UNITED STATES OF AMERICA

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FOOD AND DRUG ADMINISTRATION

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CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

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PUBLIC MEETING ON UNIQUE DEVICE IDENTIFICATION

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WEDNESDAY,

OCTOBER 25, 2006

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The meeting came to order at 9:00 a.m. in Salon D of the Grand Ballroom of the Gaithersburg Marriott, 9751 Washingtonian Blvd, Gaithersburg, Maryland, DR. LARRY KESSLER, Director of the Office of Science and Engineering Laboratories, presiding.

I-N-D-E-X

I-N-D-E-X (Continued)

P-R-O-C-E-E-D-I-N-G-S

(9:04 a.m.)

MODERATOR KESSLER: Good morning. My name is Larry Kessler. I am from the Food and Drug Administration. And I am pleased to present to you our first presenter, Deputy Commissioner of the FDA, Dr. Janet Woodcock.

DR. WOODCOCK: Thank you, Larry.

WELCOME

DR. WOODCOCK: And good morning, everyone. I would like to thank you all for coming to this important meeting. I think the topic that will be discussed today has very important implications for public health.

The FDA and the Secretary of HHS, Secretary Levitt, really strongly support the development of unique identifiers for medical products. For the FDA, this has to do with the use and, of course, recalls, tracking, identification of adverse events, and so forth. And for the Secretary, I think for his larger vision of the electronic health record and the information within that record pertaining to individual patients, something that he is very committed to.

As you know, we started this effort with

medical products in the drug and biologics area. That has had an NDC code for a long time. That code has a number of deficiencies in the modern world. And we have been going through a long series of discussions about how that can be addressed. And that will be addressed to some extent in a proposed rule that FDA will be issuing on drug registration and listing.

However, a number of years ago, we also issued a rule on bar coding of drugs and biologics that was able to use that NDC code to identify those products in the hospitals and so forth with bar code readers.

And the rationale for this was more or less backed up by reports that had been issued by the Institute of Medicine and others on medical errors, particularly in hospitals, in dispensing and handling drugs and giving the wrong drug to the wrong patient at the wrong time and so forth. And it was felt that use of this bar code system combined with the unique identifier, the NDC, could help stem the tide of medication errors that are pretty well-documented in the United States.

Now, we don't have the same kind of database on device errors, but that does not mean we shouldn't be working on this issue. I think it's

extremely important.

Our ability at FDA to conduct effective post-market surveillance is hindered by the lack of specific device identification in many adverse event reports.

For example, in one area of infusion pump MDRs, we found that half the reports lacked specific identifying information that would be needed to make trend analysis. And this, of course, is of great importance to each manufacturer.

Now, we recognize, however, the complexity in the diversity of the medical device industry and that one solution will really not fit the entire industry. And that's why the center I think has convened this workshop. They really need input. We need to understand the range of issues that are faced in doing this and the range of potential solutions and approaches to the problem.

We're also very sensitive at FDA and have been for a number of years to the need to harmonize internationally. The device industry, like all the other medical product industries, is a global industry. And we cannot have simply U.S.-centric approaches and solutions anymore. And we fully recognize this.

We're early in the process here. We are really seeking input on what the issues are approaching this and what potential solutions might be. And we are very open I think to entertaining a range of approaches and having a dialogue with all the stakeholders.

In addition to the adverse event reporting, we have to recognize that at some point as the dream of electronic health records becomes a reality, there will be an expectation that we will be able to record device information within those electronic health records.

And, as I said, this is important to Secretary Levitt, but in his January 2004 State of the Union address, President Bush highlighted the importance of IT in health care. He said that computerizing health records will allow us to avoid dangerous medical mistakes, reduce costs, and improve care. And we will need to have computer-readable identification for medical products as part of the electronic health record. There is simply no doubt about that.

We feel that unique device identifiers also can help in business areas and inventory control and everything. We have talked to some of the large

health care organizations. This can improve delivery in the supply chain efficiency. These are important issues for CMS as well as for the VA and for the Department of Defense, who have made emergency preparedness as well as battlefield readiness arguments for having unique device identifiers so they know exactly what they have on hand and they can verify their inventory and trace it down the supply chain.

So, most importantly, I think, we share the same customers. The industry and FDA share a customer base, which is the health professionals; the physicians; and nurses; the operating room technicians; and so forth; and, most importantly, the patients.

And, as we look forward over the next ten years, as the electronic health record and automation actually begin to take hold and improve the health care system and be widely adopted, our customers will be expecting that we have ready for that unique identifiers for medical products that allow them to be part of the electronic health record and the interchange of that information. I can tell you that is going to be an absolute expectation of the customer base.

So, between us, we have to forge a solution that works for everyone so that we are record for the next phase of health care, which I think will do a tremendous amount to bring quality and uniformity and lower the costs of care to the entire public of the United States.

So this is an important meeting because this is the beginning of a journey to get those unique identifiers for the devices. And, as I said, we're still working on the biologicals and the drugs to get that unique identifier up to where it needs to be, but we hope by the time that e-health record is widely used, interchangeable, we, the industry and the FDA, will have been prepared and medical products will be ready for that future.

Thank you very much. And good luck today.

MODERATOR KESSLER: Thank you, Janet, appreciate it.

INTRODUCTION AND FORMAT FOR THE MEETING

MODERATOR KESSLER: So I am going to do the obligatory logistics stuff to make sure that we all know how the meeting is going to run. And then I'll make a few opening comments before we begin the first panel.

So simple logistics. Restrooms are down

the hall. We have breakfast. There's coffee out there, et cetera. If you did not register for the meeting, if you just came in, we would appreciate at the first break please make sure you sign in so we have an accurate record of who has been here.

We are making a transcript of the presentations for the next couple of days. So when you interact from the floor, we would like you to go to the microphone. Please clearly identify yourself and speak into the microphone so we can make an appropriate transcript.

Let's see. Cell phones off, please, or put them on vibrate or something silent. The panel sessions. Our plan is to have four panel sessions today. Each one roughly will go about an hour and 15 minutes. We're going to have an opening presentation of roughly five minutes or so. And then each of the panelists will interact. So that should be about 40 minutes, giving you and the audience around a half an hour to give us some feedback.

And the purpose of the structure of this is to promote a real dialogue here. I know it's a large room and sometimes you're uncomfortable getting up, but we really hope that the people in the audience will ask questions of the panelists and will interact

with us as best as possible.

The purpose of the meeting today is to have open dialogue about what we feel is an important and very challenging set of issues that we face trying to come to grips with whether or how to have unique device identifiers on medical products.

So now a few opening comments from my perspective. As Dr. Woodcock said, the reason we are here has to do with our customers, our stakeholders, patients, and providers. And we had representatives certainly of the providers here as well.

We are here primarily to promote and protect public health. That's what we think our job is. I know most of my colleagues in the manufacturing industry feel the same way.

We also are trying to work with our foreign regulatory partners in this. We have a representative here from Health Canada, who I hope will get up and say a few things because they have been struggling with some of the same issues. And we are going to bring this issue up, as we have once before. We'll bring it up again this year in the steering committee of the global harmonization task force the end of November. So this is not just a U.S. issue. We believe it's a worldwide issue.

That's why we're here in general. Why we're here specifically, as I said, is to have open dialogue. We're here to listen. Those of us from the FDA, in particular, are trying to figure out whether and how to develop a regulatory strategy that makes sense to us, makes sense to the industry, and ultimately is a positive benefit to patients and health care providers. And that's what we aim for today. So the object today is an open dialogue about those topics.

The first panel is going to concentrate on the essential questions of the costs and benefits of such a system. At some level, if we pursue a regulatory solution to this, we will be asked to make sure that the benefits are commensurate with or outweigh the costs. And getting a handle on both the benefit and the cost side has proven challenging for us over the past year as we have worked with a number of our colleagues, our contractors, with others of our partners in the federal system, and in talking to industry. It's been very difficult to get an accurate estimate of that. So that's going to be the first part of this.

