the position that--I can't know everything that a medical-implant manufacturer bills and a medical-implant manufacturer does know what metal detectors, what all they can do, so how can you say anything is particularly safe.

[Slide.]

Facts about metal detectors. Metal detectors are used for security applications, hand-held and walk-through types. They operate by sensing disturbances in electromagnetic fields and they are designed and manufactured around the world. The major manufacturers are in Italy, Finland and the United States.

The hand-held metal detector has a search probe. The current flows to the search probe, typically operates at a frequency of 10 kilohertz to 100 kilohertz, has a field strength of 4 ammeters or less at a distance of one inch. It needs to pass within 1 to 4 inches of a weapon to be detected. And a portion of the human body will be exposed at 4 ammeters for less than a second.

Energy decreases quickly with distance.

[Slide.]

A walk-through metal detector has coils on one or both sides of the equipment. It typically operates in an unmodulated or continuous wave or pulse mode. A continuous wave operates from 5 to 10 kilohertz. Pulse detectors operate at 200 to 400 pulses per second. Frequencies below 50 kilohertz can have field strengths of 80 ammeters which is 1 gauss, at 2.5 centimeters from a panel, typically 5 ammeters at 15 centimeters from the panel. Typically, a person walking through will be exposed to 2 ammeters for a duration of 3 seconds.

[Slide.]

Work with the ASTM. Again, we are responsible for security devices. F1263 specifically addresses metal detectors an we are currently working on a document.

Let's skip down through the ASTM documents.

[Slide.]

These are the field levels here.

[Slide.]

Our next ASTM meeting will be in Norfolk, Virginia. We will be discussing the document that we showed just previously. Recommendations; we recognize that current is generally safe. We recognize that no design changes are needed to insure safety. We want to take advantage of the fact that the detector industry is willing to work with the

medical industry to establish safe levels acceptable to both groups and we want to determine the mechanisms which affect safety and provide this information to the metal-detecting community for consideration.

The last thing is we want to avoid a broad-brush approach to warnings which serves to confuse the consumer and compromise the safety environment.

Thank you very much.

MR. FLETCHER: Thank you very much.

That is going to have to conclude our morning presentation. Once again, I emphasize to the committee that we will have ample opportunity for questions and answers at the 1:45 committee discussion. But since we have a full slate of open hearing presenters at 12:45, I encourage you to get lunch and get back quickly.

[Whereupon, at 11:30 a.m., the proceedings were recessed, to be resumed at 12:45 p.m.]

AFTERNOON PROCEEDINGS

MR. FLETCHER: Let me remind the presenters that we will employ a timer. One presenter, for everyone's information, Dr. Berger, will not be presenting. So each presenter will have 15 minutes. The warning will come on at two minutes so that you can bring your presentation to a close.

I would like each presenter to give their name, title, a little bit of background and to provide this committee with any information of a financial-disclosure nature that might indicate any conflict of interest. So any financial support that has influenced your presentation, please provide this committee with that information.

**Open Public Hearing**

DR. McIVOR: Thank you. You are not going to throw the mallet, though; right?

MR. FLETCHER: Not yet.

DR. McIVOR: I am going to try not to test you on that. My name is Michael McIvor. I am the Medical Director of the Research Section of the Heart Institute of St. Petersburg in St. Petersburg, Florida. So I have my eye on Hurricane Georges as well hoping that it will hit Boca Raton and not St. Petersburg. Friends get sort of split when hurricanes come through.

[Slide.]

I did the research that you saw this morning, pieces of, that is in press. That research was supported by a number of people. It was supported by Sensormatic. It was supported by Checkpoint. It was supported with engineering support from St. Jude Medical. It was supported with support from Medtronic.

As far as my conflicts, I am not being paid to be here today. I am not a consultant with any EAS manufacturer. I don't have stock in any EAS company. I am not an officer at any EAS--et cetera, et cetera. I have no conflicts. And the money all went to the Heart Institute of St. Petersburg, not to me.

I would just like to comment before I do my part to some of the questions that came up this morning, what I was hearing, about MDR reporting and so on. If Mrs. Jones died in the shopping mall and the paramedics picked her up and brought her to the emergency room and she was pronounced dead on arrival, would anybody even ask if she went through an EAS system.

I don't think so. I wouldn't. To be less dramatic about it, if Mrs. Jones passed out at the mall and was brought in by the paramedics, I would never even think to ask, "Did you just walk through an EAS system?" We heard one of the committee members today say he wasn't even sure if he had been through and EAS system lately.

In fact, a survey in England surveying people coming out of stores, asking them, "Have you just been through an EAS system or a shoplifting kind of system?" only about 5 or 10 percent had recognized that they had just been through one. I certainly didn't pay any attention to them until I became involved in this research.

It is very difficult to document these cases, so I think searching databases and looking for MDR reports is going to be a very fruitless search. Some of these cases are bizarre. There is the man in New Jersey whose ICD heated up when he walked through an acoustomagnetic gate and he got a skin burn. You check the ICD afterwards and it is fine. How could that happen? I have no idea. I can't explain that.

There is a woman in New York who, walking past an acoustomagnetic system, was carrying her bags and leaned up against the system to shift her bags and passed out. The shop manager doesn't want her to come back and be tested. She is not too excited about coming back and being tested,. So that would never get reported.

I tried to track that one down and no one was interested in formal testing. At the NASPE meetings, which is the trade organization for pacing and electrophysiology, there was a man in Canada, 28 years old, who was pacemaker-dependent who had true syncope walking through an EAS

system.

And when he fell down, he fell out of the magnetic field so he woke up. He stood up. He passed out. He stood up. He passed out--until a nurse came by and dragged him out. Now, for some reason, he is not interested in going back and being retested either.

There was a question earlier about are other countries looking at this. There is no MDR system for other countries but I can tell you that the FDA equivalent of England told me, when I was over there participating in a conference, that they had begun to get reports and that is why they were attending the conference that I was giving a talk at.

In Canada, there have been some reports as well of interactions and that is what spawned the Medical Device Bureau, I think they are called, the FDA equivalent, to do their own study. Their findings were reported this year. In fact, they now recommend that pacemaker-dependent patients not be within 33 centimeters of an acoustomagnetic system.

There are some cases, though, that have been pretty well documented. There is a lady in Phoenix who, whenever she walks through a gate, an acoustomagnetic gate, again, her heart speeds up to 160. She gets palpatations, dizziness, nausea, and so on. And when she walks out, she

is okay. She was monitored. In fact, she has an interaction that is symptomatic.

In Germany, there was an 18-year-old woman who was pacemaker-dependent who passed out. She wore a monitor through. She was willing to do it. She passed out again. I can't tell you any of the details of that case. That came to us through sort of the lay press.

In Chicago, I know of a man who is interesting because he had all the normal symptoms--dizziness, palpations, dyspnea, shortness of breath, and so on. But he also got palpatations that stayed after he left the gates. I wasn't aware of that happening before. In fact, he was hospitalized for tachycardia and they couldn't figure out what his tachycardia was from until they realized that his pacemaker had somehow been reprogrammed.

Again, that is very hard to understand. I agree with the speaker this morning from the pacemaker association that says there is so much hand-shaking that goes on in digital coding that that is very hard to understand.

But it turns out that this particular kind of pacemaker, Telectronics pacemakers, uses the same frequency as an acoustomagnetic EAS system to measure how fast you breathe. You heard that mentioned. If you are in the field of a strong magnetic source at that same frequency, you get a DC offset in the aperture circuit of this rate-response

sensor. So, suddenly, you are reprogrammed to 150 or 160 and you stay there until someone manually reprograms you.

So there are a few cases. My own particular experience came from a patient of ours who was in one of these aisle systems. He was chatting with the cashier. He had a defibrillator in. The magnetic field of the EAS gate fooled his defibrillator into thinking he was having a cardiac arrest so he got an inappropriate shock. So that was no fun for him.

We were able to take him back. As opposed to what was said this morning, we were able to take him back and reproduce those findings. We found that whenever he went in the field, he would start to sense this very fast heart rate that, in fact, wasn't there.

[Slide.]

That tells you how we got involved in this. We did the study of pacemakers and cardioverter triggering by electronic article surveillance devices which we call by the acronym "spiced tea." So if I say "spiced teas," I am talking about our study.

When we set this up, I recognized that I am a cardiologist, not an engineer. So I sought out engineering help. The first four coauthors here are from the Heart Institute of St. Petersburg, the doctors and nurses. D. Johnson is an engineer from PaceSetter, St. Jude's. The

next two, Jerry Becker and Mark Mayotte are engineers from Medtronic. Jon Casamento you heard this morning from the FDA.

I went to them first and said, "How should I do this study?" So we tried to get a broad base of engineering support from the very beginning. We also went to the EAS manufacturers and said, "Here is the protocol we are going to do. Does it seem like a fair test?"

I understand this committee has medical people and non-medical people so I wanted to spend a few seconds on just some of the basic issues of what is going on with pacemakers in the heart.

[Slide.]

What we are looking at is pacemaker EAS-system interaction. So before we can talk about those interactions, we have to talk about pacemaker function. Before we can do that, I want to spend just a second on heart function.

[Slide.]

Basically, the heart has two different kinds of chambers. The atria are the upper chambers. The ventricles are the main pumping chambers and they are on the bottom part of the heart. They are supposed to be coordinated in their beating; upper part, bottom part, upper part, bottom part, upper part, bottom part.

[Slide.]

The way the heart accomplishes that is through the electrical systems of the heart. There is the pacemaker you are born with called the SA node. Then there is this waylay station called the AV node, atrial-ventricular node, that slows down that electrical system so the atrium can finish beating before this does.

So, normally, you have this conduction system that goes from top to bottom. When you are looking at an EKG, when the top part depolarizes, you get what we call a p-wave. When the bottom part depolarizes, you get this big spike, a QRX complex. Then you get a reset.

[Slide.]

That is enough with heart function. What about pacemaker function. When you conducting normally, you don't need a pacemaker. But if your heart pauses, then, if you put a pacemaker in, it will see that pause and start beating for you. That is basically what a pacemaker does.

[Slide.]

So the pacemaker has to do two things. Here are the normal beats, as I have just shown you before. And then, if there is a pause, there will be a pacemaker spike and a pace beat. So the two functions of the pacemaker, then, are to sense the native heartbeat and to capture the heartbeat.

[Slide.]

So when you are sensing, the heart has a beat and the pacemaker says, "Yes; I saw it." The heart has a beat, and it says, "Yes; I saw it." Then, when there is a pause, the pacemaker will say, "I better put out a beat," and it goes down the wire and paces the heart. So those are the two functions of the pacemaker, pacing and sensing.

[Slide.]

So, with that background, one of the things I wanted to mention, too, is if you have muscles outside the pacemaker system moving, you can cause this noise on the EKG. This is a lot like what EAS systems do. For example, if you are shampooing your hair and using your shoulders, or gardening, then that signal can be interpreted as a heartbeat and the pacemaker thinks your heart is beating when, in fact, what is happening is your shoulder muscles are moving.

[Slide.]

So enough with pacemakers and enough with hearts. What about ICDs. That is what got me into this. It turns out, in our study, we could not make defibrillators misbehave. That was a very surprising thing. We thought it would be easier to make a defibrillator misbehave than it would be a pacemaker. But, in fact, for whatever reason, we couldn't.

[Slide.]

But I would, in addition to the two published reports you heard about this morning, give you this patient report. Here is an electrocardiogram recorded by a defibrillator in a patient. You see there are normal heartbeats here. And then the patient comes up to an acoustomagnetic gate. You can see the pulsed noise of the acoustomagnetic gate.

But you can also see inside there are normal heartbeats. So he is still having normal heartbeats all through this noise, but the defibrillator thought this was a cardiac arrest and the square symbol here tells us that he got an electric shock there.

His defibrillator thought he was having a cardiac arrest and so it charged up and fired and shocked him, which, again, is like getting hit with a baseball bat--not lethal, but unpleasant.

[Slide.]

Let's talk about EAS systems a little bit. You have heard about the different kinds. It helped me a lot when Sensormatic taught me about what kinds of EAS systems there were to realize that there are transmitter gates and then they are designed to interact with a tag, and the tag puts out its own signal for the receiver.

You have heard about the three kinds of gates, the

magnetic audio frequency or VLF or extremely low frequency, or ELF systems. Here you put out a signal. What the tag does is put out a harmonic. So if this is 300 hertz, then this will be 600 hertz. So the receiver is looking for a 600-hertz tag and, if it sees that, the alarm goes off because you are shoplifting something.

[Slide.]

As opposed to that, the swept radiofrequency tag is different. What it does is when the signal goes through, it causes a phase shift. You can see that the top of this wave is out of sync with the others. So when you see a phase shift in the receiver, you would go off.

[Slide.]

An acoustomagnetic has a different approach using pulsed powerful focused magnetic signals that interact with the tag and the tag resonates like a tuning fork. So the receiver is looking for a very specific signal.

[Slide.]

This is data from Jon Casamento measuring the magnetic field. You saw this this morning. Some of these systems are designed to have peak magnetic fields at the chest level or at the waist level where you are going to put your shoplifted articles.

[Slide.]

Here is an acoustomagnetic system showing about

the same thing, peak magnetic fields in the chest-waist area.

[Slide.]

But look at the swept radiofrequency. You don't see anything. It looks like a blue carpet on the floor here. There is no magnetic field of anything to speak of.

[Slide.]

So how do these two interact? That has to do with the idea of environmental magnetic interference. If a pacemaker sees a signal come in, it may interpret it as a heartbeat but, if it is going at 58 kilohertz or 300 hertz, it knows the heart is not going 300 times a second. So the pacemaker gets confused, as you have heard, and what it does is it decides, "Well, I don't know what is going on, but I am going to just pace until the rain stops."

[Slide.]

Another interaction is this noise, like the mypotential sensing although, in this case, it is the EAS field. Although there is nothing happening, the pacemaker thinks there is so it turns off and there will be a pause.

[Slide.]

This is another cartoon showing that every time the signal comes through, the pacemaker thinks that there is a ventricular beat.

[Slide.]