After the first panel, we're going to assume in a sense that we're going to move forward.

And the remaining three panels will be about different parts of how to implement such a system if we go forward. So the first panel is really about the #whether#, the costs and the benefits. And the second, third, and fourth panels are really about mechanistic issues.

We're hoping to get out of here by 4:30 today. We may finish a little earlier, depending on the debate. There's a lunch break scheduled. And, Jay, can you tell me about the lunch break?

MR. CROWLEY: Lunch is on your own.

MODERATOR KESSLER: It's on your own.

MR. CROWLEY: There are plenty of restaurants around here.

MODERATOR KESSLER: You can eat in the hotel. And then you can walk down toward the REO, anywhere. And then there are a dozen different restaurants. You can ask recommendations if you'd like.

Anything else logistically on this?

MR. CROWLEY: No.

MODERATOR KESSLER: Thank you.

It's my pleasure to introduce John Eyraud from ERG, Eastern Research Group, to make the first presentation. John?

THE BENEFITS AND COSTS OF A UDI SYSTEM

PANEL DISCUSSION

MR. EYRAUD: Hello, everyone. I am John Eyraud with the Eastern Research Group. We're an FDA contractor. And we have been doing some work for the agency over the last couple of years in various pieces to look at aspects of the UDI question on the health care sector.

A start on definitions. And one thing I would like to emphasize about our report, we're providing some information here and even some very preliminary cost numbers. The numbers are changing as we speak. And by the time our report hits the Internet or it's released by the agency, numbers will have changed, which is an aspect of our work. We are providing some information here. And I hope you just understand the context in which it is offered.

A start on a couple of definitions and our sense of what it is we should be looking at. We're looking at a UDI as a serial number or another kind of identifier on a medical device or simply a lot number when that is sufficient, hopefully something electronically readable.

Our understanding is that it might not be necessary to serialize everything as we look at this

question. In general as I go forward, the concepts that I am talking about represent our take on things and don't represent an official FDA idea or perspective on things. And I'll explain that further as we go.

We have tended to focus on the incremental costs in looking at the medical device industry for the lowest level of existing labeling. We haven't examined all of the supply chain implications and some of the other kinds of labeling that might also be affected.

And in our conversations with industry thus far, there are some consistency issues. And I think that we have not always held exactly the same assumptions as industry in our discussions. And we are still trying to work some of that out.

Again, we have tried to kind of anticipate if FDA were to make guidelines or recommendations or regulations in this area, how they might approach the topic. So we're not representing any official policy.

But we have looked at -- let's see. Where am I here? We have looked at a couple of things here. The goals for patient safety benefits, first of all, three main areas: better identification of the devices implicated in adverse events. This would be

extremely valuable to the agency and help the agency better sort out what some of the problems have been in the field.

Also, an area would be more rapid and more accurate recalls, hospitals would be able to identify, locate devices more quickly and remove them from service as might be appropriate.

The last topic, enhanced capability for post-market surveillance, this would be an area of enormous benefit in research and in evaluation of device operations. But it is hampered at present by so much difficulty in identifying and comparing some of the models of medical devices that are used.

Okay. Now, in order to achieve some of these benefits, the UDI would have to be coupled with some changes and enhancements in information technology in the hospital sector.

The UDI hopefully, though, would if medical devices were identified with unique identifiers facilitate a lot of development of hospital IT systems, facilitate hospital capture of the devices ID as they are coming into the facility and any other locator systems they might employ, facilitate ID of specific model information that might be useful in the health care system and, again,

comparisons of effectiveness of medical devices.

Now, we took a really quick cut at recall savings that might be applicable in the hospital. We have a few data points on this which we have extrapolated somewhat aggressively and considered the possibility that fully functioning UDI capability in the hospital might allow the hospitals to save as much as half of the time that they spend executing a recall when it occurs and made a number of other assumptions about the share of recalls that hospitals have to react to and what have you.

And in looking at that, we generated an estimate of about $35 million in savings, again a very preliminary figure. And those assumptions going into that are subject to change but, you know, kind of a nice number as to what some of the possible enhancements and savings could be there. It certainly is a difficult area for a lot of hospitals to execute the recalls as efficiently as they would like.

Again, the hospital infrastructure development we're looking at the need to capture the UDI in the incoming devices, ideally capture the device information as the devices are used in patient care. Hopefully this would feed into an electronic health record and would help care-givers know who was

treated with which devices for those episodes where there is some problem and need to go back and re-evaluate some aspects of the care.

Most aggressively, a UDI could even be used to facilitate the locator systems in the hospitals and even for some devices possibly internal GPS systems to locate devices, you know, as might be necessary or might be helpful for various purposes. A lot of time is simply spent locating devices to use on patients in the hospital.

Okay. Looking at in a basic sense some of the hospital costs to implement some of the UDI requirements, we have made some preliminary cuts at what this means in order to have the hospital get the data from devices, get the UDI numbers into the electronic health records. And it would take a fair amount of investment in scanning systems. Additional wiring of the hospital to capture electronic information would probably be incurred, substantial training for staff. Initial cut at some of those costs comes to a first year investment cost of 1.4 billion.

Now, a lot of this is a complicated issue because we're looking at -- hospitals are making a lot of other investments, like bedside bar coding of

medications.

And in some ways, some of the UDI technologies could piggyback on those technologies as they're used in the hospital. But UDI would require certainly some additional investments in a lot of the same areas and additional implementation of probably personal digital assistants and scanners for doctors and medical staff.

Okay. We have pulled from the literature some of the other costs just for some very crude comparison. Some of the costs have been estimated for electronic health records.

Most of this information was derived from some work published by Renu Kaushal and some other individuals. And the electronic health record capital costs for a fairly advanced and a high-level model system is quite large. And UDI is a relatively small cut on that.

Turning to device manufacturing, some of the main cost components would be the internal planning necessary to implement UDI, addition of online bar code printing capabilities, the relabeling exercises that would be required, and then IT integration and a variety of integration exercises that would be part of that exercise for manufacturers.

A number of challenges would seem to be imposed there. A number of small firms would need to add an online printing capability that they probably don't have and often might not be really interested in adding. Considerable IT system development might be needed for some firms to track the additional information that they're now attaching to their devices.

For some of the large firms we talked with, they estimate costs of several million to add a UDI capability throughout their establishments. We've got widely varying costs I should emphasize. And the model for applying these costs to the industries remains somewhat uncertain.

Another thing for the large manufacturer certainly is a need for some fairly lengthy implementation period to get the systems in place and add them into the complicated logistics of manufacturing.

Excluding for the time being the IT costs and, again, very preliminary numbers here, with some basic sets of assumptions and cost estimates, we generate a total estimate of a bit over $400 million for the medical device industry. I mean, the industry is huge with thousands of establishments. So it

doesn't take all that much pro forma costs to generate fairly big total numbers there.

IT integration, we have sort of thrown the kitchen sink into this. And based on the data we've gotten from a number of manufacturers, again, I would emphasize that in talking with the manufacturers, we have not absolutely been able to make certain that all of our assumptions are entirely coordinated, but we've got a wide range of costs here. And if we extrapolate out to all the large firms in the industry, in particular where some of these terrific integration costs are, we get pretty big numbers. So there are some challenges awaiting us.

External to the individual firms, there are, of course, costs implied in sort of the standard-setting exercise in order to develop consistency in the UDI protocols in a product data utility that would allow people to know and interpret the UDI numbers that they are seeing.

And there would also be a considerable training in communication for users. As it is now, some people in hospitals complain about trying to take information off some of the device packaging and being confused by which numbers are applicable in which cases. So there is plenty of work in standardization

required.

We're still collecting information. So if you're out there and you're interested in this area, we would love to hear from you. And we're particularly interested in the sort of awkward and somewhat disruptive elements of this in your manufacturing establishment or in the hospital. And please give me a card or something. We would love to contact you if you want to offer information.

Thanks very much.

(Applause.)

MODERATOR KESSLER: I like the part where John says if you're the kitchen sink with the estimate and then the other part where he says, "Care to offer your estimate?" So I think he's hoping that some of you will sort of put some number in the hat. Maybe we should have a little hat up here for John.

So a few logistics things I need to go over. Again, I would like to ask those of you who did not register to please go out at the break and sign in so we know who is here.

For those of you in the back, there are seats over here on the left. And there are not very many. After they fill up, we will begin auctioning them off and put into John's estimate.

Panel, there are a lot of mikes. The way we have done this, you have to push to talk. So just remember that as well.

A few other things. At the end of the fourth panel, a number of people have actually asked to make brief presentations. And we will give them an opportunity. They will come up here. They will sit on the dias. They will have their PowerPoint stuff loaded.

And if you wish to make a presentation and did not tell us ahead of time, please tell either Jay Crowley back there, who is raising his hand right now, or Dave Racene, who is hiding. Just tell them so we can get this stuff loaded and be ready to do that at the end of the day.

There are some vendors here who have put their stuff in the hallway. There are certain kinds of technologies that are relevant to device identification. Please recognize, as you would imagine, these do not represent FDA endorsements. We don't make any money from their vendors. They are just there. So please go visit them as well.

Two other things I would like to mention. One, the issue of diversity, we recognize at FDA -- and this is a very important point -- that the scope

and diversity of the medical device industry is enormous. We're talking about products that are the size of a fingernail and the size of an automobile.

So we really recognize that we are in an area where it is not clear that one size fits all. And we are not here to try and shoehorn you or the panels into a regulatory decision that is going to work well for somebody and be absolutely untenable for others. So we're here to talk about diversity and how we can use this as an exciting opportunity to figure out how to use modern technology to enhance patient safety in health care and not try to make a solution that will be inhibitive.

That is going to be a challenge because the technology of information identification is also a moving target. So designing a regulatory solution that is flexible over time is a challenge. So we really look for your suggestions, not only to offer estimates of cost stuff but how to do this. So that is going to be later.

And, finally, one of the slides that John put up I think was very important. We need to figure out to what degree not only in the cost side are we talking about costs but are there health care savings, whether it's the manufacturers, providers, patients.

And getting savings estimates is just as important as part of weighing the checks and balances here.

I am going to introduce the panel members now, give them a few minutes to talk, and then open up the floor for discussion. So Jon White is from the Agency for Healthcare Research and Quality. And he is part of their section that does the health IT awards for all of AHRQ.

Next to him is Marcel Salive from the Center for Medicare and Medicaid Services.

Michelle Allender is from Bon Secours Health. She's Director of Clinical Resource Management.

Next to her is Joe Pleasant from Premier, Inc. Joe not only represents Premier but also participates in the Global Standards 1 group, GS-1, has been working on this exact issue. And I hope he will provide that perspective for us.

And, finally, on the right is Paul Pandiscio from Johnson and Johnson.

So this is our panel. And I will start on the right with Jon.

DR. WHITE: Good morning.

MODERATOR KESSLER: Good morning.

DR. WHITE: Thank you. It's always a

challenge to follow the first speaker. It's always a challenge to follow a good speaker. There's a story about it.

A man dies in the great Johnstown flood, where the dam burst, and goes to heaven and wakes up. God is standing before him. God says, "Oh, thank Myself that you're here. You know, we have been waiting for you. We have got a panel discussion that we have got you on, a flood. So we need you to come down the hall. We've got you as the second presenter."

And the man is going, "Oh, thank you. Thank you, God. I'm glad to be on the panel. Who am I following?"

And God says, "Noah."

But, nonetheless, we'll try to carry on. I do not have quite as much data for you, but if I don't have enough data, I can tell a story.

I do work at the Agency for Healthcare Research and Quality. I am a family physician. But, interestingly, somehow I managed to wind up managing the health IT portfolio at the agency.

So you can probably imagine that we place a premium on information and data. And, actually, in my practice, we place a premium on that, too. You

know, occasionally I cut something or occasionally I inject something, but, by and large, we manage information as providers. It's what we do.

The story relating to what we're going to talk about today, as you can imagine that the agency would think a lot about safety and quality of care. About a year and a half ago, the director of our agency, Dr. Carolyn Clancy, was approached by a group of orthopedic surgeons. He said, "Listen, we have this problem." And this is not to pick on hip implants, but this is the story. "We have this problem. We have had a number of our operations fail recently. And we're kind of suspicious that it's the actual device, the implant that's doing it. But we have gone back through the records, we have no idea what we put in. So this is what we think, but we can't figure it out one way or the other. Can you help?"

And we thought about that a lot. There's no way to either disprove that and say, "No, no. It's actually not the implant that's doing it but some technique that you're using in the procedure" or say, "Well, actually, it is the implant. You need to do something about it." So it's the absence of data that keeps us from being able to provide better care.

So I probably come down on the benefit side, as you can probably imagine. There are certainly costs and issues associated with that. I know very well because I spend a lot of my time thinking about information systems and expensive information systems frequently. So there is a trade-off to be had, but I am looking forward to really discussing that with you all today.

So thank you.

MODERATOR KESSLER: Thank you, Jon.

Marcel?

DR. SALIVE: I have a story about going third, but I won't tell it. I know Dr. Clancy probably gets very nervous when the orthopedics come forward.

Actually, I was at a meeting this week downtown. And I was with the early adopters, the carotic stent and cardiac stent people, who were meeting down in D.C. And every person whom -- I registered, I got my name badge. It came with an RFID and a bar code -- not a bar code, an electronic strip, magnetic strip. You can tell I know this stuff really well.

As we were going in and out of the sessions, it was tracking where I was at all times and

keeping close tabs so I don't cheat on my CME requirements, I think.

But I go into a panel discussion like this. And unlike our high tech method here, they had digital dots printing out the names of each person. And I noticed, though, when I was watching one of these panel discussions that, despite all of this high tech, the wrong names were under the wrong people.

(Laughter.)

DR. SALIVE: And so my good friend Dr. Mitch Krukov, not a good friend of mine, but he's a panelist for you guys at FDA, was listed as some I think Italian doctor.

DR. WHITE: This is what we call new and improved errors.

DR. SALIVE: Yes. So despite all of his RFID and his magnetic strip, I think he sat at the wrong seat or something. And they had beaming in video-live cases from Italy and New York. You know, it was a very high tech meeting, but that was what was going on.

I'm from Medicare. I know everyone wants to know what Medicare is doing on this. I think I want to focus, too, on the benefits, though. I think to us, I would agree with the first speaker that the

benefits deal with to us the assurance of health benefits to the patient. And that's most important to us.

I'm in the coverage group for Medicare. We deal with the evidence for coverage, for new technologies in particular, but we also are well-aware of all of the past technologies that are still in use and the ones that have kind of fallen by the wayside.

I don't deal with the electronic health record, but that is also a big initiative throughout Medicare and CMS. And also I think the value for patient safety is prominent in this discussion.

I wanted to focus a little bit on the comparison of effectiveness between devices. I think that is an important issue for Medicare in that we want to see an increase in value for the health care dollars spent.

And I think if we don't really look at that -- and I know I have to not disparage FDA too much, but when FDA approves something, some of the devices are approved by a grand-fathering process. And that process doesn't always give us evidence of health benefits. It assumes that evidence is in place.