With atrial oversensing, there are two wires. We would like this to beat first and then this to beat. So, normally, what happens is if you have the top part of your heart beat, that signal will go up that top wire and tell the pacemaker, "Yes; I saw a beat in the top part of the heart." Then the pacemaker looks at the bottom part and, if nothing is happening, puts out a pacemaker spike.

So, with atrial oversensing, if you have a very frequent field coming in, it will be sensed by that upper wire and then you will get a paced beat. So what you get then is very fast heartbeats down here because you are trying to track that fast EAS signal up here. We call that EAS-induced tachycardia in our study.

EAS-induced pacing is when a strong field comes in and directly causes a voltage in the wire. So if you have a strong field coming in, you can directly induce paced beats even if you are not connected to a can up here.

I would like to take credit for being the first one to report that, but it is not true. It was reported by Lucas before us.

[Slide.]

So the four kinds of pacemaker interactions, asynchronous pacing where the sensing is turned off because the pacemaker doesn't know what is going on, ventricular oversensing which gives you pauses, EAS-induced tachycardia

from trying to track that fast rate and EAS-induced pacing where you get extra beats.

[Slide.]

So what we did in our study was first have patients walk through. Now, we didn't think that was a rigorous enough test because when you are measuring an electric field, you do that with a loop. If the loop is parallel to the system, it will see nothing. But if it is perpendicular, it sees a lot.

So if you look at this map of the magnetic flux in an EAS system, there is really nothing going on in the middle so you would see nothing there. If you were over here, you would get a maximum signal if your pacemaker was this way but, if you were standing in front, you would get a maximum signal if your pacemaker was oriented this way.

So, the orientation is important. In our protocol B, we had patients rotate over two minutes and then go through. Then we moved them 50 percent closer. Then we had the famous hugging, intimate, response between patient and pacemaker.

[Slide.]

These are the EAS gates we tested. I guess I can skip through that for time.

[Slide.]

These are the measurements we made. I don't think

you care about that, either.

[Slide.]

These are the magnetic-field measurements we made. The only thing I would point out here is there is order of magnitude, or two orders of magnitude, difference between the magnetic flux of the acoustomagnetic systems and the others.

[Slide.]

These are the pacemakers we tested. Suffice it to say, we tested all the different manufacturers. This is where the rubber meets the road. Everybody has already heard from this morning that swept radiofrequencies did not interact with any pacemakers. A few, 4 percent, of pacemakers interact with one of the magnetic audiofrequencies but 96 percent interact with acoustomagnetic.

[Slide.]

This is an example of asynchronous pacing. Here, you see the top chamber of the heart and the bottom chamber are coordinated. Over here, you see they are not coordinated. Here is the top chamber. Nothing happened because the pacemaker is not looking anymore. It is just pacing until the rain goes away.

[Slide.]

Ventricular oversensing; here are some pauses.

The pacemaker thinks that the heart is beating and it is really not.

[Slide.]

Here is the case of some extra beats. We don't know if those are asynchronous pacing or EAS-induced pacing but we know for sure that these are EAS-induced pacing because, look, there are two paced beats close together in a VII pacemaker.

[Slide.]

Here is a patient that exhibits a number of those. I see I am running out of time, so I am going to keep moving here.

[Slide.]

Why acoustomagnetic? I think there are three reasons; the operating frequency, the pulse transmission and the high EAS-induced voltage.

[Slide.]

This is Faraday's equation which I don't pretend to understand but it tells me that the voltage that an interfering source is going to give you. It depends on the frequency of operation and the field intensity.

[Slide.]

There seems to be an order of magnitude, again, difference between what acoustomagnetic can do and what the others can do.

[Slide.]

The Europeans had this norm, European norm 56001/A1. If you want to sell a pacemaker in Europe, you have got to recognize that there is going to be some interference. So, if you are down here, your pacemaker has to operate normally. If you are in there, then you have a defined operation like asynchronous pacing.

Up here, it is undefined. When you look at the different EAS systems; swept radiofrequency, of course, they didn't interact. Magnetic audiofrequency, well, they are going to interact sometimes. Unfortunately, acoustomagnetic is outside that undefined range.

[Slide.]

So, has anyone done anything wrong? No; I don't think so. But when you are looking for a 10 millivolt signal, if you have a swept radiofrequency system putting out a 114 millivolt signal, there is no problem. But if you are putting out--what you can do is filter out the trees from the forest. You can still see them. But if you are putting out a 3,000 millivolt signal, it is hard, especially if it is pulsed, to see the trees for the forest.

MR. FLETCHER: I am going to have to stop you here.

DR. McIVOR: Okay.

MR. FLETCHER: Thank you very much.

DR. McIVOR: Thanks for your time.

MR. FLETCHER: Our next speaker will be Dr. Harthorne. We made a switch in the schedule.

Once again, please be reminded of the request of the committee that all disclosures and potential conflicts of interest be revealed to the board.

DR. HARTHORNE: Thank you very much. Good afternoon.

I'm Warren Harthorne. I'm from Boston, Massachusetts. I'm director of Pacemakers Services at the Massachusetts General Hospital, and I'm a member of the faculty at Harvard Medical School where I have been associated for 36 years. And my involvement in cardiac pacing themes dates back to the early 1960s, at the very beginning of my training, and as evidenced by the authorship of over 100 manuscripts and books on that particular topic.

I was a founder and first president of a professional organization that is known as NASPE, the North American Society of Pacing and Electrophysiology, which is the preeminent physical profile group dealing with these issues. And I have a clinical practice that follows several thousand patients with cardiac devices. The NASPE organization is not a trade organization. It's a tax-exempt educational society.

The interest that I acquired in possible

interactions between electronic article surveillance systems and pacemaker devices arose through a separate consulting role that I served for an organization called the American Medical-Legal Foundation of Rittenhouse Square in Philadelphia, and this organization reviews hospitals which have lost their Medicare accreditation or which are simply trying to improve the quality of care which they provide. And in that capacity, I perform in-depth reviews of several hundred medical records of patients who receive cardiac pacemaker devices.

Through that affiliation, I was asked to perform a review of a rather cumbersome and lengthy document that is by the Georgia Tech Institute, and it's in that direction that I come to you today. As far as compensation is concerned, as a consultant I do receive compensation that varies somewhat according to the complexity of what I'm consulting on, and it generally ranges from $200 to $300 per hour of work. I don't have any financial interest in the topic at hand today. I don't own stock in any company involved in this. And on the one hand, my interest is piqued by the technical aspects of this topic, but also, being a clinical cardiologist with a large number of patients who rely on me for judgment and wisdom about their life-styles, I feel I have a responsibility to ensure that they are properly informed.

This is a particularly serious concern as a physician. We find ourselves facing this issue all the time, not just with pacemakers and defibrillators, but heart valves and other prosthetic devices and medication. And it's imperative that we physicians do our best to help patients lead normal lives and protect them from anxiety-provoking, capricious reports of device interference which are largely theoretical and of little practical concern.

It's not really my responsibility to do this, but I would like to just say a few remarks about the two speakers who follow me. There were some rather irritating remarks made this morning concerning compensation as far as consulting is concerned. Drs. Parsonnet and Zipes are amongst the world's most revered academicians in the field of cardiology. Dr. Parsonnet essentially introduced cardiac pacing to this country. Dr. Zipes equally well basically introduced defibrillator therapy, and not just to this country but to the world. And to infer that these gentlemen are hired guns I think does a disservice.

So a pacemaker device which we're talking about today is basically an electric stimulator. There's a defibrillator and a pacemaker with the appropriate leads attached to the heart and to the device. These devices offer quadrillions of programmable options. Once the device is implanted, we have the option of fine-tuning the system

to suit that individual patient. The majority of devices in use today are dual-chamber and sequentially stimulate the top chamber and the bottom chamber.

The stimulation of the heart chamber is modified by circuitry which detects spontaneous, normally occurring heartbeats through use of a sensing amplifier. The sensing amplifier is tuned to detect signals that reflect those seen in the atrium and in the ventricles of the normal heart and to reject, where possible, environmental signals that surround all of us, such as radio waves, garage door openers, TV channel controllers. And a problem may arise when the environmental signals overlap the frequency of those signals from the heart, such devices as hair dryers, electric razors, dental cleaning devices, depilation equipment used in hair removal, and certain types of audio equipment.

Today's conference relates to the possibility of interference by electronic article surveillance systems, and we've heard of the million or so people living in this country with cardiac pacemakers and the nearly million installations of these systems in stores. So the exposure must be uncountable in terms of daily interactions of patients with devices and these types of systems.

The handful of case reports to the medical literature I believe attests to the relatively infrequent

occurrence of any problems. Most patients walk through these gates in a normal walking pace that takes the time perhaps of two heartbeats.

The George Tech report which I reviewed showed that only minor transient alterations from baseline function, which are clinically irrelevant and have no implications as far as patient health, were observed. In those situations, the devices, which were suspended in saline tanks, had to be in a very narrow range of proximity and a very special orientation toward the emitting pylons. There was no instance of pacemaker reprogramming, and I don't think there's any such instance that's ever been documented.

The variations in function of which the George Tech scientists found included brief, momentary, upper rate response. The vast majority of pacemaker devices are programs to an upper rate of 120 to 125. So this infers a premature beat. Now, as I stand here, I calmly have premature beats, and I expect many of you around the table are also having premature beats. They occur in the normal population of people, including those with pacemakers, and they may be induced by the EAS system, but are of no clinical relevance whatsoever.

The inhibition of pacemaker devices has been alluded to. We'll talk more about that in a minute. This

is when the sense amplifier in the lower chamber of the pacemaker detects a signal and may cause the device to skip one or two heartbeats. For there to be an extended period of suppression of pacemaker stimulation, the patient must remain standing in a precise orientation relative to the EAS source and for a specific period of time. And it's unrealistic to think that most individuals would do this, particularly if any symptoms of dizziness arose.

Finally, the occurrence of asynchronous or fixed-rate pacing has been alluded to. This occurs when the device detects noise of any type, whether it's electrocautery in the hands of a surgeon, the EAS system of a store, and the device says I don't know if there's a heartbeat or if this is extraneous noise, so I'm going to pace in a fixed-rate mode. And that will cause competition with the native heartbeat. This feature is essentially clinical follow-up, and when we do our follow-up clinic visits, we intentionally induce asynchronous pacing to confirm that there is depolarization of both chambers of the heart. It is the fixed magnetic rate of the pacemaker which is the end-of-life indicator of battery function.

And I might digress for a moment to mention to you one of the major follow-up methods in use, and that's the use of a telephone monitor in which the wearer of the device attaches wrist electrodes, and the device converts the

electrocardiogram to an audible sound. The telephone is placed in the cradle of this device, and the electrocardiogram is transmitted around the world. I have a patient who lives on the beach in Micronesia who transmits his electrocardiogram to New York City and it is then faxed to my office.

This intervention involves the patient taking this magnet--it's a 90-gauss magnet--placing it over the pacemaker device during the transmission to convert the pacemaker to an asynchronous or fixed-rate mode. That is a legal requirement by Medicare for reimbursement of the monitoring procedure.

The major company involved in this type of monitoring is one in New York. There are multiple different companies. That particular company monitors 100,000 patients and told me yesterday that they have performed six million telephone transmissions with a magnet held in place over the pacemaker device for 30 seconds. Can somebody show that? We have a projectionist.

[Slide.]

Just to show you what this looks like on the electrocardiogram, this first slide is taken from a report from a patient who lives in Hollywood. The name is deleted, but many of you would know him as Spartacus. He shows in the upper panel a normal sinus rhythm; in the bottom panel,

the rhythm is still normal sinus, but the pacemaker device has been activated by the application of a magnet. But this is RONT(?) pacing. He does this every six months. We check his pacemaker function. It's working normally.

If you'll just put the other one up, please?

[Slide.]

The other panel here is a patient who is less interesting socially, but she has a dual-chamber pacemaker, and the magnet is applied in the bottom panel. The patient has her own intrinsic rhythm, probably atrial flutter fibrillation. You'll see dual stimuli on the bottom panel, and note the close proximity of those dual stimuli when the magnet is in place, and then about the fifth, sixth, or seventh panel, the stimuli are farther apart. That's non-physiologic AV delay induced by the use of a magnet. It is a normal phenomenon in dual-chamber pacemakers and should not be construed, as has been suggested in the preceding report, to be an anomaly due to EAS exposure.

Can we have the slide off, please?

So every forum, every office clinical evaluation--before I came down here from Boston yesterday, I saw a dozen patients in the office. Every single one of them had a magnet put in place, had a computer programmer put over the pacemaker device to read out the intrinsic finding. At the present time, as I mentioned, it's estimated there are

approximately 200,000 patients undergoing telephone telemetry through commercial firms six to twelve times yearly. So I do not have any concerns about asynchronous fixed-rate pacing. And I believe this has relevance to the conference today.

The study that Dr. McIvor has shared with us is of interest, and it focuses our attention on those features of pacemaker device function that we should understand and interpret to our patients. It's soon to be published in the journal Pace. He studied 50 patients with pacemakers and 25 with defibrillators exposed to these types of systems of varying design. The defibrillators got off scot-free, and Dr. Zipes will tell you about his study of that same topic.

Of the patients with pacemakers exposed to the acoustomagnetic type of surveillance, four types of response were identified, three of which to this observer are of no clinical relevance whatsoever. They included suppression of single-pace beats, transient pacing of the upper tracking rate, and reversion to the design backup mode. As for the fourth observed effect, three patients were reported to show symptomatic inhibition of pacemaker function while standing in a static position with a specific orientation to the emission pylons. The problem with those observations is that at least the illustration submitted with that manuscript demonstrate a perfectly stable underlying rhythm

in those patients. So one wonders if the symptoms were the product of suggestibility.

In conclusion, ladies and gentlemen, the paucity of case reports in the literature in the last ten years of symptomatic interference with medical device function suggests the lack of a significant occurrence. Similarly, the tens of thousands of Holter monitor rhythm recordings that are done each year in patients with defibrillators and pacemakers in place refute concerns of dangerous alteration of those devices by electronic article surveillance systems. In over 30 years of experience of treating thousands of pacemaker recipients, I am not aware of any patient who has been harmed or injured by these devices. Irreparable harm to consumer and pacemaker patient anxiety and confidence levels can result, however, from irresponsible allegations of potential harm that have proved to be non-existent over many years of pacemaker follow-up. These patients are elderly, unsophisticated, and easily alarmed over news articles, which tend to be inflammatory and sensational.

I thank you very much.

MR. FLETCHER: Thank you.

Our next presenter will be Dr. Zipes.

[Slide.]

DR. ZIPES: Good afternoon, ladies and gentlemen. My name is Douglas Zipes. I am the Distinguished Professor

of Medicine at Indiana University and Chair of the Division of Cardiology and of the Krannert Institute of Cardiology. I, too, am a past president of NASPE.

I am a consultant for Sensormatic and am paid to do work for them, as I am a consultant and paid to do work for other pharmaceutical and device companies.

My background is in heart rhythm problems for almost 30 years. I have published approximately 600 articles that deal with heart rhythm problems, pacemakers, and defibrillators, and 11 books. I am the editor-in-chief of three journals, one of which is an electrophysiology journal, and I have been fortunate to receive the Distinguished Scientist Award from both NASPE and the American College of Cardiology.

Sensormatic has asked me to perform a study of my design to evaluate the interaction between EAS systems and implantable cardioverter defibrillators, and I'd like to share the data from that study with you as it exists today.

This is a trial that is the evaluation of potential interactions between implantable cardioverter defibrillators that have pacemaker capabilities as well built in and the electronic article surveillance systems.

[Slide.]

The study is ongoing and aims to evaluate this potential interaction between the ICDs--the defibrillators--

with their pacing capabilities and EAS systems. We plan to study a minimum of 200 patients, and we're using all clinically available ICDs and sensing circuits. We're studying both routine exposure and extreme exposure, which I'll define for you, to two electromagnetic and one acoustomagnetic EAS system.

Individuals are recruited from the defibrillator clinics at the Krannert Institute of Cardiology at Indiana University and at Methodist Hospital, with which we are aligned. All patients gave informed consent, and the institution approved this study.

The ECG of the patients is continuously monitored and an external defibrillator is present. The therapy for the ICD is inactivated by the programmer before the patient is tested. Thus, we can monitor whether the device saw an abnormal heart rhythm and might have responded to it, but since we've inactivated the therapy, the patient's at no risk and would not receive any therapy from the ICD. And we don't alter the sensing or slow heart rate pacing therapies.

[Slide.]

The EAS system exposure is as follows: Routine exposure is a 10- to 15-second walk--it's a very slow stroll--through the middle of the gates, a very slow shuffled. As a matter of fact, one elderly individual using a walker could walk through the gate in easily less than 10

seconds. So the 10 to 15 seconds is an extreme, which I don't think one would encounter in daily exposure.

However, we tested two extreme functions as well. One is a 2-minute exposure, approximately 0 to 6 inches from the gate transmitted, and the patient basically strolled, turned around, and spent 2 minutes within the transmitter. And the defibrillator was at the clinical sensitivity that it was set for that particular patient.

In addition, after doing this, we then did what we call extreme-plus pacing, which is, again, the 2-minute exposure with the ICD at the clinical sensitivity or the maximal sensitivity that did not produce T-wave oversensing. For the non-physicians, it's the highest sensitivity that we can set in the pacemaker while still having it function normally. And then we programmed the device to pace at 20 beats above the patient's intrinsic heart rate, and it either paced the ventricle or dual chamber, depending upon the function of the device.

With the ICD and the pacemaker, we found no alter--or we did not alteration in the pacemaker programming for the individual patient. We interrogated the ICD after the patient walked through each gate pass for any sensed events. We had an ECG strip of each gate exposure, and the analysis was the observation of any potential alteration in the normal function of the ICD.

[Slide.]

Now, these are the results of 102 patients who had been subjected to that type of testing so far. During the routine testing--and I remind you that's a 10- to 15-second pass--there were no changes from baseline. ICD interrogation showed no spurious events or reprogramming at all.

During the extreme exposure--this is 2 minutes, now, within the gates--two devices showed VF, ventricular fibrillation, detection. That means that device would have detected what it thought to be ventricular fibrillation or sudden death, and would have delivered a shock in response to that. But since we had deactivated the therapy, obviously the patient did not receive any shock. Otherwise, there was no change from baseline, and there was no device reprogramming at all. When the patient left the exposure area, the device returned to absolutely normal function, as we would expect and as has been everyone's experience--almost everyone's experience, I guess.

The extreme-plus pacing--now, this is the patient who has pacing activated, and this is, again, 2 minutes in the testing chamber--19 devices showed one to two beats of pacing inhibition. That means your heart rate went from 72 to 70. That's basically what it means.

ICDs with VF detection in the extreme exposure

showed complete pacing inhibition. What that means is that the device, if it senses ventricular fibrillation to be present, turns off its pacing, as it is built to do, because it does not want to trick itself into thinking that there are beats happening--that is, the pacing stimuli--and, therefore, not to deliver a shock. So this device functioned absolutely normally, as it is built to do by the engineers. And, again, there was no device reprogramming at all.

[Slide.]

One hundred two patients walked through this testing system; 99 patients had no relevant interactions whatsoever, and the relevant interactions occurred only in the extreme exposure of 2 minutes within the testing chamber, as I indicated. Three patients had the relevant interactions. A patient with a Medtronic defibrillator, a 7219, and possibly very important, this patient--the pulse generator was in the abdomen. Now, we don't do that anymore today. This is an old type method of implantation, and it could be that's where the main sensing area is when the patient walks through the device, the EAS system. In addition, it produces a much larger antenna between the lead and the pulse generator, which certainly could account for spurious sensing.

The second device was a CPI device which has VF

detection, spurious VF detection, and also had an abdominal implant.

The third device, which was a Ventritex device, that showed total inhibition of pacing, also had an abdominal implant.

Now, I stress each of these patients had an abdominal implant and were exposed to 2 minutes within the EAS system. Those are the only relevant exposure problems that we saw.

[Slide.]

This summarizes the data on the devices and the numbers of patients who went through. The CPI device, virtually all of their devices, this shows the number of patients with an individual device who were tested. Zero were affected during routine exposure. Zero. One had VF detection, as I indicated, during the 2-minute exposure time period.

[Slide.]

This slide summarizes the Medtronic devices that were tested. Virtually all of the Medtronic devices available, showing the number of patients with the devices. Zero had any abnormalities during routine exposure. The relevant interaction was the one VF patient that I told you about earlier with the abdominal implant.

[Slide.]

This slide shows the few patients with Intermedics, Telectronics, and Ventritex. Zero were affected during routine exposure. One had pacing inhibition with the abdominal implant that I indicated to you earlier.

[Slide.]

So, in summary, in this study of ICDs and EAS systems interaction, there have been no relevant interactions noted during any routine exposure. Rare tachyrhythmia detection associated with extreme exposure, that is, the ventricular fibrillation detection during the extreme exposure, and this was with older ICDs and just with the abdominal implants. They were more common but minor, not clinically relevant, one or two beat per minute change, pacing inhibition; but, again, only with the 2-minute exposure, and there was no device reprogramming whatsoever.

So from these data--and the study is not yet completed--I would absolutely agree with Dr. Harthorne that these devices are quite safe as built to be used with the patient walking through the device, not leaning, not loitering. Those things are fine. But I see no problems whatsoever with normal exposure of patients who have ICDs to these EAS systems.

Thank you.

MR. FLETCHER: Thank you.

Our final presenter during the public hearing

portion is Dr. Parsonnet.

[Slide.]

DR. PARSONNET: Good afternoon, ladies and gentlemen, and thank you for the opportunity to present some material to you. I am director of the Pacemaker Center at the Newark Beth Israel Medical Center, director of Surgical Research, and past director of surgery at that institution for 27 years, co-founder of North American Pacing Society, a special organization about which Dr. Harthorne made such flattering comments about me before.

I implanted the first pacemaker outside of Boston and Buffalo, the third pacemaker in the country, in 1961. I pioneered the development of the nuclear pacemaker developed by the Atomic Energy Commission and the Nuclear Regulatory Commission. I've been a consultant to the government in many capacities on pacing issues. I have run a pacemaker center, the first one in the country, which evaluates pacemaker and defibrillator patients. We follow 1,500 patients a year according to Medicare-prescribed guidelines. My professional practice is a private practitioner. I'm a cardiac surgeon. I no longer do coronary bypasses, although I did the first ones in New Jersey. I did the first heart transplant in New Jersey. So I've been around.

Because I'm in private practice, I have an independent income, and I was asked to be a consultant to

Sensormatic, which I agreed to do, but I came here today because I feel this is an issue of concern to my patients and what your deliberations will have you do and what they will hear from you and what they will hear in the future. I am not on a salary from them. They have reimbursed me for my expenses here.

I have one other role in life. I'm the board chairman of the Jersey Symphony Orchestra, and I met an $11 million budget this year. I had to raise a lot of it. And so Sensormatic knows my interest, and they made a voluntary contribution to them. And if they make another one, that would be ducky.

[Laughter.]

DR. PARSONNET: But I didn't ask.

So to go on with the subject, let me have the next slide please.

[Slide.]

You may have copies of what I have written, but I would like to take a sidestep from it because much of it has already been said. And I'll emphasize a few things from my clinical experience and some research experience and my clinical feelings about things.

To start off, let's look at the worst case. What could happen if there were life-threatening arrhythmias, damage to the pulse generator, phantom reprogramming,

intermittent pauses and extrasystoles, and could deaths occur.

[Slide.]

Let's talk about the life-threatening arrhythmias first. Dr. Harthorne talked about the application of a magnet over the pacemaker. Now, the magnet reverts the pacemaker to a fixed rate, which means it fires regardless of what the heart does. The magnet reverts it to something like the noise mode or VOO fixed-rate pacing. Now, that produces competition with the naturally occurring beats, and some of those competitive electrical stimuli fall in what's called the vulnerable period of the electrocardiographic cycle, and I think Mitchell Shein talked about that this morning.

Now, when that happens, the vulnerable period, if it is stimulated intensely with a strong stimulus in the laboratory, you can produce extra beats or runs of beats or ventricular fibrillation. And I want to point out that from my laboratory experience, which I did years ago when I was developing, helping develop defibrillators and we were trying to potentially produce ventricular fibrillation, that in order to produce a stimulus that would be strong enough to produce ventricular fibrillation, we had to go to something like 40 volts applied directly to the heart.

Now, pacemaker output is about 5 volts, and you

can, as Dr. Harthorne mentioned, alter this sensitivity to a stimulus by making a patient--the heart sick by producing a heart attack, tying off a coronary artery, for example, or by very significantly altering electrolyte balance by infusing acids into the bloodstream. But even so, it takes a lot more stimulus than a pacemaker output to produce a lethal arrhythmia.

We have more clinical experience to support that, and that is, in the implantation of a defibrillator, we want to intentionally induce ventricular fibrillation so that the defibrillator that's being implanted can be tested before we leave the operating room. In order to produce ventricular fibrillation, we have to stimulate the heart in a vulnerable period--that's one way to do it--with something like 200 to 300 volts, hundreds of times more energy than a pacemaker produces.

So when we talk about the dangers of fibrillation by stimulation in the vulnerable period, we're really talking about almost non-existent danger because the stimuli we use have to be so far in excess of what a pacemaker produces as to be not even logical.

My clinical experience has one other issue. Since I began putting in pacemakers, the first four or five years, the only pacemakers we had were fixed-rate pacemakers. There was no such thing as a demand pacemaker or a pacemaker

that sensed the activity of the heart when turned off. All of the pacemakers were fixed-rate. I put in hundreds of those. In addition, we put in 19 nuclear pacemakers that had a half-life, a battery half-life, of 86 years. We still have 15 or so of those running.

Those devices constantly during the course of the year pace on the apex of the T-wave with a vulnerable period, and we have never seen any events that would be lethal.

[Slide.]

So we can summarize that by saying that stimulation is unlikely to produce arrhythmias. The most stimulation will do will produce pauses, and as Dr. Harthorne also pointed out, all of us, including me, are having these extra beats all day long with no consequence.

[Slide.]

Damage to pulse generator has never occurred. We have never seen it. It's been years and years since we've seen a pacemaker suddenly stop. In the early days, when everything was new and the pacemakers were not implanted in hermetic seals, we occasionally had pacemakers stop, but nothing happened to the patient. They would return to their status quo ante.

Phantom reprogramming, we found occasional cases years ago. We have not seen any recently. Those we have

seen tend to be something done by another doctor in another office and who hasn't told us that the pacemaker was reprogrammed and then we find it when we see the patient in the clinic.

[Slide.]

Now, how about death? This is something that I want to mention because we haven't heard this before today. Pacemakers are implanted in most patients for something called sick sinus syndrome. That's a slow heart rate which has pauses, which may produce lightheadedness and occasionally fainting. It may have runs of fast beats, but it's a living situation. Sixty percent of the patients have that. Now, I run a survey of national pacing every four years, which is published every four years, and we know that about 60 percent of patients have these. And so if the pacemakers just stop abruptly, nothing would happen. The patient's heart would go back to the status quo ante. Now, this is hypothetical. The pacemaker is not going to stop suddenly, but I'm presenting to you a worst case.

You asked a question about default mode. If the default mode got stuck and the default mode was no output, nothing would happen to these patients, certainly.

Now, how about those who have complete heart block, heart rates are very slow? They only amount to about 5 percent of the patients. They're very rare, and those

patients, if the device failed suddenly, may have a fainting episode, but they'll survive it. We don't see or hear of sudden deaths from pacemaker failure.

[Slide.]

Just a brief comment about other forms of AMF. We have heard about cellular phones and microwave ovens and radar fields. I just want to remind you that the only trouble that I tended to hear about the weapons detectors in airports, before people understood what this is all about, when a pacemaker patient went through the weapons detector, somebody who has detected the foreign metal, instead of asking do they have a pacemaker, because they hadn't heard of them yet, tried to pull it out or grab it to see what was in there. So we had patients complaining about people grabbing them to find out what that hunk of metal was. But we've never seen any problem from the weapons detectors in the airport other than kind of silly stories.