Other devices are approved based on

trials. Some of these trials don't give us high quality evidence of benefit either, I would have to say. There's the new non-inferiority trial that I think is in vogue.

And, you know, at Medicare, it's very frustrating when something is FDA-approved on one of these pathways, saying it's equivalent or not inferior or something else. And then people come to us and say, "But it's better. It's really better."

And we see the evidence. We know what is going on. And we want to see better evidence that it is, in fact, better. And we want to encourage that to be collected.

And I think it is fine how FDA does their business, but for us to pay, we would like to see evidence of comparative effectiveness. And we have payment incentives in place so you can be paid more, that the providers can be paid more for something that is, in fact, a substantial clinical improvement.

And so I think developing that evidence, this type of data can help us develop that evidence. So our standard for approving something for coverage is, is it reasonable and necessary for diagnosis and treatment of illness? And that is, our standard is not the same standard used by FDA for safety and

effectiveness. So we have some differences there.

While we have held a very high standard for reasonable and necessary, we are developing a process that's called coverage of evidence development. And we used that a few times to cover promising technologies with the caveat that data must be collected on the care that's provided under this coverage with evidence development to ensure that there are, in fact, health benefits being accrued by the patients.

So one example of this is the implantible defibrillators. And I think we announced that coverage close to two years ago. And there were some groups that were very well-studied, and there was solid evidence of benefit by the defibrillator implanted in those patients.

But there were other groups that the evidence was not so solid that we thought was promising. And we said that we would expand coverage to those groups with the contingency that the data be collected into a patient registry. And that registry is now operational. It's been going since the time of that decision.

I would say there are some data quality problems, particularly for the device type and the

device model, the brand. There are multiple defibrillators on the market. There are, in fact, combination cardiac resynchronization devices with defibrillators that are also doing the same function as well as some other functions. So it's a complex area. This would help us get that data and understand, I think, the effectiveness and benefits the patients are getting.

So I think that is one incentive. The data quality handwritten by the cathlab nurse, which I think is how this is most commonly done, has some potential pitfalls that this might overcome.

So I think there are a lot of good incentives for this. I understand some of the barriers to it. And I know that we have had a lot of discussions in Medicare about what kind of payment incentives could we provide. And those are still, I think, quite ongoing discussions.

Thanks.

MODERATOR KESSLER: Thanks, Marcel. And I want to thank him for in just a few sentences and of his pippy observations speaking about the limitations and problems that we have with the entire 510(k) system.

(Laughter.)

MODERATOR KESSLER: Those of you in the industry who are really fond of 510(k) maybe we'll have a separate meeting with Marcel and CMS later.

Michelle?

MS. ALLENDER: Good morning, everyone.

MODERATOR KESSLER: Good morning.

MS. ALLENDER: I actually am a registered nurse. I have a background in administration managed care as well as surgical services and perioperative services. So I hope to add to this discussion and any questions that you may have the clinical perspective of how this system may affect those clinicians working in the field.

I have worked probably about 20-plus years in the field and then more recently the past 4 years at the corporate office for Bon Secours Health System. And, to say the least, it has been trying to track recalled devices.

We are currently looking at a system to help us address the notification of recalls but not necessarily the tracking of the recalls, which the UDI system would add significant benefit to.

As my colleague said regarding cardiology items, the same thing is done in the OR in terms of all of these manual logs of trying to track devices

and literally going through possibly hundreds of patients' records to find out and track down if something has been implanted or used on a patient that has been possibly recalled. So I hope to add some benefit to the discussion.

MODERATOR KESSLER: Thank you.

MR. PLEASANT: Good morning. In terms of recall improvement, unlike just about every other product sold in the United States, medical devices really can't be electronically tracked or inventoried. So finding those recalled products is certainly unreliable.

As one of our hospital executives said, we receive several recall notices per month which require a manual chart review, as Michelle said. And every patient that might receive that is a period of time that we don't know that we can track that back. Significant workload is associated with that.

There is tremendous concern with care-givers, et cetera. One large health system was also recently adversely affected by three very public class I recalls. And we have some documentation around what they went through in terms of having to spend time trying to track those patients down.

Another Premier Hospital executive said a

significant risk to patient care and safety is the possibility of implanting an outdated device or using an outdated device because we cannot track outdated information and bar code technology or lack of a UDI. It's not available from the manufacturers.

Another area, a significant manual process that takes a lot of time for hospital admissions as well as hospital folks, there's a significant cost associated with having to do that.

Another one of our executives believes that UDI will improve their ability to process recalls because currently they have risk management safety and clinical engineering working together to establish manual logs in the hospital so that they can actually extract that information when a recall occurs.

So, again, I applaud John and them for beginning to attempt to identify costs, but that's a significant cost and I am not sure we really have been able to identify what we continue to work on.

In terms of adverse event reporting, accurate and reliable device tracking would enable all of us in the supply chain in health care to be able to better track potential device defects and be able to take a look at those adverse effects on our patients.

Premier currently has a very large

database. And we do this tracking and try to look at adverse effects around drug information because we're able to utilize an NDC. And I think in the medical device area we would be able to do the same thing and be able to help identify those adverse effects.

Reducing medical errors, being able to correctly identify devices, tracking through health care system and inform proper practitioners about potential dangers would reduce errors. According to a by the ERG, UDI has the potential to facilitate education and device compatibility problems. Implantible materials have actually turned out to be incompatible with MRI devices resulting in injuries and deaths.

From the standpoint of the cost, as we have already heard, many hospitals are in the process of implementing electronic health records right now. And the fact that they are having to deal with the lack of a standard not only in the medical device area, which they really haven't gotten to, but they are having to deal with it in terms of clinical processes, et cetera, and having a lot of work done in standards area there, it's only a matter of time before medical devices need to be able to pass, be passed electronically in electronic health records.

And shame on us that are involved in this if we don't deal with that right now. Being able to pass that information from one hospital by way of an electronic health record will have significant impact and benefits to patients in terms of actually their electronic health record identifying for them what they have had in other places.

And we have even heard personal health records, being able to have a personal health record that shows clearly what kind of device or what kind of work has been done for that particular patient is really critical. So we need to get about establishing standards for medical devices for that purpose.

In terms of the cost, we have talked a lot about this cost. And I know that John's work is something that we can all kind of add to. I just add that in terms of the work that we have been doing with CHES and the work that the Department of Defense has been doing, there is a lot of cost in terms of our hospitals particularly having to synchronize their medical device databases with other supply chain partners.

There are many hospitals spending over $100,000 just to synchronize their master item files with others in the supply chain. And that's a small

part of it, but there's an awful lot of work that goes on in terms of trying to get the supply chain efficient.

MODERATOR KESSLER: Before we turn it over to Paul, I just want to take the Chair's prerogative for one second. Early in your discussion, Joe, you mentioned that you actually have either data or documentation about some of the hospitals who had to go through the recall process. So can you provide that?

MR. PLEASANT: Yes.

MODERATOR KESSLER: Is that publicly available or is that proprietary?

MR. PLEASANT: Our plan would be to provide that in a response back to you in terms of the upcoming response period.

MODERATOR KESSLER: And in terms of your last comment about the supply chain efficiency and the costs that hospitals are currently bearing to try and synchronize the systems, do you have some sense that we are moving or need to move towards one uniform system so that after an initial investment and training we have something that's working for your hospital so they're not spending money every year trying to resync?

MR. PLEASANT: Absolutely. Other industries have done that, as many of you know. The grocery industries and others have a consistent weighing of product data utility, where they all synchronize their files.

It allows them to do that in an efficient way versus every hospital going out and trying to synchronize their them masters and their descriptions with other partners that they have. And, quite frankly, that gets out of date every month, for that matter, and new products are introduced. And it may or may not get synchronized across the supply chain.

Take significant dollars out of the system. Make it significantly more efficient.