The microwave oven issue arose years ago. There are signs every place: Don't go near the microwave oven. We've never seen a problem with that. I always tell patients now to be light about it, I say, Be sure not to get in the oven.

[Laughter.]

[Slide.]

So I would summarize this comment by saying there

should be no danger to life if, in the worst case, pacemakers were to cease abruptly. The induction of a sustained serious arrhythmias by an EAS device is not anticipated to occur. Risk to the pacemaker patients is infinitesimally small. Damage to a pacemaker and phantom reprogramming is unheard of in our experience.

[Slide.]

I'd like to make a final comment that I mentioned before. That is, as a clinician, it's my responsibility to make the patient comfortable with the device. As a matter of fact, I would like the patient with a pacemaker or defibrillator to forget he or she has the device, to live a normal life. We want to return a patient from an uncomfortable situation to a normal life, a normal occupation, whatever they are, whatever age. We have lots of young people, children. So if patients hear from any source about dangers, if they hear unsupported stories, dramatic stories, they can become terribly frightened.

Our most recent example of that was--you may have heard or I'm sure you all know about the Telectronics Acufix lead system. I have probably the largest series of patients in the country. We have 619 patients with the Acufix lead. That was a wire to the heart that had a tendency to tear some of the heart, and there were some deaths reported. We called all our patients, tested them all. It turns out the

only danger to the patient, real danger, was inexperienced people taking out those wires because there was more damage and deaths from removing them than leaving them alone.

But the point I'm trying to make is that patients, all patients, heard about this Telectronic lead, we were besieged with phone calls with patients who had everything else in them, nothing like those leads, wanting to know are they in danger of their wires in their heart.

So I think it's very important that we all understand that the proper context of the problem ought to be presented to the patients, and they have to be comfortable with what they're wearing.

[Slide.]

I want to conclude, before the red light goes on, that from my clinical experience I think there is no reason to expect any meaningful consequence to pacemaker patients from EAS devices.

Thank you for your attention.

xx MR. FLETCHER: Thank you very much.

First of all, I'd like to thank all of the presenters for adhering very closely to some very tight time schedules. We are now entering the part of the meeting where we dedicate some time for committee discussion. All of those who presented, since there's no room for anyone to sit, what I would ask is, if there's an area of specific

question, please move quickly to a microphone so that you can respond. And if members of FDA staff have any additional information, please have them come forward also, Dr. Jacobson. Thank you.

Are there questions or comments from the panel? I'll start with Jane.

MS. EHRGOTT: Yes. Could someone please list what FDA would like us to act on today?

MR. FLETCHER: That's a good point. Dr. Jacobson?

DR. JACOBSON: Well, in your handout, you had a number of items--

MR. FLETCHER: Could you move closer to the microphone, please?

DR. JACOBSON: We had a number of items and questions that we were looking to have some kind of reaction. One was the general reaction on the installed base of products. I think we--our feeling was that we needed to have more information on testing. I think Dr. Zipes' study, we're really looking forward to that being completed. That's the kind of information that we need to get developed. Looking for appropriate in vitro surrogates for clinical testing, and the proper recommendations to give to the users of these systems. And we were looking for advice on what industry might want to do in terms of signage, perhaps. Then we're also looking for advice on

what FDA can be doing in terms of issuing advisories or targeting information to particular groups.

I think we're very much in agreement of the need not to alarm or frighten patients. The idea isn't to frighten people. It's to make sure that appropriate information is out there. In fact, our advisory was really geared toward physician information so that if they got questions or if they wanted to do some counseling, they would have additional information.

In terms of future products, we were looking to get some discussion going on the appropriateness of monitoring adverse event reports, that we totally agree that our MDR system is just a red flag kind of collection of anecdotal reports, is not meant to mean clinical studies or things that have to be analyzed in-depth. They're really just kind of red flags and might support research directions or something for the future.

We're also looking at support for the idea of pursuing a consensus standard group to try to get good design characteristics listed for all the industries, for the security as well as the medical device industry. So there's a lot going on there already, which you heard some of today.

MR. FLETCHER: Our guests and--

MS. KAUFMAN: My question is for the physicians

who had a clinical practice, and Dr. Harthorne and Dr. Parsonnet specifically mentioned they do, so I guess that's where my questions are directed. But if the other two have clinical practices, I'd be interested in their response, also.

The question is: Do you offer any advice to your patients relative to the systems? And if so, what is that advice?

DR. HARTHORNE: The answer is yes. We don't dissect every single exposure in society that these patients might come in contact with, but we do encourage them to use judgment when they're around electric motors or high tension wires or anywhere there might be some radiation of energy that could interfere with their pacemaker.

I might just add parenthetically, we test every patient for pacemaker dependency. It's part of a routine clinic or office visit that when they come in, we turn their pacemaker off. We don't shut it off, but you program it down decrementally until you demonstrate an escape rhythm, and we worry less about those people who have an escape rhythm than those who are pacemaker-dependent. But we talk about electrocautery during surgery. I'm probably consulted four or five times a week by the surgeons regarding--it's usually a woman having a breast biopsy who happens to have a pacemaker, and the surgeon's going to use electrocautery.

So there are lots of aspects that we advise them on.

EAS systems, the subject really hasn't come up that much. There is some mention in the literature and patients have called in, and we told them to ignore it.

DR. PARSONNET: I think you asked what we do routinely. I tend to be a little less specific than Dr. Harthorne. I tend not to bring the subject up unless asked. Now, most of the patients I see are old. I'm talking to their families. The younger patients who are likely to be more active, they're more likely to ask questions of what they can do. Can they play basketball? Can they do other things? So I'll discuss those with them. And since I believe what I told you, that I think the issues about electromagnetic interference are very small, I don't raise the issue unless it's asked. Once in a while I will if somebody works in an industry where they're going to be exposed to a lot of electromagnetic interference. But I try to pooh-pooh it. I believe what I said to you before. I think it's important to downplay it.

DR. ZIPES: I didn't indicate in my presentation, but I take care of lots of these patients as well, and I would underscore what Dr. Parsonnet and Dr. Harthorne said. I don't specifically go through a menu with them, avoid this, avoid that; but, rather, I stress to try to live a normal life and forget that you have the device in place. I

think that's absolutely essential.

The devices are built to function automatically. I tell my patients who have the implantable defibrillator, it's like have an emergency room in your chest, and it will monitor your heartbeat and it will do what it's supposed to do, and ignore it. Get about life and do your thing. And I think it would be absolutely appalling to have something like they have to worry about every time they go to buy a new book at Borders or go shopping and worry about going through an EAS system and consciously think of that each day.

MS. KAUFMAN: Dr. Zipes, I have another question for you while you're there. You mentioned the abdominal implants. Do you have any idea what percentage of the implants are abdominal today?

DR. ZIPES: It's a small percentage, 5 percent, 10 percent, probably, and it's going to dwindle even more as those patients die because we're not implanting them in that fashion anymore.

But do remember, true, it's 3 out of 102. It may be significant. But we need some more data.

MS. KAUFMAN: And if I could ask you just one more question, you three obviously are aware of the issue, or non-issue, as the case--you know, however you prefer to look at it. Do you think that most cardiologists are aware of

just the issue in general, you know, not making a decision as to whether it's real or not but just that there is some--

DR. ZIPES: My bias would be no, because I think it's a non-issue and no one has really thought about it. Now, there will--has been a bit of tumult in some of the publications, and perhaps these isolated anecdotal case reports may stir some interest. But I would bet that the vast majority of cardiologists are not aware of this as a potential problem because none of them think that it is.

MS. KAUFMAN: Thank you.

MR. FLETCHER: Bob?

MR. TUROCY: Bob Turocy, and I have a comment for Dr. McIvor, and anyone else who is looking for data that would complement the FDA's medical device reporting.

Our corporation markets devices, and that is medical devices, within the European Community. Now, we must comply with the medical device directive there, and what the Europeans use is what is known as a vigilance system, which is almost identical to the MDR report. So if anybody's going to do any studies, I would suggest that they look at the vigilance system for additional data.

DR. ZIPES: I'd like to respond just briefly if I may. I think those kinds of reportings are important only to raise an issue that then needs to be looked at in a prospective controlled fashion, such as the study that we're

doing now. These anecdotes can inflame and do potentially more damage than good in certain instances.

MR. TUROCY: I agree with the anecdotal information. However, if the manufacturer is involved with a thorough investigation, he will implement and determine what is the cause of the failure. So I agree with the anecdotal statement, but manufacturers do have a responsibility to determine the cause of the failure and take corrective action where necessary.

Thank you.

MR. FLETCHER: Dr. Jacobson, do you have a--

DR. JACOBSON: Yes. I want to just say I certainly don't disagree with what you just said in terms of manufacturer responsibility. I do just want to make a point about the importance of a prospective study that would be suitable for peer review. That is, not just doing a study that shows interactions, but also I think it's really important that we get some careful evaluation of the clinical significance of those interactions. That was one of the big pieces of the pacemaker-cell phone study, and what took a lot of time was to try to describe what kinds of potential interactions were possible and what was the clinical relevance of those. I think a number of speakers have tried to get to that point this afternoon. It's not enough to have interaction. It has to be one that really

makes a difference for the patient.

MR. THOMAS: Yes, Dr. Zipes, I've got a couple of questions regarding your experimental presentation. Today we had a fairly extensive seminar on various types of devices. Is it my understanding that you were testing all four of the different frequency ranges or just a single EAS detector? And, also, did you evaluate any metal detectors in the study that you--

DR. ZIPES: We evaluated no metal detectors and only three devices of the Sensormatic system.

MR. THOMAS: And which device did you not test, which frequency range?

DR. ZIPES: I can tell you the ones we did test. We tested the Acoustomatic, the P-Magnetic, and the AisleKeeper.

MR. THOMAS: An additional question. I don't fully understand, because I haven't done the reading at this point in time myself, the in vitro experimental assemblies. And I'm assuming that the University of--pardon me, not University of Georgia but Georgia Tech has that. Can someone explain briefly what the in vitro assembly is like? Is it physiological or is it merely a water bath in which the device is suspended and then externally radiated?

DR. HARTHORNE: You're right on the last point. It's a water bath, basically an aquarium in which the device

is suspended but wired to the outside to record interactions that are brought about by exposing it to the EAS system. I have not seen it myself. I have seen it described.

MR. THOMAS: In your opinion, is that an appropriate in vitro evaluation of the performance of that, or do we have to have something that is more physiologically relevant?

DR. HARTHORNE: Well, it's a standard method of testing devices, and I think it's accepted in the research community. I don't think there's any substitute for the human body. All of us range in size from relatively petite to relatively huge, and when you bury the pacemaker device down deep in someone's body, it's insulated through bones, flesh, and whatever else is around it. And there's no way of simulating that in a test lab.

MR. THOMAS: And another question that I have, I got the impression from you and the other two speakers who followed you that you don't think that we should have posting of these EAS devices in terms of a hazard warning to the patient, that that should be warning or discussion only between the physician and the patient?

DR. HARTHORNE: My personal view is that the manufacturers of these medical devices are doing a perfectly fine job. The patients read these books over and over again. There is mention in there of potential sources of

interference. If you start placing signs in stores, you're going to have a rash of hysterical patients who will then have symptoms that they never would have had otherwise simply because they feel they should have them.

I'm still seething with relative indignation about an article that appeared in Forbes Magazine within the past year in which the reporter alluded to "old gomers" dropping dead--and that's a quote--patients with pacemakers walking into stores having a particular type of device, and falling down dead. That simply doesn't happen. It's erroneous, it's hysterical, it's inflammatory. And we had dozens of phone calls from terrified patients fearful of going shopping. So if anything comes out of this committee meeting, I would encourage something that's carefully considered and does not provoke hysteria amongst patients.

MR. THOMAS: Thank you.

MR. FLETCHER: With that point, I do want to remind the committee that as far as our deliberations are concerned, we're focused or should be focusing in on whether or not these EAS devices are hazardous or not hazardous, or whether we need more information. That's really where we need to get to.

MS. EHRGOTT: Are there any active studies going on on the spinal stimulators?

DR. JACOBSON: None that we're aware of.

MS. EHRGOTT: Because I think we only heard about pacemakers today.

MR. FLETCHER: And defibrillators.

Dr. Cardella?

DR. CARDELLA: Is Dr. McIvor still here?

MR. FLETCHER: I think he had to leave.

DR. CARDELLA: He had to leave. Okay . My question was: Of the 48 out of 50 interactions with the Acoustomagnetic system, which protocol of transit through the gates did that occur with? Does anybody know that?

DR. SHEIN: From Dr. McIvor's presentation, Protocol A represented just a simple straight walk through the system. Protocol B was when the patient stood in the center point of the system and turned around. Protocol C represented standing in the 75-25 point, closer towards one of the towers. And D is when the patient leaned against the tower, both parallel and perpendicular to it.

MS. KAUFMAN: If you add up all the incidents under A, B, and C, I believe it comes to like 56. And if you add up all the incidents under the D scenario, it comes to like 70. So the D scenario clearly, if there is an impact, has much more of an impact, and that was the one where they're hugging or close--

DR. SHEIN: Right.

MS. KAUFMAN: So if there is a hazard, that

clearly seems to be more of a hazard than any other scenario.

DR. SHEIN: Well, you might look at that bottom line. I'll offer what I offered earlier today, that it's illustrative to look that there are still a fair number of responses in the A and B column.

MS. KAUFMAN: Yes.

MR. FLETCHER: Yes, Dr. Marx?

DR. MARX: One of the only things that it seemed to me that the entire group of speakers agreed upon was that pacemaker patients, spinal stimulator patients, and defibrillator patients should be counseled to just walk at a normal pace through EAS systems, and that seems like very reasonable advice. My question is: Is that message getting to the patients? And if so, whose responsibility is it to get the message to the patients? I'm not asking any--whoever would like to answer, I'd be happy to hear it.