MODERATOR KESSLER: Thanks.

MR. PANDISCIO: Good morning. I would like to thank FDA for having me here today. I do work for Johnson and Johnson. I am here in the capacity of representing AdvaMed for the manufacturers' association.

To the point of UDI directly to patient safety, we believe that sufficient study and evidence doesn't exist to directly show the link between UDI and direct patient safety benefits.

That does not mean that we don't see

potential for value chain efficiency benefits from better visibility into system-wide inventories and product movements.

Some keys here, though, to even potentially get at those efficiency or we'll call them value chain or supply chain types of benefits are the system would truly have to be system-wide. And I think that's an absolute must. What I mean by that is a system that is well-adopted and deployed, manufacturer all the way through provider to the point of use.

Further, I believe the standards that would drive the UDI system would have to be global in nature. I know that theme has already come up once or twice this morning. But I believe wholeheartedly in the convergence of standards to drive global visibility and, in that, enabling the structure to be in place.

And, finally, the point again to potentially get at the supply chain efficiency benefits that are there, this whole system would have to be very carefully and well-constructed.

And what I mean by that, just a couple of points, is we really need to design this for adoption. It's not really going to do us any good if

manufacturers are labeling product, are putting unique identifiers on product, and the chain ends there or even ends at our distribution point.

We really have to understand the inventories in the system, be it regulatory incentives, cost reduction incentives, or other, or evidence that maybe will exist in the future directly linking to patient safety benefits.

Those incentives will need to be in place throughout the chain to drive adoption. And I firmly believe that that really is the only way we are going to see benefits here.

From a major cost standpoint, I think some of the reporting that has been done from our perspective does a pretty fair job with identifying the categories of cost, label changing, project management associated throughout the chain, some capital costs, particularly if a recommendation were made to utilize some form of auto identification, be it bar code, RFID, et cetera.

And perhaps, as has been highlighted, the largest cost truly is a systems integration cost. And, again, to the point of a well-constructed system it is going to be essential to derive this benefit, not only in the U.S. but globally.

We're going to have to make this adoption systematic. This won't be able to be in the vast majority of cases any type of a paper-based system. We talk about potentially uses in the EHR, development of evidence-based medicine.

And so the systemic adoption and building this into systems from an integration standpoint is going to take time. And it's going to be quite expensive.

It doesn't mean it can't be done. However, what I would ask people to think about is from a standpoint of tying into major systems integration and upgrade initiatives that are underway for similar or other purposes as well may be the way to get this done. And, again, I think this is a theme that we have heard a bit this morning.

For manufacturers, our ERP systems, our inventory control systems, are on upgrade schedules, we do make continual investments in these systems. And to marry enhancements like the potential of a UDI with the upgrade cycles of these systems, which tend to be on something like a five to seven-year horizon, seems to potentially present an opportunity to capture these new capabilities.

From the standpoint of auto

identification, I do believe some form of systemic auto- identification is necessary to drive this system as well to count on removable labels or paper-based pen and paper types of systems to capture this system-wide is probably not realistic and certainly not realistic in my opinion globally.

And the final piece to add is just from a complexity standpoint. Well, if we do these things right, the potential for efficiencies may exist. We do have to keep in mind relative to the drug industry, medical devices have an order of magnitude, at least one order of magnitude, more products to be dealt with. And so appropriate timing and consideration of that complexity must be taken.

Thank you.

MODERATOR KESSLER: Thank you, Paul.

So in a minute I am going to turn over the next half-hour to you to make comments. Please remember to come to the mike, identify yourself. Before I do that, I want to make a couple of comments about just what we heard from the panel and ask one question.

Speaking of Paul's most recent point about making the system-wide integration, I want him to be aware that we have spent a lot of time working with

our federal partners. And I have to give a lot of credit to Michael Fitzmaurice specifically and the Agency for Health Care Research and Quality, represented by John, who have been major players in helping FDA move this forward. So it's really been terrific.

We have also had a lot of discussion and cooperation with the Center for Medicare and Medicaid, with the Veterans Administration, with Department of Defense. And I think it's important that if we move forward, that we do it in a coordinated federal effort.

Having said that, it's very interesting we get phone calls occasionally from parts of the government and they say, "Oh, I'm the UDI guy from this part of the government," a week later we get a call from somebody else in another city and they say, "Oh, we're the UDI part for the same part." So it gets confusing sometimes. The good news is there's only one Center for Medical Devices as far as I can tell.

Let me ask one question of Marcel, if you don't mind. Can you speak -- and if it's not in your purview, you can say so -- for one or two minutes -- and maybe John could add to this -- about the CMS and

AHRQ perspective on the electronic health record. Where are we today? Where do you think we're going to be in three to five years?

As Paul mentioned, if we have a horizon that's about three to five, maybe seven years, although I think seven may stretch the patience of some of their colleagues, but if we had a three to five-year horizon, do we think we're going to be in a place where there is an electronic health record that's collected through pre and post-market surveillance that is important for CMS that the supply chain can be moving along the way? Where are we on that?

Marcel, your comments, please?

DR. SALIVE: Well, that's one of those questions where I like to answer by saying that if I did know the answer to that, I would not be working at CMS.

(Laughter.)

DR. SALIVE: You know, probably I would have a much better job.

DR. WHITE: What could be better than working for at CMS.

DR. SALIVE: I love my job, by the way.

(Laughter.)

DR. SALIVE: Actually, I was at a meeting a couple of years ago. I thought a visionary person there made a good comment, which was that if we do nothing, we will have the electronic health record everywhere by 2013. And so that is in your seven-year horizon.

So I think we're not doing nothing. There's a lot going on. And so there are incentives to be built into the system. We have provided some small amounts of funding at this point I think to selected groups.

There's always a discussion at Medicare about new initiatives and how do they tie into this piece. And so I think that's important to recognize.

You know, we have had discussions with the Orthopods, actually, about could we somehow facilitate device identifiers being placed on the billing forms. And I think we said to them, "The ball is in your court. You need to push back." That's not a small task, actually, because Medicare does not control the billing form.

There's now a national uniform billing committee, which deals with that, but there are some modifications being made to that. And I agree with the comments of kind of patience and synchronizing

things and getting them right the first time so that it can be successful.

So I do think we will be there, but, you know, the exact road we're taking I'm not that familiar with that one.

MODERATOR KESSLER: Jon?

DR. WHITE: Well, that's where I come in. First, there are a couple of things I want to say. Mike Fitzmaurice has really been a leader for this. I am kind of his proxy. So I am grateful for that acknowledgment. Mike is a wonderful person to work with and has been around for a long time.

Before I talk about the electronic health record, health IT stuff, just after the discussion, I realized that it's kind of five on one. And we'll talk Paul as one of them.

How many of you are from device manufacturers? Raise your hand and keep them up.

(Whereupon, there was a show of hands.)

DR. WHITE: Okay. How many of you think that UDI is a bad idea? Keep your hand up.

(Whereupon, there was a show of hands.)

DR. WHITE: Okay. All right. And so we can start from there. I didn't think that was going to be the case, but I just wanted to ask. And that

helps me think about the discussion report.

Okay. Electronic health records and health IT generally speaking, there has been a lot of activity in the federal space over the past two years. It's kind of felt like being in a washing machine, frankly.

The Secretary has made it a very high priority. The President has made it a priority. The Secretary has made it a priority. There are a number of processes that are moving forward.

There is a federal advisory panel called the AHIC, American Health Information Community. If you go to the HHS Web site and go to the front page, go to the bottom right-hand corner, there is a health information technology that you can click on. And all the meetings are public. There are workgroups. Those meetings are all public. You can watch it streaming if you don't want to come to Washington to watch it. So a) feel free to tune into that, b) There are other federal processes going on. Two years ago, there was a national coordinator for health IT appointed. There had been a number of contracts and activities going on through their office that are doing things like harmonizing standards relating to medical information, a lot of the things that I think you referred to talk

about medical processes and how do we start to structure that data, as opposed to, you know, my bad doctor's handwriting, which I have right here on the paper in front of me in a chart.