DR. PARSONNET: I think I have to reiterate and say that I don't think I have to tell the patients that, because you all heard that millions and millions of times a year people are walking through these things, and Dr. Zipes emphasized that you don't want people walking up to a device and thinking about it, because that's not clinically wise. If you had--I know you--but if you had a pacemaker, you don't want to think about it when you walk through the door.

So I don't think it's wise to advise them about it, and if asked, I will tell them what I'm telling you, that there is virtually no problem and not to think about it.

DR. MARX: Have you ever had patients who seemed to notice an association where they'd say, oh, every time I go into Hudson's I feel funny, or anything like that?

DR. PARSONNET: No. On the slide I didn't read from, I tried to emphasize the fact that I see 1,500 patients--I have telephone monitoring 250 times a week. I see every day in the clinic anywhere between 10 and 15 patients--when I'm not in the operating room, I see them--and I just don't hear complaints about going in and out of department stores, libraries, airports, anything. You just don't hear it.

Now, Dr. McIvor said, well, if somebody dropped dead in the department store, how do you know it wasn't the pacemaker that did it? Well, that's a hypothetical--I mean the EAS device that did it. That's a hypothetical question, you know. "Are you still beating your wife" type of question. And you just don't know that. People drop dead often. Six hundred thousand people in this country drop dead every year of heart disease. But they're not going through EAS devices.

So it's the kind of thing that you want to avoid. You don't want to alarm them, especially something that I

regard as trivial.

MR. FLETCHER: Dr. Jacobson?

DR. JACOBSON: I think you asked a really good question, and the answer is in terms of who gives the information to the patients. One avenue for that is information from the manufacturer in the patient information books that these patients get.

That varies. We are in the process of looking at what kinds of information is in those books, particularly for the neurostimulator patients where it is a little bit more uneven in terms of what information is getting out.

One of the purposes of the advisory going to positions is for us to try to give information to physicians to counsel their patients, and in fact, one of the questions for the group is what do you think we should be telling physicians so that they can counsel their patients.

And this question of--what we have in our draft right now is fairly straightforward. It says be aware that systems can be hid, do not linger, and if you think it is important, you can ask for alternate forms of search for metal detectors, for example.

One of the--we talked long and hard about whether we should say "what" straight through the system, and we are still a little uneasy about that. It is a slightly different message to tell patients you are okay if you walk

straight through the system.

We do not have a lot--we have some studies that say, well, they did get interactions in a protocol, in Protocol A. Are they significant interactions? So this is a little different from walk through and you are all right as opposed to do not stay near these systems, do not linger.

And we would appreciate--maybe we are making much too fine a distinction here.

MR. THOMAS: Looking at the data that was presented earlier today by the FDA on the summary of the--

MR. FLETCHER: You may need to get a little closer to the mike.

MR. THOMAS: I am sorry. Thank you.

Looking at the data that was presented by the FDA this morning on the MDR reports and that summary page and trying to change how I am looking at it, I have a question.

The SynePace AFP2, is that an abdominal implant, or would that be implanted elsewhere? That is the devices that they say is a pacemaker that was a severe reaction and the patient lost consciousness.

DR. ZIPES: Just the pacemaker?

MR. THOMAS: Just a pacemaker, and I do not know how they are implanted. I am not a pacemaker.

DR. ZIPES: It would be extremely unlikely.

MR. FLETCHER: You are going to have to come to a

mike.

DR. ZIPES: Which number are you referring to?

MR. THOMAS: Item No. 28. It is the loss of consciousness under the pacemaker through an EAS device.

DR. ZIPES: The size of the initial defibrillators led to their abdominal implantation, but the pacemakers without the defibrillator capabilities are so small that I think it would be extremely unlikely that that would be an abdominal implant. It would be most likely a pectoral.

MR. THOMAS: Yes. This occurrence was in April of '95.

DR. ZIPES: Very unlikely, but Dr. Harthorne knows--

DR. HARTHORNE: I have not seen the sheet you are talking about, sir. I am guessing at what you are trying to describe. I am not aware of any--you said something about AFP. That happened to be a model number of a particular pacemaker years ago.

MR. THOMAS: Let's see. Well, it says the security system was an EAS system, and the manufacturer of the pacemaker was Seimens. The device is called SynePace AFP2, and now you know as much as I do about the device.

DR. HARTHORNE: I am familiar with the system. Seimens is a Swedish company. The device in question has been recalled for technical flaws. I do not know of a

specific example of this particular patient, though.

MR. THOMAS: From what I have seen here in the NDR reports, from what we have heard this afternoon, it sure looks like to me that the initial evidence that has been presented is that there is indeed not a problem with pacemakers and EAS devices, but there certainly seems to be some concern with the airport metal detectors.

I would like to maybe entertain some discussion among ourselves here about making a recommendation to the FDA that a standard laboratory for evaluation be considered or a site be considered for evaluation of the interaction of these various devices with both metal detectors and EAS systems.

It sounded to me like we have a system at Georgia Tech that is used to evaluate EAS systems, but it was unclear to me that we had something like that for the evaluation of metal detectors, and it appears to me that the issues are really with metal detectors and not with EAS devices, from the data that we have in front of us.

MR. FLETCHER: Let's hold that point while more discussion goes on.

Did you wish to respond?

MR. PODHRASKY: Yes. I spoke on the metal detector issue earlier.

MR. FLETCHER: Okay. Would you reidentify

yourself?

MR. PODHRASKY: Bob Podhrasky from Garrett Metal Detectors.

I just want to--before you review--I was very unhappy when I saw the format of that report because it put metal detectors in the upper left-hand corner, most common incidence, most severe effects in red, and I don't know that it is representative of metal detectors.

I will offer that again. As I said, of the 15 incidents of metal detectors and the reports you have here, six of those were related to one particular cardiac implant. So I would just--before you take a great deal of action, I would suggest you study the information presented and look beyond the first page of that report.

MR. THOMAS: I think that is fair. No problem.

MR. FLETCHER: Once again, I am hoping that the committee is coming to the point where we can give a recommendation to the FDA as to whether or not we feel that these devices--we have received enough information to say that these EAS devices are hazardous, potentially hazardous, non-hazardous, or whether or not there is just not enough data for us to come to any conclusion at this point in time.

MS. KAUFMAN: On the one hand, I think that the small number of incidents that we have seen can give us all a level of comfort that if there is a hazard, it does not

appear to be a really great hazard.

On the other hand, I am a little bit concerned about Dr. Zipes' statement that most cardiologists are not--are not even considering this as a possible--as even a potential issue.

So I am not sure that the data we have--how complete it is. So I am of the opinion that we do need to gather additional data, and it would seem to me that it would be advisable for FDA to notify a cardiologist--not that they should notify patients. That is a completely separate issue.

What I am suggesting is that we notify a cardiologist that this is a consideration that they just need to have in the back of their heads; that when--if the patient reports something that this would just be one of, I presume, many questions that might be asked, and then the FDA try and--that we start trying to gather additional data.

MR. FLETCHER: Jane and then Bob.

MS. EHRGOTT: What I would like to see before that done is for FDA to make a better review of the accompanying literature to these devices as to the warnings that are already supplied by the manufacturers, and then determine if that is appropriate to mitigate any general blanket letter.

MR. FLETCHER: Bob?

MR. TUROCY: Bob Turocy. From my experience, I

believe the FDA already has that information from manufacturers. So I think the information has already been presented to physicians, as well as anybody else. So that is already contained in premarket approvals. So why would we have to do it again?

MS. EHRGOTT: Well, then, the thing is why are the physicians using that information? Why do they need another piece of--

MR. TUROCY: I cannot answer for the physicians.

MR. FLETCHER: Is there a physician who would like to answer for the physicians?

DR. PARSONNET: If the information is available in the label that comes with the device, which it does, it strikes me as sufficient, and I think, Ms. Kaufman, you wanted more information. How are you going to get it? I mean, here we are, clinicians--I tried to figure out before how many pacemaker implants I have seen, something like 120 a year for 30 years, 30,000. Maybe I've done my math wrong. And I see 1,500 patients a year. I don't hear of problems.

Now, you think of all that time, I would year something. Do we need data to prove that? Are you going to do another 30 years of inquiry to prove that a clinical impression you have three people here who have lived with this technology for their professional lifetimes tell you it is not dangerous? We do not see it. I am not saying there

is nothing there. Obviously, there are arrhythmias that are insignificant, and they last for a beat or two, but I don't know how you are going to get more data. It is not dangerous. It is in the label. People are not asking me the questions. So I think you are not going to get anywhere with that approach.

MS. KAUFMAN: Do you disagree with Dr. Zipes' statement that most cardiologist are not even considering this as a potential issue and, therefore, may not even be asking their patients questions about it?

DR. PARSONNET: I do agree with them. I think they are not aware of it because they have never experienced the problem. They do not go to medical meetings and hear me get up and say, "Listen, EAS devices is something you have to worry about." They hear Dr. McIvor talking about it, but they do not hear us.

We give courses at the American College of Cardiology. All three of us have been involved in courses for 25 years on pacing, and we mention electromagnetic interference. We talk about pacing on the T-wave. We talk about vulnerable periods. We do this as an academic issue, but nobody leaves those meetings saying I have got to go home and tell my patients not to talk through weapons detectors. It is just not clinically wise.

MS. KAUFMAN: So, in summary, your advice to FDA

is to do absolutely nothing. Is that correct?

DR. PARSONNET: I would be sure that the information was available on the label; that if a physician wanted to find out what the dangers are, he can open the booklet that comes with each device, read through it and see what it says. If he has questions, he knows how to call his field representative and find out about it. There are plenty of ways he can find out if he thinks there might be a problem.

MR. FLETCHER: Dr. Cardella, you had your hand up.

DR. CARDELLA: I have some general comments for anyone, I guess.

You need to understand what this group of panelists, I think, is feeling. We see presentations that list MDRs for these devices, and then we hear a litany of highly regarded experts saying that those MDRs are insignificant or are not of concern, and I want to be sure that the group understands that we are not just splitting hairs about definitions.

It is very difficult to make decisions in the face of what on the surface seems like wildly disparate reports, and I think the panel needs to understand whether the cardiology community and the cardiothoracic surgery community, indeed, believes that all 46 of these reports are trivial and insignificant events or if the reduction of the

pulse to 31--if you go into an idioventricular escape rhythm, some people become very sick from that. They may not die, but if there is the risk of inducing that, even at a small risk, for intellectual honesty, we need to know if that does, can, or has occurred. And it may be that your very large practices have been very lucky. That is the skeptic's way to look at it.

And that is, I think, what people are struggling with. That is what I am struggling with, and I think if I am struggling with it, maybe they are, too.

DR. HARTHORNE: What I was hoping to emphasize in my short presentation was not that these observations that Mike McIvor has presented do not occur. They do occur, and he demonstrated them. And we need to know about them and look at them in our own practice.

The fact is that they are irrelevant. They are interesting to look at, but a premature atrial stimulation is of no consequence whatsoever.

So, if the energy being dissipated by the EAS system causes the pacemaker devices to fire one or two beats early, it is the equivalent of having a brief burst of superventricular tachycardia. You are a physician.

If it causes a device to inhibit from one beat or two beats and your heart rate goes from 72 to 70, it did not go to 30. If you looked at the space between the two

pacemaker beats during the inhibition and assume that that was the continued heart rate, it might end up being 30, but in a worst case, if a patient gets into an EAS system field and he cannot get out, for some reason he has got a great big guy in front of him, a great big guy behind him, and they are rushing saline and he is stuck there, he is going to fall on the floor.

That is kind of a ridiculous way to look at it, but when people feel dizzy, they get away from whatever is making them feel dizzy.

So I share your concern, if one wants to become very theoretical and say, well, this could happen, he could bev the repair man who fixes the EAS system and he has to hang around it all day long, I mean, you can construct circumstances.

The fact is in three very busy practices in this country, we simply do not see it as a clinical problem, and I would ask each of you who go shopping every day how often going into Home Depot or any other store have you seen somebody fall down. People drop dead all year long. I do not remember seeing one, but they tell me it happens, and I do not know that it happens with any greater occurrence in exposure to an EAS system than sitting on an airplane or walking through a train station.

So our concern is not that the information is

incorrect. The information is correct that Dr. McIvor presented. Our concern is how you process that, and our interpretation of it is that it is interesting, but irrelevant to clinical practice.

DR. CARDELLA: And what about the interactions with the metal detectors, the hand-held wands?

DR. HARTHORNE: Again, I can only speak from personal experience. I have had thousands of patients through the years who have gone flying, and most of them will take out their little pacemaker card because the manufacturer told them to, not because I told them to, and identify themselves to the ground steward and say I have a pacemaker, and the ground steward will go over them with his little hand-held wand.

I do not know of any circumstances where a patient has been harmed by that. Others might, but I do not, and I do not know of any case reports.

DR. CARDELLA: There are some indicated.

DR. HARTHORNE: There are some, but I am not familiar with them.

DR. CARDELLA: That is a little bit of the difficulty, I think, everyone is having.

DR. HARTHORNE: Right.

DR. CARDELLA: I think if someone has v-fib and loss of consciousness, I would call that a severe reaction

and something that perhaps ought to be addressed if it had a significant incidence.

If it is a trivial, 1-in-10-billion occurrence, then maybe it doesn't need to be addressed, but I object to the idea that those reactions are being trivialized, at least that is the way it seems to me.

Somebody who develops a v-fib, loses consciousness and drops, I think that is a severe response, whatever the--whatever the device that induced that, and maybe what I don't understand is that you guys are saying that the device did not induce it. This is an event that would have happened to that guy had he been standing out in the middle of a football field, and I do not know that. If that is your position, then we need to hear that, but I would to have some expert person tell me yes, that is credible. That could have happened that somebody would induce v-fib and drop from this because everybody is making it seem like it is unrelated. That is what bothers me.

DR. HARTHORNE: We are sort of addressing different topics here. My interest is in cardiac pacemakers, and I think he was telling us about defibrillators, and you are talking about both of them, sort of.

DR. CARDELLA: Right.