Those processes are moving forward. I would be extraordinarily surprised if we did nothing to have widespread adoption of electronic health record by 2013. I think we will get there.

The numbers right now depend on the size of the medical group, actually. For very small groups, it's in the single digits. For large medical groups of 50-plus, it's well over 50 percent. So there's varying adoption, but it's out there and it's moving ahead. And there are some processes trying to bring that together.

UDI can plug into that. Okay? There are numerous, you know, for my NIH colleagues, receptor sites where that can happen. And we can talk about what the best way to that is later on in the day. But there is a lot of standardization effort that is moving forward. And we have been involved in that to a degree. We can talk about that.

The other thing that I just want to really quickly mention is that -- so that's health IT. There's also a quality measurement movement that's

been happening at the federal level as well, again, promoted by both the President and the Secretary with some urgency.

And we're starting with things like do clinicians do the right things for you as the patient and trying to measure that, but that is going to expand. It will start small, but it will expand. And it will encompass this field eventually.

Like it was said before, it will happen eventually. But I think there's real opportunity for the folks in this room to be leaders and to anticipate that and be ready and do some really good things ahead of time.

MODERATOR KESSLER: Thank you, Jon.

So I would like to open the floor. For those of you who would like to make comments, please feel free to come to the microphone.

I think we have been challenged in a way. Jon says five against one. Paul I think challenged us to speak to the patient safety question. And there has been a lot of talk about the cost issue and not as much about patient safety. So if someone has comments about that?

MR. PANDISCIO: Could I just make a quick follow-up comment before we --

MODERATOR KESSLER: You can. I see no one going up to the microphone. So I'm trying to figure out. Maybe I should offer incentives, like a free 510(k) or something, --

(Laughter.)

MODERATOR KESSLER: -- or, you know, waive a user fee or something or, you know, give you a trip to Canada to visit Don Boyer in Ottawa in January, something like that.

Paul?

MR. PANDISCIO: Thank you very much for the opportunity, just very briefly and just to be clear -- and I hope the tone of my voice didn't lead you to believe something that I didn't actually say because I don't think that any of the manufactures think UDI essentially is a bad idea.

I think the case that we're trying to put forward is if, in fact, there's a patient safety benefit, let's get this right. Let's find out where. Let's document it in peer review type of analyses, not do it in a blanket type of way, and truly get to root cause to really derive a benefit versus move too quickly in a non-systemic way that potentially could cause future work and in the end potentially delay the benefits in total. So just to clarify that as well.

MODERATOR KESSLER: It's great to have industry be concerned that FDA might move too quickly.

(Laughter.)

MODERATOR KESSLER: I have that on the record.

MR. PLEASANT: Larry, just a comment, just to follow up with what Paul was saying. I agree with him. I think the industry as a whole has to work together to make this right.

I don't think that we can look at one piece of the industry and say that that group has to do it and we should put all the burden on them. I think it needs to be a consolidated effort.

So I'm not interested in picking on Paul or the manufacturers because I think we have to work collaboratively to make that happen.

MODERATOR KESSLER: Thank you.

Sir?

AUDIENCE DISCUSSION

MR. SCHULMAN: Hello. My name is Seth Schulman. I work for Genzyme Corporation.

I actually wanted to make a couple of over-arching comments, which I guess are -- I don't want to say that I'm speaking on behalf of Genzyme officially because, well, you might not like what I'm

saying, but you might. But it actually ties in very nicely with the question that you had posed, John, as to do we all think that UDIs are a good thing or a bad thing.

I'll say that I do think that it is a very good thing. However, what I do think is a bad thing is limiting the scope of it to devices. And I say that, and that's why you might not like me because it's making it a much more complicated process.

But I think we're looking at tracking devices, being able to have granularities, where they're going, recall information, et cetera, et cetera. There are a lot of similar programs going on with regards to drugs and devices, such as the Pedigree Program, which is similar. It's related. It's not identical. But I think there could be a lot of overlap in that.

And I think we really need to look at that from a whole supply chain perspective, a whole customer experience, that we're not setting up a system in a regulatory framework that is going to have to change down the road as we get more combination of drugs and devices or that we're having hospital supply chains setting up two different systems, one to accommodate all of the requirements for drugs and

biologics and the other one to accommodate all of the requirements for devices.

I am particularly interested in that because I actually work on a product which is a device. However, one of the primary distribution channels is pharmacies and specialty pharmacies.

We have gotten a lot of feedback from our customers in our supply chain basically saying we want to comply with the Pedigree Program because our systems are going to require it.

So if you don't, we're not going to be able to sell your product. So I think we really need to consider that as distribution channels change and develop over time that we're not putting it into a regulatory framework that is going to end up being conflicting with the other products.

MODERATOR KESSLER: Thank you.

Jon?

DR. WHITE: That is an excellent point.

Two thoughts. The first is with the support of CMS, we're conducting a number of pilot studies under the Medicare Modernization Act to set electronic prescribing standards. And in my spare time, I'm the project officer for those. And that is going to be coming out soon.

A number of those issues have raised their heads. We're looking at RxNorm as an example and NDC codes and trying to think about where that is and should go. And I think if Randy Levin is here, we'll probably talk about that later this afternoon.

The other thing that I want to mention is that we also have a program called CERTs, Centers for Excellence in Research and Therapeutics, which, actually, in theory people think about as pharmaceuticals, but actually extends to covered devices, too.

So at least we fully recognize and support that concept that there are a lot of modalities. You know, if you talk about devices, you talk about devices, but there are a lot of modalities that it extends to. So it's a great comment.

MODERATOR KESSLER: Thanks.

Jim?

MR. KELLER: Good morning, everyone. My name is Jim Keller with ECRI. I had a couple of questions for John, actually, related to the cost information.

I'm just curious about some examples related to assumptions that were made on the two charts that you had in your presentation: the one on

estimated recall savings and then the potential hospital costs of UDI.

I just thought it would be interesting to hear some examples of what helped you generate those charts. And I assume that there would be published information at some point in time about that.

MR. EYRAUD: Right. The estimated recall savings, we had a number of conversations with hospitals about their experiences there. And there's also an estimate from John Hancock. I mean -- John Hancock -- Johns Hopkins --

(Laughter.)

PARTICIPANT: Different American.

MR. EYRAUD: -- about their recall experiences, in which they quantified the amount of time they spent basically trying to execute recalls. That was probably the most well-considered number we had.

Some of the other conversations I thought were a little casual. And we didn't put all that complete faith in what some of the hospitals said because we didn't really ask for a formal accounting of this.

We also had some input from -- well, I'm not sure if I talked with you, but I also talked with

Dick Fiddleman from RASMAS. And I don't recall if I had a specific data point that went into those specific extrapolations, but he was sort of part of those discussions.

The other thing was about the hospital costs of UDI. We are mainly looking at the costs of employing scanners sort of throughout the hospital to capture the UDI information and put it into electronic health records. To some extent, we also had some scanning systems assumed for a purchasing or incoming material in the hospital. It's not quite a comprehensive look at hospital costs, but those are the main areas.

Does that address your question?

MR. KELLER: That's helpful.

MR. EYRAUD: Okay. We can maybe talk at other points.

MODERATOR KESSLER: On my right.

MR. MONROE: Hello. I am Napolean Monroe representing Henry Schein. We are members of DTA, Dental Trade Alliances; and HIDA, Health Industry Distributors Association.