DR. HARTHORNE: And I cannot comment about the

defibrillators. It is not my area of expertise, but for a pacemaker patient, I have not seen anything that concerns me that what you are describing will occur.

DR. ZIPES: I would like to respond to you because, in no way, would I want to trivialize ventricular fibrillation.

I think, though, what we are talking about, at least with the implanatable defibrillator is that the device spuriously senses the presence of VF from the EAS system in a patient in a regular rhythm, calls it VF and delivers a shock unnecessarily, at least that is what the reported cases have been.

Now, perhaps you know more of a device actually inducing the VF. I would be happy to look at that, but in any event, as I present it, 2 of my 102 patients, when they stood for 2 minutes in the EAS system, would have received a shock had we not deactivated the therapy because the ICD saw the EMI and called it ventricular fibrillation. Indeed, that is not trivial by any means, but it took an extreme set of circumstances to induce.

This was 2 minutes staying right in the gate. This is not just walking through with ordinary use.

Indeed, I would love to see the cardiograms that McIvor says were these important interactions because, if they are no more than intellectually interesting hiccups,

like Dr. Harthorne says, then they are totally trivial, though they are real. It is the patient who has a heart rate of 200 and goes down from an EAS device that clearly would get everybody's attention, but it has not happened. I am not aware of an event like that.

So, while there are interactions--and what I tried to do with my data is to apply clinical significance or lack thereof of the interactions.

MR. FLETCHER: Did you want to speak, Dr. Podhrasky? And then Dr. Jacobson and Dr. Lipoti.

MR. PODHARSKY: Again, I want to be sure that my point was totally clear, and I am certainly encouraged by the information I am receiving from the medical profession about their opinion of safety of EAS systems and metal detectors, but regardless of what this panel decides today, I will get a letter next week that will ask is your metal detector safe as far as my cardiac implant, and I will have to answer that person.

I am here to represent the metal detecting industry. We are prepared. We have been working on some voluntary standards. We are prepared to continue those standards, and those standards will be much more meaningful if we get the cooperation and the participation of the FDA and the medical implant manufacturers, and I have been talking to people over a year to do that, and that is

exactly what I would like to do.

Again, my position is I feel like they are safe. I feel like there is every reason to demonstrate they are safe, and I am prepared to work toward that end.

MR. FLETCHER: Dr. Jacobson?

DR. JACOBSON: I just wanted to say it is really good to hear this kind of a discussion because, believe me, it mirrors the discussions we have been having in-house about this issue, and to hear you all struggling with it is just sort of underscoring the problems we have been having, too.

I still think the bottom line that we have is that we agree that we do not see a major public health problem here. I said that at the very outset.

What we are struggling with is we do see potentials for interactions, but they are based on our anecdotal reports. They are based on some good studies, but that are limited. They are not comprehensive in terms of looking at all of the technologies of the same study in a nice reproducible format that we can really evaluate.

We are looking for advice on how do we give physicians information in a way that is helpful and not hurtful and does not raise anxiety levels, and how do we encourage the development of better information so that we can make intelligent decisions and that we are not sort of

struggling with these anecdotal things.

I do want to come back to the importance, too, of being able to evaluate the relevance of the effects when they are seen, and I think that has to be an in vivo/in vitro package. They have to be looked at together.

And also, we need to make sure that we are not lumping all the device types any more than we lump any more of the security device types because, obviously, the neurostimulator present a very different set of issues.

MR. FLETCHER: Dr. Lipoti?

DR. LIPOTI: In the face of uncertainty, I always err on the side of doing more research and gaining more information, and so I would like to suggest a course of action which would get us some more information so we can make a better quality decision.

I am also struggling with so what does this really mean. I think one of your best ways to get better information is to improve the quality of reporting to your medical device reporting, and the only way you can do that is to write to the people who would report and to ask them for more complete information.

So you have a draft in here of important information that would--a request for information that would go to cardiologists, neurologists, cardiovascular surgeons, neurosurgeon and emergency physicians.

Now, I am concerned about the emphasis in this particular draft on recommendations for patients, and I have heard what the distinguished panel of physicians have said. So I believe that should be modified, but if you ask people for better information, maybe next year when we come back, we will have something to make a better decision on.

I am particularly concerned about the lack of information on spinal cord stimulators. The information that we have gotten almost all afternoon has been on pacemakers and defibrillators, and some of the problems that you have uncovered are these spinal cord stimulators.

So I would like to suggest that you allocate a time for one of your scientists, Jon Casamento, to do some additional work in this area. I thought his presentation this morning has some of the best science that I have seen all day.

I think he might have some ideas for testing spinal cord stimulators, not in clinical studies, but in the laboratory, to gain some additional information.

I think the work that--you have heard from various people that they would like to work with FDA on some consensus standards, and maybe this committee has already done its job in bringing this issue as one to everyone's attention, and there will be perhaps more work done on consensus standards because I think there are no consensus

standards for the spinal cord stimulators. That has to be an area that you get to work on, so that you can prevent problems.

So I think FDA has done some excellent work and they are moving in the right direction. I would really like to express my thanks for bringing all of these experts to us today.

MR. SAVIC: Stan Savic.

I am concerned that we do not look at these particular devices out of the context of all of the possible interactions with the cardiac implant devices. Is the Center looking at it, or is there data on other sources of interference, I should call it, such as computer monitors, hair dryers, electric blankets, TV remote controls, in terms of relative incidence of some of these observations? Is there any type of a database such as the incidents that have been discussed in here, for example?

And I would just direct the Center to look at the entire issue of interference with those devices.

It is clear from an engineering standpoint that if you have different types of security devices operating at different frequencies and different physics, you will get different effects out of it. So far, it does not seem that as diverse as they may be, they appear to rise to the level of public health concern, and I think you kind of expressed

that, or at least you said not as serious public health concerns, but the only other comment that I would offer is I think earlier there was a comment on either labeling or putting notices in locations, something to the effect that says do not linger or pass through.

And I think a lot of the studies kind of focus that there are significant effects that you can see, even though they may not rise to the level of public health concern, that you see if you stay there for 2 seconds or more.

I am not sure that I would agree with the statement that if a given manufacturer were to put a sign on his devices or on the floor in between the two probes that it would say something, do not linger, just move through, for example, without any reference to cardiac implant devices; that there would be any adverse effect to either that manufacturer versus the stores that may be using another brand that does not have that.

But I would urge the industry through their association to look into the possibility of saying something to the effect, do not linger, do not stand here. It is as simple as that, perhaps.

I am not sure that it is necessary, but I would certainly encourage an industry look.

MR. FLETCHER: Jane?

MS. EHRGOTT: A couple of things. I would like to agree with Stan there. Many industry groups develop general labeling and warning statements for their entire industry and maybe that would be a good place to work on determining whether this is appropriate or not.

Second of all, the IEEE SCC 34 would welcome any activity to develop a performance standard for these units. So I would give you the name of one of the officers, and they are currently writing performance standards for cellular telephones. This would be one place where there might be an opportunity to develop standards for the U.S. in this area.

Now, the other thing is I have a question about CENELEC. Would the CENELEC, with the adoption of the current CENELEC standard or--I do not know if it is an existing standard that is being written--would that mitigate any of the issues that were raised today?

DR. JACOBSON: You would have to ask if anyone else at FDA can answer that one because I am not sure I can.

MS. EHRGOTT: Would the adoption of the CENELEC standard--I do not know whether it is a current or proposed standard--mitigate any of the issues that were raised today?

MR. BECKER: I am Jerry Becker. I will fill in for Jim Putzke who has left.

There is a CENELEC standard, EN50061, which

contains the EMI criteria for pacemakers, the implantable pacemakers.

This is a standard that has been adopted. It is in place and, being utilized in the European Community, has a guidance for low frequency EMI control for pacemakers.

If you look into the details of the field intensities that will be equivalent to that standard, unfortunately the standards that pertain to biological safety and these EMI standards do not mesh properly.

So, just complying with that standard does not preclude the type of interactions we are discussing.

DR. JACOBSON: Mitch just told me that that is one of the standards that has been proposed to us for review to see whether we would recognize it or not. We have not reviewed it yet.

MR. FLETCHER: Okay. Cass?

MS. KAUFMAN: Based on the information that we have heard today, and particularly of interest is the lack of clinical impact from what we have heard from the panelists of these incidents, I am not comfortable with requiring labeling or patient notification, although I really am very sensitive about the medical community taking a paternalistic approach to patients. I certainly understand the issue of unnecessary alarm as well.

But if I am one of these physicians and I deal

with these patients who have such implants and I am not even aware of even a potential issue, that I might even ask this question, I think it is information that I would want to know, and so I would suggest that we consider advising FDA to send a letter to these physicians, but a different letter than what has been drafted here.

For example, this letter says that these individuals may be adversely affected, and I would suggest that we tone that in a manner of saying we are just trying to gather information, not put it in the context of adverse effects, but we just want information, and just to advise them that we are just trying to gather information. And if their patients report such problems, that this, again, might be one of many questions that they would ask.

I do not think that we should suggest that they give particular recommendations to patients at this point in time. It just does not appear to me that we have enough evidence to go to that level at this point, but I agree with Jill that I think we do need a lot more information. It would seem to me the best way to get that is to at least have the physicians involved recognize that this might be a question that they would want to ask.

MR. FLETCHER: Dr. Marx, did you want to say something?

DR. MARX: Oh, I would concur with her opinion

that I think that some of these recommendations for patients are way too strong based on the evidence that we currently have, and I would also definitely think it is--you asked specifically about the issue of requesting alternate exits and entrances, and I think it is way, way early for something like that because that would be a huge big deal.

One thing I would add is that I think the issue of the nerve stimulation devices is potentially much larger than that of the pacemakers because you have--here, these are things that the patients definitely felt, and they were unpleasant. And it is a much smaller population of patients who have had these devices for a much shorter period of time. You have not had these devices implanted for 30 years. You have only had them implanted, I think, for less than 10, and I think that that is potentially an issue that needs to be addressed by these consensus research efforts between industry and the two different industries because, as a larger population of patients has these devices, they will be very unhappy.

DR. ZIPES: I consult for a company who does make those devices, though I do not have firsthand experience.

I would like to make two comments. Number one, the numbers of patients with those devices is very small. It may increase, but it is still pretty small.

Secondly, the adverse effect is minimal in the

sense that it is pain in the back. It is not like you are going to have a sinkable spell or ventricular fibrillation or one of these things. So I, as much as I can, would advise caution in moving too quickly in that area and try to get the data first.

MR. FLETCHER: Follow-up?

MR. THOMAS: Not really a follow-up, but I would like to just voice my support of what Joe and Mary said on the voluntary standards and the fact that I agree that we need more information.

The neurostimulators, I do not know enough about them to know whether that is a problem or not because nothing has been presented.

If we say we have a low end, we have a high, and in terms of NDRs, that is the highest number, and they are all either severe or moderate, but from what I am hearing from our physician experts, these are neurostimulators. It is like a pain in the back. I hate to say it that way, but I think that is what it sounds like.

So maybe it is not as much of a problem as what we might be thinking about, but what I would like to strongly encourage is some things that I have heard already started, and I do not want to see that drop into a black hole, specifically the continuing development of voluntary standards by the various professional organizations for both

the security system devices, as well as working in coordination, in conjunction with device manufacturers, the medical device manufacturers.

I think we all agree that we need more information, and I also think we all agree that we do not see this as a significant public risk, but it is an issue that probably should be looked at and not soaked underneath the table, and at the same time, we want to ensure that we do not cause public or physician alarm in this area.

It is one of those interesting scientific areas that I think probably needs further investigation, and that is what I would strongly recommend that we look at the science associated with this, as well as creation of voluntary versus required standards.

MR. FLETCHER: Bob?

DR. TUROCY: Bob Turocy.

I was wondering of the industry of the surveillance systems are currently using standards, and if they are, what are those standards?

Say, for example, UL or IEC standards, and that would be used in the design of the manufacture of the product.

DR. DAVIES: There are some standards such as the NCC95 1991, which is also a IEEE standard. There are CENELEC standards, two standards which relate to different

frequency ranges. Both of those standards are about the safety of electromagnetic fields, and we comply with those. And there are many standards at national level as well which are complied with.

DR. TUROCY: In addition to the product standard, how about quality system standard? Say, for example, an ISO 9001, if you are designing, do you produce it and service the device, or what the FDA uses in the medical device industry, it is known as the quality system regulation, or formerly the GNP. You have a quality system in place.

DR. DAVIES: Right. The company which I represent, Meadow, does not use ISO 9000, but I cannot comment on the other EAS manufacturers. Maybe there are some here today who can comment.

DR. TUROCY: What ISO standard do they use? 9001?

DR. DAVIES: They don't.

DR. TUROCY: They don't?

DR. DAVIES: No, they don't.

MR. FLETCHER: I think, hopefully, Dr. Jacobson, the comments the committee has made has given the FDA the direction that the committee would like to see.

I think all of us agree that at this point, the data that we have seen, the data that we have heard does not indicate a serious public health problem. However, there is some troubling information about, you know, certain

instances where there have been occurrences that need to be further investigated. And I know there is concern that there may be instances that we are just not aware of where problems have occurred, and perhaps they have been put in one category or another and not put in a report that could be focused upon.

So I do not know what more we can provide at this point except that this is an area that we would like to see further investigated and more data collected.

And I agree that as many volunteer standards that can be coordinated and agreed upon, it should be pursued.

Joel?

DR. ELDER: Elizabeth, based on that conversation or the information that we got from the medical community this afternoon, I wish to withdraw my comment about changing the title of that draft letter. That would be inappropriate.

[Laughter.]

MR. FLETCHER: Jane?

MS. EHRGOTT: I was just wondering. Do we have to vote on whether to release this letter or not, or you are just taking our suggestions?

MR. FLETCHER: I think in this case, we will just give guidance. We do not need to take a position.

DR. TUROCY: Bob Turocy again.

One thing I would like to say is that the industry that wishes to take a proactive step and word towards resolving any issues or coming to some conclusion deserves a pat on the back. So keep up the good work.

MR. SAVIC: From an industry member perspective, not so much as a suggestion for FDA or even a suggestion for the industry, let me just say that some of the representatives on the TEPRSSC over the years, myself included, and perhaps I might even speak for some of the others, have originally started, and some of us have started with the very first TEPRSSC committee.

And there is a great tendency to come before this body from a business concern of a manufacturer not wishing to either get his product appearing somewhat inferior in some of these issues than another manufacturer's product or someone's marketing department thinking that maybe they can get one step ahead of the competition.

In the end, after the first few exchanges, I think they all see that if there is a problem, it is an industry problem, ont a manufacturer-specific problem, and I would certainly encourage the industry to work together through ad hoc committees, industry associations. Perhaps there are competing industry associations. That is not a reason why they cannot form ad hoc groups to work out on the technical scientific issues and, in fact, maybe meet occasionally with

the Center staff and exchange and offer their information.

There is no advantage to one system over another, from my personal experience, no matter what the market share may have been at that time or no matter what the marketing people may have thought they could capitalize.

MR. FLETCHER: Anyone else?

DR. JACOBSON: Can I make just--

MR. FLETCHER: Yes, Dr. Jacobson.

DR. JACOBSON: I just wanted to say thank you to the committee. I know this has been a tough discussion, and we really appreciate the input you gave us.

You will be hearing more about the electromagnetic compatibility issues because this is a--sort of tackling compatibility issues is going to be sort of slow and steady work for the Center over a number of years. We had kind of a formal statement of that in the 1995 conference, but we are doing exactly what Mr. Savic said we should be doing, which is taking a look at the devices that we are responsible for, trying to prioritize those in terms of what might be affected by electromagnetic compatibility concerns, and making sure that we are raising the consciousness of the interested industries to deal with the problem.

And it has been--we are talking about this particular industry today, but the next hour or two, you are going to hear a whole different type of story, and I think

one that has different ramifications. It is really a success story, I think, but I would like to just underscore the fact that we would like the industries to take--to work together to solve this because it is--it presents tough engineering problems, and those things are really most amenable to cooperative efforts. And working on voluntary standards is one way to do that.

MR. FLETCHER: Thank you.

We will now go into our afternoon break, please. Be back by 3:05. I thank all presenters and all those who contributed to the discussion.

[Recess.]

MR. FLETCHER: This is the afternoon session. Please take your seats.

It is our last presentation. I do not think you can say too often thank you. So, for those committee members who are rotating off, once again, I extend to you my very heartfelt thanks, and the thanks, I am sure, of those within the Food and Drug Administration's CDRH whom you have assisted with your comments and whom I am sure will probably be in touch with you for other things over the next year.

I want to thank all of you, and just so I make sure that you do not get away before, everyone have a safe trip back to your destinations, and I look forward to seeing and hearing from you in the not-too-distant future. So,

once again, thank you to all of you.

Our next presenter is Don Witters, who will give us a presentation on medical telemetry systems.

**Medical Telemetry Systems**

MR. WITTERS: Thank you, Mr. Chairman.

I will make this relatively brief. I know that you have been in your meetings for a day and a half now, and everybody is--2 days, okay. Everybody is really probably anxious to get out.

I am Don Witters, leading the Center for Device and Radiological Health, Electromagnetic Compatibility Work Group, that is addressing issues that Dr. Jacobson spoke of involving many different devices, wheelchairs, infusion pumps, hearing aids, cardiac de-fibrillator and pacemakers, spinal cord stimulators, and other things.

[Slide.]

My purpose here today is really to inform you about the concerns that we have with electromagnetic inference with medical telemetry and what we have been doing in conjunction not only in the Center with the device manufacturers, but also with the Federal Communication Commission and other parties like the American Hospital Association.

Basically, I would like to leave you with this thought, that electromagnetic interference--I will refer to

it as EMI--most people do--with medical telemetry system is a continuing challenge requiring communication and cooperation. That is really where we are driving, and we are certainly getting cooperation throughout this.

I would refer you to Tab O of the handout notebook that you have, which does have our public health advisory on the issue of digital television interfering with medical telemetry, wireless medical telemetry.

There are also some other information that I can make available, if you would like. We have a letter that we send out to manufacturers. I will mention that in a minute. We also have been involved with the American Hospital Association, American Society for Health Care Engineers, who prepared and performed a survey of over 5,000 hospitals to try to get more information on this, and understand what was going on.

Basically, wireless telemetry can be vulnerable to signals and interference from various sources and this needs to be addressed, we are working towards solutions with many different parties involved in this.

[Slide.]

What I am going to cover today very briefly, what is telemetry, I will give you a brief understanding of what it is and the fact that the environment is changing.

Dr. Jacobson mentioned about the environment

changing. This is dramatic as we go forward with technology. It is changing ever-rapidly.

How many of you have cell phones? How many of you have cell phones that are digital in transmission? A few years ago, there were not any digital cell phones. Now they are proliferating and probably will take over the market.

Have you ever heard of digital TV, sometimes referred to as HDTC? This will take over, and according to the Federal Communication Commission, by 2006, the analog systems now on will be shut down, and this will take over. If you have ever seen it, it has dramatically improved.

They have it over at a local place, the Museum of Radio and Television News, the Newseum. It is dramatic.

There are real challenges for medical telemetry. What I am going to go over are two specific cases, very particular, that we have been working on.

One, that we already know there have been incidents involving EMI-2 telemetry from digital television broadcast. Two, the challenges, which are future, but we can see them on the horizon as the manufacturers and the Federal Communication can, in those telemetries operating in the mobile radio services bands. There are different bands where these can operate. Those are the two primary ones.

Also, I will discuss what we are doing to meet these challenges because there are a number of things that

are done and can be done in the long term, as well as the short term.

[Slide.]

Let me begin by giving you a real quick overview of wireless medical telemetry. It is essentially a system with the patient at one end, a wireless signal, radio signal sent to a central station being monitored and viewed by a nurse physician or whatever clinician is over there to monitor that patient.

You have in the case of cardiac monitors basically a little box that is connected to electrodes that the patient is monitoring cardiac respiration, other physiological measures being sent back to the central station.

This is sent on basically, primarily two different frequency bands, one being vacant television channel bands, the other one being the mobile radio service bands.

There was a survey that was performed very recently after the incident in March with digital TV by the American Hospital Association, American Society of Health Care Engineers, primarily by Dr. Joseph McLean, down at the Walter Reed Army Medical Center, who was here this morning, but unfortunately had to leave, of 6,000 or so hospitals throughout the country.

In that survey--I have some copies here, and I am

sure Joe would be willing to share them if you would like--it turns out that about 61 percent are operating in that mobile radio service band, and about 39 percent in the television bands. There are other bands.

However, one must understand with telemetry that the signal and the telemetry is viewed relatively unofficially by the licensing regulators, the FCC in particular, and is resigned to what is called secondary unlicensed user.

These users have to accept interference, but cannot cause it to the primary licensed user, and therein lies part of the concern. We think that in general, medical telemetry is a very critical type of use of the airwaves and needs to be raised to a higher level than that.

[Slide.]

To give you an idea of where we are talking about, this is the radio frequency spectrum, just very quickly, a few things here. The television bands are in this area, in the megahertz region. The mobile radio service would be just below the UHF channel, and to give you an idea that the spectrum is crowded and will increasingly become more crowded, you have FM radios, cellular telephones, emergency broadcasts, fire, police, that sort of thing, AM radios, microwave ovens, radars. There is an increasing use of the spectrum.

[Slide.]

I am going to talk first about the digital TV and what has occurred there because this is an actual occurrence. This is not an academic exercise for us.

In Dallas, Texas, in March, the digital television began to broadcast on a previously vacant channel. Medical telemetry has been allowed by FCC to be utilized--vacant channels in their geographical area, and to date, that has worked relatively well because vacant channels exist throughout the country.

Now, with the advent of digital television, they are using these previously vacant TV channels. The broadcasters in this case--and nobody is pointing fingers--were doing what they were told they could do, which is broadcast in these channels that the FCC allowed them to do.

The clinicians were using that unused channel that they have used for many years, according to what the FCC said. There was a little bit of a miscommunication.

Unfortunately, in the case of this incident, it did overwhelm at least 50 beds of telemetry, perhaps even more, at Baylor Medical Center and Methodist Hospital down in Dallas, Texas, when this digital signal became active, and it was only a test. This was a low-power test that they are allowed to do.

They were not aware that there was medical telemetry operating in this channel that was previously unused.

The medical telemetry and clinicians were not aware that this test was going to happen, and consequently, when this did happen, the patients were left where they needed to have some sort of telemetry, but this took down those people systems. They did not take them all down because there are different channels in different places, but a number of these, it did take down.

It overwhelmed--the wireless system was no longer functioning for those particular patients. The first priority is obviously to the patients. They got them back on wired systems.

Secondly, because they are experienced and very knowledgeable at Baylor--we had spoke with these gentlemen several times--they were able to track this down and find out there is a problem. Somebody is using this channel to broadcast where it had been vacant for years.

They called the television station and asked them if they were, indeed, broadcasting, and they were, and asked them if they could cease, and they did.

The hospitals were left in a predicament. They needed that telemetry, but they also knew that that channel was no longer available, and they had to do something.

There are two things that really they did. First, at Baylor, where they spotted this, they were already in the process of purchasing new equipment that would work elsewhere in frequency. That would speed it along in working with the manufacturer who recognized the need, immediate need. It was not cheap. It was over $200,000 for that system.

Secondly, at the other hospital, they re-crystalled. You may be familiar with the crystal tuning that is in the scanners, for example. It is the same sort of thing. Some of the older technologies, you actually have to physically change these crystals in order to change where they are operating at. That was done. That was, again, not exactly cheap, close to $30,000.

We think this really at the moment, because of what has been done and the fact that it was recognized and dealt with, which I will speak to in a second, as really a success, as Dr. Jacobson said, and probably has solved this at least for the moment by coordinating and communicating.

When I speak about that, I mean the public health advisory that you have. That is what we did to advise the hospitals and the clinicians about this. The manufacturers, of course, were aware of this.

There was also a letter sent to the manufacturers asking them and making recommendations that they include

more information about telemetry, where it operates, because part of the concern that we had is the hospitals might not necessarily have that information with them. The manufacturers in many cases set this up, and then they are responsible for maintaining it. In some cases, third parties maintain it.

We also were in direct contact in coordinating efforts with the FCC on this. The FCC immediately recognized the potential for problems and contacted the broadcasters, the National Association of Broadcasters, who very quickly got out the word to broadcasters that they needed to contact the users of telemetry in this area, in their areas, and they also provided public information which we in some cases helped them develop, which is on their web site. If you would like to look at it, I do have their web site information right here. It talks specifically to this issue.

They also had to provide some information about where these digital television broadcasts would be in local areas, which channels would then be used in the next few months and the next few years. That is located there, too.

One of the other things that FCC has done to address this is make this issue very important in licensing to the broadcasters.

Now the broadcasters are required to notify the

local hospitals and health care facilities about this information and make a very good effort to contact the local hospitals that might be using this, so that they have some real way of getting that information out and making the message heard.

So that is what has been going on with digital television. It may not go away because--I will speak to that in a minute, but in general, just because you know about the digital television broadcast or other television broadcast, broadcasters are coming online all the time, and new technology is always coming into focus.

[Slide.]

One of the other areas is the mobile radio service telemetry. This is a different band that these are working on. It is actually 450 to 470 megahertz, under the UHF TV band.

The FCC had proposed some changes. Digital technology is here. It allows you to do more with less spectrum. So you, therefore, could have more users.

Your typical digital cellular telephone, for example, you may have six or eight conversations on a single frequency because they are able to multiplex this together, as opposed to the old analog system where you had one conversation, one frequency. As you can see, that lets you use more frequency, much more efficiently.

The FCC does that. That is one of their primary goals, and, of course, technology has changed so that many other users can now use this technology.

As I mentioned, we found out after the digital television that 61 percent of the wireless telemetry is in this area. However, once it was clear that t here was a concern with telemetry, the FCC put on hold their proposal for changing this band, specifically because of the medical telemetry concerns, and it is on hold now.

I spoke to the FCC gentleman in the wireless bureau last night about that, adn it is on hold until we get some handle on this.

These efforts are being coordinated right now with FCC. We are also working with the American Hospital Association, AHA, who have stepped forward and said we need to get a handle on this, we need to really step forward and take charge, and they are doing that.

They just met last week with parties involved, manufacturers, users, the FCC, the National Association of Broadcasters, to really come up with some way that they could propose to get us from where we are now, where there is concern, to where there might be a separate spectrum for the medical telemetry, raising them to a higher level where they would not be interfered with. And hopefully, the problem would go away in that sense, but it will take a good

bit of effort to get there.

[Slide.]

There are continuing challenges with wireless telemetry. As I said, the environment is changing. Digital television, digital radio broadcast, digital cellular phones are coming. There is increased competition for spectrum. Everybody wants a part of it, and they are selling this, if you haven't seen, on auction and some of the money they are raising are very large numbers. Congress has mandated that, only in certain sections.

We believe that there will also be at the same time an increasing use of telemetry in not only things like cardiac monitoring, but many other areas, in such an array that this probably will increase to a place where patients may even be going home with telemetry so that they are monitored continuously.

Our concern and the concerns of the Hospital Association and clinicians is that this be clear of interference, even small amounts or short-duration interference, if it is in a critical time or critical patient, can be very serious concerns.

[Slide.]

So what is being done to meet these challenges? In the short time, it really boils down to communication and cooperation because it does take time to decide where to put

the medical telemetry, and it takes time to design and build and then sell and then get into any significant portion those kinds of devices.

Also, the industry is involved. The wireless industries, mobile radio and the people who use it, are really again not in communication in general with the medical device industry. We need to get that crossed, and the AHA has certainly promoted that.

Regulators such as FCC and FDA play a part in this obviously, and there are ways that I will speak to in a minute about how we might be able to make that a little bit better.

Information about this like the public health advisory certainly get this out, certainly make it available to the hospitals, the doctors, the patients, the manufacturers, so that people know about this, and believe me, this was very fast. Within a few weeks, these notices were out. FCC had the broadcasters listening, and it was heard very loudly and very clearly.