Most of the work that has been done, and rightly so, is on the impact, high-risk devices, and hospital costs and benefits. We would encourage

looking at the effect on individual practices and on the distribution network, distributors such as Henry Schein. I don't know if there has been any study done already or if there is any contemplated or if there are comments from the panel about any considerations that have been given.

MODERATOR KESSLER: Thank you.

John, can you address that because I am not sure we have handled issues of distributors.

MR. EYRAUD: We have not gotten far on the distribution chain, quite frankly. I mean, it has been a lot of interest, but we haven't really had enough information yet or had enough chance to compile information about it.

MR. MONROE: We are deeply engaged in Pedigree. And, just as Mr. Pandiscio says, whatever happens needs to be system-wide because it will affect down to the individual practitioner level.

The example given in the Federal Register was latex gloves. A medical device, yes. We distribute a lot of them. And what consideration is being given to the depth of applicability? Thank you.

MODERATOR KESSLER: So stay up there for just a second. I'm hoping that you and maybe the organization who represents distributors would be

willing to work with the FDA and with ERG to help us figure out what kind of impact it would have and how the system could work to your benefit.

MR. MONROE: Our interests are the same as yours.

MODERATOR KESSLER: And then back to the latex gloves issue, in terms of depth of applicability, that's actually a technical issue that we are going to handle sometime later today. So I hope we address that later. Thank you.

MR. MELIA: I'm Dick Melia. I'm a member of the board of the Hypertrophic Cardiomyopathy Association. And, Larry, you asked about patient advocacy, your types of comments. I'll wear that hat for a moment, although I worked with Larry before on the FDA.

Up to May, I was Director of Research Sciences for the National Institute on Disability and Rehabilitation Research. So I guess I have a little bit of a research orientation as well.

In the last week, I have had the opportunity to attend the third international summit on hypertrophic cardiomyopathy that was just held in Minneapolis. And I heard some very interesting reports from the 13 nations that were represented at

that conference in relation to the use of registries and registry information and observational study information that relates to this heart condition of hypertrophic cardiomyopathy, which is one of, as you may know, the leading conditions that is treated by the use of ICDs.

I also have had the experience in the last week of reviewing some projects at the Office of Science and Engineering Laboratories related to cardiac resynchronization therapy and related ways of using technology in relation to serious health conditions.

My point is that we are making great progress in the use of observational methods and the use of registries to collect this information. And I believe that the point was made about the diversity and the many, many different types of devices, many, many different types of challenges.

I believe there is a great opportunity for using our advances in the areas of quasi-experimental designs and observational studies to do improved research that could bring together the types of quality work that I have seen that AHRQ can do and that CMS can do.

I've coordinated work with projects that

with both of these agencies -- and I've worked with the FDA in the past and now wearing a patient advocacy hat, I'm very optimistic that improved models of quasi-experimental and observational work can give us information that we vitally need in this area.

Thank you.

MODERATOR KESSLER: Thank you.

Comment from the panel? Okay. Jon?

DR. WHITE: I'm full of comments today. Cardiothoracic surgeons have an excellent registry. I don't know how many of you know that, but they for a number of years have been very carefully tracking outcomes, procedures, a number of things. I've come across this in the quality measurement world.

There is great data available on registries. All data is not the same. And the level of structuring that data is critical. There are great opportunities, but I don't want to assign too much hope, you know, the belief in new and shiny things that without some hard work, it will just happen. It can happen, but it's going to require some serious forethought.

MODERATOR KESSLER: Marcel?

DR. SALIVE: Yes. I think I would just link that comment to the earlier comment from the

gentleman from Genzyme and say that, you know, complex, very sick patients have multiple co- morbid diseases and a lot of different therapeutic strategies being applied to them.

I think when we're trying to conceptualize tracking all those strategies, some are devices, some are maybe drugs and biologics. Others may be even things like cardiac rehab, which doesn't have anything as far as I know that the industry provides. Maybe it does these days.

So I think tracking all of that at the patient level is going to be very important. And being able to link that and know because sometimes it's a confounding factor, sometimes it maybe enhances the results of the device. You know, we don't really know at this point. There are a lot of hypotheses that we can look at in this if we get this data collected. And, really, ultimately that is the issue, how do we get it aggregated at some larger level so that it can be looked at this way.

I mean, I think the day-to-day patient management issues are very much on the forefront of the developers of technology for EHR, but the next step is this public health impact question.

MODERATOR KESSLER: I think one of the

issues we face is while I think the area you raised is very important, trying to estimate not only the theoretical but the practical benefits we would see from that has been a challenge.

Over here?

DR. SLOANE: Elliot Sloane, Professor of Information Systems at Villanova University's School of Business. I'm a voting member of the Health Care Information Technology Standards Panel, which is on behalf of the Secretary of Health and the President, working on moving the electronic health record forward.

We had our first significant but not giant step forward by vote last week. We put forward recommendations for the first part of the standards for the first deliverables for prototype testing next year for an electronic health record. That's a portion of the electronic health record that we all envision.

We also by vote last Friday created a priority list to go to the Secretary of Health and to Dr. Colander regarding the priorities for next year's accomplishments and achievements. And in that, the 200-member panel by consensus agreed to include medical devices as a priority area for inclusion in

the next generation; that is, next year's definitions for the electronic health record.

And I would like to know from the panel, do you see that as a priority? And if so, are you willing to encourage, I believe, those decisions for setting next year's priorities will happen in the next month? Do you see that as enough of a priority to voice those opinions to the Secretary of Health so that the medical devices are on that list?

DR. WHITE: Is that going to be presented at next week's AHIC meeting to the Secretary?

DR. SLOANE: That is correct.

DR. WHITE: Okay. All right. Is your expectation that if that is set as a priority that there will be standards that can be harmonized or that the group would potentially come back to the Secretary a year, year and a half later and say, "Standards do not exist. You need to have some process for developing standards for it"?

DR. SLOANE: That's correct. What should come from AHIC or AHIP, I guess, is the next --

DR. WHITE: AHIP is America's Health Insurance Plans.

DR. SLOANE: I'm so confused. Keep the acronyms straight. HCITSP is supposed to receive a

mission statement that tells us which standards to work on for the end of September of 2007, to then be piloted and applied in 2008.

DR. WHITE: I think it's a great lever to move forward this discussion is my short answer. Of all the various contract activities that are going on to the national coordinator's office, I have the greatest faith in the HCITSP process. So I'm really glad you're here, actually, a number of excellent people working on it, great community to come together and enter that.

The Secretary has placed priority on that. So as much as we say, you know, #you really ought to do that,# your comment probably carries equal, if not greater, weight, and the group's feedback to the Secretary. And ultimately it goes to the Office of the National Coordinator and Dr. Kolodner, as you mentioned, but I think it's a great lever to move that forward.

MODERATOR KESSLER: Paul, did you want to comment?

MR. PANDISCIO: Yes. I would certainly support that. I think that's good news. And I think we again in the medical device area have to get ahead of that, rather than waiting until it's legislated and

required and people start doing their own standards. So let's get on with doing standards now so that we'll be prepared when it's really time to put it into the health record.

DR. HENSTEN: Thank you.

My name is Arne Hensten. I am from the University of Tromso in northern Norway. My background is quality control of dental materials in the Scandinavian countries, in IOM, Scandinavian dental materials.

And our experience is that when we're trying to identify what has gone into patients. We meet a lot of problems. One is that dentists have forgotten their material science they're working on: water, air, soil, and fire, and maybe dental amalgam as the fifth element. And we're trying to get into a better context.

Now, building, looking at the quality control of dental materials we find that manufacturers are also in a situation where they say that products may change but brand names are forever. Having it that way makes it difficult to really go in and do any kind of sensible risk analysis or whatever is put into a patient.

Building a new dental school with 100

chairs up there, I now have the opportunity to implement a full quality control from the central sterilizing unit to the materials used to the patient, and also all the devices used to the context and for the medications.