In the long term, we are still looking at a number of things. Separate frequency, raising telemetry to its own channel, its own standing, will go a long way, we believe, and it is time to come to do that, so that all manufacturers and users know that if you operate in those bands, that is telemetry and nothing else.

Regulation options include the quality systems regulations for continued improvement. The state-of-the-art is being pushed. There is a lot of things that can be done to optimize the technology.

Again, most of these telemetry systems have been around for many years. They are using older technologies that require wider bandwidths, more signal in a larger space. That needs to be improved, optimized. Perhaps digital technologies like the cell phone or other technologies that transmit information from one place to another needs to be improved.

And also risk assessments probably play a part in this by the manufacturers, by the clinicians, what are really the risks and seriously approach those in a way that will help solve this.

[Slide.]

Now, I mentioned the FCC web site. So I am going to put a plug in for ours, of course. We have a web site under the Center web site where we have information on electromagnetic compatibility. On this web site, we also have links to the public health advisory and other sources of information, especially about wireless electromagnetic compatibility.

[Slide.]

I would like to finish by leaving you with the

thought that I mentioned at the beginning. I think, and we think, this issue will continue to challenge wireless telemetry well into the future, but there are ways we have been pursuing. We think these will be effective communication information, improvements, and optimization, separate frequencies, working together really towards a common goal of minimizing the risk to the patient from this particular issue.

Thank you.

MR. FLETCHER: Thank you.

I am going to take off my chairman's hat for a minute.

Have law enforcement agencies also been brought into the discussion? Because there are devices that they use for home detention that work off wireless system.

MR. WITTERS: That particular aspect, we have not explored, but there are those. They are probably in different bands. They could be secondary users. I just cannot speak to that, really.

But I can tell you that in terms of the emergency vehicle transmission, they have their own channels. Medical telemetry, for whatever reason, does not at this time, but we think--and FCC appears to agree--that their time has come, and they are looking at ways to give them spectrum.

Yes.

MR. FLETCHER: Dr. Cardella?

DR. CARDELLA: I have two questions. Does the FCC have jurisdiction over secondary users? In other words, do they know about telemetry in a given unit occupying a certain portion of the radio frequency spectrum?

MR. WITTERS: Well, what you are asking is a couple of different things.

First off, they are well aware of the manufacturers of telemetry, and although I did not mention it, I meant to--they did send a letter out to medical telemetry manufacturers after the digital TV issue and did directly ask them to make some effort to address this.

There is coordination with the FCC on this issue. The FCC does not have jurisdiction over the entire spectrum. There is another Government agency that does deal with things such as users, such as the military and other Government-protected bands, but it is increasingly competitive in the bands that FCC has. They have tremendous pressures on them and tremendous things put on by various parties.

DR. CARDELLA: And my second question was the establishment of a digital TV station that is new in an area, how big of an area does their antenna black out or invalidate for telemetry use? What is their range?

MR. WITTERS: It depends on the power.

The digital TV signals will be approximately the same power and area of the analog televisions.

Now, you can have up to a megawatt, about a million watts, and go out 50 or more miles, maybe 100, and depending on the atmospherics, even more than that. So there are areas, wide areas, particularly in urban areas where it is more crowded, and this may be more acute.

Part of what we have talked with the American Hospital Association is to come up with a better handle so that FCC understands from the medical telemetry end what the requirements are, and part of what they have sent to the FCC in answer to that general inquiry, what are your needs, included such things as how many channels do you think you need.

Some of the clinical engineers that were in these meetings and we talked to indicated that they are now using as many as 20 leads right now on some patients, typically a lot less, but 20, and the range that they are using can go anywhere from bedside to down the hall or 200 yards or so, but in the future, this may change. It may go miles.

Obviously, you want to protect that if you can, and there are ways to do that.

MR. WILSON: Dennis Wilson.

I guess my question would be, if by 2006, which is essentially about 7 years from now, they will have

completely taken over the television business, can't we move fast enough on the telemetry side to respond to that?

MR. WITTERS: Well, in the telemetry, as I said, this really is more of a success. We already know, and the FCC has made it clear, where the new channels will be. That is on their web site.

So a user, a clinical or hospital facility, can certainly look that up and say am I using telemetry in that area right now and make a change. They have time for the most part.

Also, from the other end, the broadcasters have to make a good-faith effort, and many of them are making a very good-faith effort to contact local hospitals, clinical facilities, even nursing homes that might be using this, to make them aware that we are going on broadcast on this channel, it was previously not use, if you have anything in there, you need to make arrangements to move it to a different frequency.

MR. SAVIC: Stan Savic.

I just can't help but make a few comments as the representative who works for a company that is not involved in manufacturer or broadcast of digital TV signals, but basically the company that got an Emmy Award for investing digital TV systems, meaning getting the most patents out of it, and the company that had the first digital TV

transmission from Milwaukee to Chicago successfully demonstrated to all the FCC officials and so on.

You are all familiar with the TV channel numbers, 2, 3, 4, 5, and then 56, 57, 58, 59, and yet, in every area where you receive your channels over the air, you only have channels and then some blank channels. So you go like from 2 to 5 to 7 to 9 and 11 and so on.

The channels that are not used in your area are what FCC calls taboo channels, and the reason for making a taboo out of using them is because they will interfere with each other and your picture will look lousy.

Digital TV has eliminated the need for blanking out taboo channels because with digital signals, you do not have to worry about interference. There are algorithms that decipher the picture.

So, in effect, digital TV has made possible use of every single channel number. Now, over the years, in cities where these stations have been well established, it was clear to users of other services that maybe they could do something on that frequency, as long as there is on TV broadcast there. So that is how some of these systems involve, and yes, every manufacturer of telemetry devices would have to file with FCC at some point in time, tell them that they are going to broadcast the signal on that frequency.

So FCC does know about it, but that has been going on over such a long period of time that I think, for all practical purposes, we have to assume that they do not know who is on what frequency where. So certainly the approach that the broadcasters would take, either through public notices or just scanning and contacting all hospitals, would be a good one.

In the process of implementing this new digital TV, high-definition TV, FCC is taking all channels, I believe, from Channel 54 and up and reassigning them, or making them available for reassignment for other uses which means that Channels 54 through 83 are basically to be given back to probably for some use.

MR. WITTERS: It is actually Channels 60 through 69 that will open up, and they had been told by Congress that four of those TV channels must go to public service type of uses.

MR. SAVIC: I was just going to suggest that you should certainly lobby for your--

MR. WITTERS: Part of what I did not have a chance--but I did not have all the time to do all the details, but we certainly have. We certainly have made the case that maybe that should be a good use for this.

You are absolutely right. Digital TV is not the bad guy. It is simply a new technology that allows more use

of the same spectrum.

Right now analog does have to be apart by one channel. Digital will allow it to be put in next to each other. High-definition is definitely the way of the future, and it will open because it will basically move down most of the channels into lower and lower channel numbers, so that some of these channels will be open.

There are some channels that are definitely taboo. One channel, in particular, because it is close to radiostronomy, is a potential because radiostronomy has to have this particular part of the spectrum. They kept it open, but we think that maybe that is a candidate because typically medical telemetry is a lower power type of system that probably would not interfere with something in Puerto Rico or in Arizona or in some of those bigger, more sensitive systems.

So there are ways that we have been working in alternatives to address that, and FCC has made it clear, just the other day, that they were very willing to work with us and find solutions for this.

DR. ELDER: When I first heard about the incident in Texas, I was a little bit concerned about it, and I guess my level of concern rose when I heard it was just a test of the digital TV signal.

I think FDA is very right to consider this a

success story, and I would just like to compliment them on a timely and appropriate response with this public health advisory on that issue.

MR. WITTERS: It took a lot of work and a lot of coordination with FCC. We made them aware of this. We allowed them to help us evolve this. Plus, we were helping them, and it was something that we both saw needed to be done very quickly and it was a lot of work on a lot of part--both of our agencies.

DR. LIPOTI: Separating for a moment the medium from the message, I think you did a good job with the medium, and that you are dealing--you acted as a convener. You brought together all of the interested parties and they are working out a solution in a cooperative manner, and that is great, but the message is the problem.

You see, medical telemetry is monitoring somebody's biological function, and TV is TV. I have a 4-year-old and an 11-year-old, and I know about TV. And it seems to me that the effort that you had placed on raising the medical telemetry to being a primary user rather than a secondary user is where you really need to place your effort because it is essential that somebody be monitored, but it is not so essential that we watch Scooby Doo.

MR. WITTERS: Well, the broadcasters would perhaps disagree.

That is absolutely correct. For a long time, we have been concerned with this. Dr. Jacobson sent a letter 2 or 3 years ago to the FCC asking them to consider this. So we have been working quite a while, and they are right now, in fact, looking at a candidate broadcast bands, frequencies to put this in. They have agreed that we, between us, or anybody else do not want to see patients harmed or, in the worst case, somebody die because of that sort of thing. No.

DR. LIPOTI: Just as a follow-up, I want to comment on the equity issue. It cost Baylor College Hospital $200,000 to revamp their system.

MR. WITTERS: A bit more than that, yes.

DR. LIPOTI: $30,000 for them to re-crystal.

MR. WITTERS: The other hospital, yes.

DR. LIPOTI: And they are bearing the cost of this problem. Whereas, the folks doing digital TV are making a lot of money off of these commercials.

So, to the extent that they could subsidize the transfer in the benefit of public safety, I think it would be a benefit for all of us.

MR. WITTERS: I cannot speak to the cost issue. That is a real tricky business. There is a lot of very formidable-type people on both sides of that, but I think the key to recognizing and keep our eyes on is the fact that the Federal Communication and the broadcasters are coming to

the table and offering real solutions that look very workable to us, and the manufacturers of medical telemetry and we are coming there and saying yes, we need to get there, and this is how we can do it.

MR. FLETCHER: I notice that there is someone from the audience who wishes to address the panel. Procedurally, we will continue panel discussions until such time as those are exhausted. I would ask, however, that if you are representing the industry, please identify yourself at the time you come to the mike.

MR. WITTERS: This is Mr. Julius Knapp, who we have been working with from the FCC.

MR. SAVIC: For Jill's benefit, mostly let me just say that digital TV is not just TV, and it is not about TV. Digital TV brings into an ability to use a huge part of the spectrum which could not be used at the present time. So that is the biggest advantage, and then in doing so, there are all kinds of new services contemplated. So it is not just picture entertainment broadcast.

You will see TV broadcasters competing with telephone companies and vice versa and so on. It is a whole new level of technology, and it--for example, one channel can broadcast six channels of digital television. So you could have six movies that you do not want to watch. That is the advantage of the change from going to digital from

analog. So you will be swamped, I am sure, with channels, but it is a lot more than just television picture.

MR. KNAPP: Thank you. Good afternoon. My name is Julius Knapp. I am with the Federal Communications Commission, the Office of Engineering and Technology.

I was tempted to intervene sooner with some of the questions, but Don and everyone else was doing such a great job answering them that I was just thrilled because I think they have been far more attentive to what has been going on at the FCC. If you were to ask me about the FDA regulations, I would not do as well.

Just a couple of comments that I wanted to pass along. First of all, the FCC does take very seriously any risk of interference to medical telemetry devices. There are a few flavors of that, as you probably know. Some of the medical telemetry devices have been operating in TV spectrum.

When the problem came to our attention, we worked closely together. It looks like through coordination, the interference can be avoided.

The Commission has advised all of the broadcasters that as a condition of their licenses, they have to coordinate with their local health care communities. So we are trying to take every possible step that we can to make sure that digital television's implementation does not cause

interference to medical telemetry devices.

Some of the devices are operating in the spectrum that is used by land mobile equipment, the business radio services, taxi, fire, police, and so forth. That is spectrum that because of the growth in the radio communications field has become very congested, and the Commission has tried to accommodate more channels by basically dividing the existing ones.

Now, this creates a potential for interference for the medical telemetry devices that are in that spectrum. We have frozen any assignments under the new plan, and we are trying to work on a solution where we can still allow the new land mobile stations to go forward, at least in parts of the spectrum, either through coordination or avoidance of the channels that are being used by medical telemetry.

It is a complicated problem, but we won't go forward until we are sure that everybody has been consulted and that we are confident that this can work and we will not cause interference to the medical telemetry devices.

Lastly, the Commission recognizes that there is a need for a long-term spectrum home for medical telemetry devices, and we want to move forward as quickly as we can.

There was, I thought, a very constructive meeting last week with all sectors of the industry looking at new spectrum for medical telemetry devices. From the

Commission's point of view, we would like to have that moved forward as quickly as possible, and we are very committed to doing that.

So I just wanted to make a few comments to let you know that the Commission does take this all very seriously. We are devoting efforts on our side to make sure that interference does not occur and that there are long-term solutions.

Thank you.

MR. FLETCHER: Thank you.

Are there any further comments or questions from the committee?

[No response.]

MR. FLETCHER: Once again, I want to thank all the members of the committee. I want to thank Dr. Suleiman, Dr. Kaczmarek, Dr. Jacobson, and all the members of the FDA staff, and all of those presenters who, one, brought us a great deal of information to consider and talk about and give recommendations on, and, two, adhere very well to the time table that was very tight.

I appreciate the opportunity to have chaired this meeting, and I wish God's speed to all of those who have to travel. May you reach your destinations safely. I am sure we will be communicating in the future.

I do not know if we have any indication as to

where. So I will ask Dr. Suleiman if he wants to say anything.

DR. SULEIMAN: I have enjoyed staying next to Roland and saying nothing. I think he has done a real good job, and we got through what was an extremely difficult agenda. I want to thank Roland again especially.

I think the FDA staff who participated during both days did a really good job from my opinion, and I think the advisory committee members all contributed, I think, in a veyr important and diverse way.

So I want to really make sure you understand how much I appreciate it and I think the agency appreciates it, and I think we are even ahead of schedule.

MR. FLETCHER: So, without further ado, I am going to use my crab mallet and adjourn this meeting.

[Applause.]

[Whereupon, at 3:45 p.m., the meeting was adjourned.]

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# *CERTIFICATE*

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.

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