The thing we find difficult in this situation is to write a good specification for what kind of literature used for medical devices or whichever one. And I would appreciate any kind of help in getting the facts down on paper to how to really write the specification where you put it in all of these quality aspects into the system that will benefit the patient hopefully at the end.

Thank you.

MODERATOR KESSLER: Thank you.

MR. PANDISCIO: Excuse me. A quick comment to that. Just to reiterate, you know, I think to help drive the efficient use of data, right, I had mentioned earlier sort of a consolidation of global standards. And truly getting it right is certainly a piece of the answer here.

Just a quick anecdote of my own on behalf of Johnson and Johnson, this time for medical device products. We have many, many, as many of you probably well know.

We currently bar code label with a bar code identifier, product identifier, well over 90 percent of our products, all the way down to unit of use, far over 90 percent.

The issue again back to the systemic uses, a fraction, I mean, a very small fraction of that, is really read and inputted into a system and integrated globally.

So, I mean, just another anecdote. I think manufacturers are willing to do things to drive efficiency, to look for other benefits that may exist that data supports. But I do think a consolidation of standards in partnership with all of the different nodes of the supply chain is not only unnecessary, but it's an absolute must ingredient to get this right.

MR. LITTLEFIELD: Good morning, everybody. My name is Patrick Littlefield. I am from WaveMark. We are a company that is currently in market doing work with a process supply chain in EDI space.

What I would like to say is as an initial observation, the discussion appears to be largely focused around the cost and appears to my perspective to be light on benefits.

I would encourage both the FDA and the participants to continue to look at the benefit side.

Our work in the market suggests that the supply chain is rich with opportunities for both participants. That is, the providers and the device makers to benefit. And I firmly believe that with proper kind of regulatory framework and guidance, market forces can be harnessed, such that this is actually a win-win and not simply a subcost?

I want to recognize obviously investments will need to be made, but I believe that systematically there are rich opportunities here for everybody. Again, properly framed, the market can help get this job done.

MODERATOR KESSLER: Thank you. I think we echo your sentiments in trying to figure out how to get from here to there. So some day we would like to be able to work with you on that.

Don?

MR. BOYER: Good morning. Larry mentioned that there was somebody here from Health Canada. That is me. My name is Don Boyer. I am Manager of the Licensing Services Division in the Bureau of Medical Devices.

The reason I am here, as most of you should know, Canada introduced a new set of regulatory requirements in 1998. I worked on a working group

beginning in 1992 which put together 16 regulatory proposals for the new regulatory framework in Canada. And in conversation with the FDA about a month ago, I was happy to dust off one of our regulatory proposals dated December 1995, which called for a bar code identifier in Canada.

That is why I am here. We are still very interested in this initiative. Unfortunately, Canada being an importer nation, population about 30 million people, we import about 70 to 80 percent of our medical devices. It's very difficult at that time to convince industry that they would need to bar code every single one of their medical devices. So it did not fly at that point in time.

However, you will notice in our medical devices regulations that each medical device on its label must contain an identifier. We were able to capture the word "bar code" in there. However, it says a unique or combination of letters and numbers or a bar code identifier. So it is in our regulations. It just is not used at this point in time. So we're ready to go when you're ready to go.

I would agree with everything that I have read so far that has been published by the FDA on this. Two things I wanted to mention from Canada's

perspective. Because we are an importer nation, one of the major reasons we wanted this identifier was for import control. I haven't seen that yet in anything published coming out of the FDA, but being an importer nation is very important.

We don't have the resources at the border to be able to scan product coming into the country to verify its regulatory compliance before it enters the country.

The other initiative or the other thing that was mentioned in our proposal of 1995, it would be a good way for users of medical devices to verify the regulatory compliance before purchase through some type of unique scanning system.

The last comment I want to make is I want to just echo Paul's comments on the panel there. I believe it is extremely important that this happens at an international level. However, sometimes things that occur at the international level take a long time to get design developed and implemented.

I do agree there are forms out there already, whether it's global harmonization task force or ISO or some other mechanism. That's the area which we should be starting at.

Message to the FDA: Please keep us

involved in this process. We're very interested. Thank you.

MODERATOR KESSLER: I want to thank Don for coming and acknowledging the fact that we're about ten years behind the thinking of Health Canada.

(Laughter.)

MODERATOR KESSLER: And, as Joe was saying, we're probably a decade or more behind the grocery industry. So it's easier for them to identify that the 14-ounce box of Corn Flakes is on sale this week and we can't figure out what implantible cardio defibrillator went in someone last week at a cost of $26,000, so fascinating.

I think the last two comments, I will do Sandy first and then Bernie. And then we'll take a break. So you guys are between us and a break.

MR. WEININGER: Thank you.

Sandy Weininger from the FDA. I just want to make a few brief comments to tie this very strongly to safety.

We do an awful lot in the agency trying to figure out whether hazards were appropriately mitigated and what the consequent risks are and what the mitigations are acceptable.

And if you can't even figure out what the

particular product configuration is, it's really hard to do something about it. And so in a number of databases that we have, we just can't figure out what is the device consistently from product to product.

So from a safety perspective, I mean, I can't show you an article or evidence that points that out, but I think an intellectual argument could be made fairly easily.

Thank you.

MODERATOR KESSLER: Thank you.

Bernie, last comment.

MR. LIEBLER: Bernie Liebler from AdvaMed.

I want to make a comment on the framing of the question a bit because earlier I forget who on the panel asked the device manufacturers "Who of you think this is a bad idea?"

That's a little bit akin to the old joke about "When did you stop beating your wife?" You know, the question might more appropriately have been "Have we made the safety case appropriately? Is it compelling? And is it convincing?"

Janet Woodcock said, "We don't have the kind of data for device errors that we have for drug errors, but we do have the solution." And I'm not sure that that's compelling either.

I'm also going to tell one short story. I had an incident this summer that I would have preferred not to. I was in a major health care facility in northern Virginia. It's brand new. It's about a year and a half old.

They did invest heavily in it. Each bed has its own PC installed for entering data into the patient record. There are no charts. There also are no bar codes.

When they came to administer drugs, they checked the patient number on the wrist band. They asked you your name. They checked it against what they had. They asked you your date of birth. And then they gave you the medication.

They did not use bar codes. This facility is about a year and a half old. So if bar codes are the panacea, why was it left out of that design? I don't know, and I'm not saying they're bad. I mean, my point is we have to frame the issue. And are we getting to the right place the right way?

Frankly, eventually yes, the answer is that we probably will be doing everything electronically because that's the way we do it. But let's do it right.

MODERATOR KESSLER: Jon and then Marcel?

DR. WHITE: I asked the question earlier. And I would probably make it more akin to the question of when are we going to stop beating the patient because the issue is that we don't have the data. That's correct. And I don't want to make assumptions based on absent data.

But ultimately the reason I became a doctor and the reason that we all do what we do is to provide health care. And ultimately that means to patients. And I feel like it's my professional responsibility to them, not just as a doctor but in representing the public interest as a member of the federal government, to say we need to recognize that there is an issue and we need to do something about it.

I would want to do it in a thoughtful way. Okay? I mean, that's not about slap dash stuff. But I am about let's do something about it. So agreed.

MODERATOR KESSLER: Okay.

DR. SALIVE: Can I?

MODERATOR KESSLER: Marcel?

DR. SALIVE: I wanted to just say I did start working back when at FDA in vaccine safety and was part of the bar coding workgroup for that, which I know has accomplished a great deal probably.

I think I will answer the AdvaMed comment with this. Okay? Look, you don't want to be in the position of blocking this by saying there's no data on patient safety. I know you didn't say that, but you want to be proactive on patient safety because you don't want the Vioxx equivalent in your industry, whatever that may be.

You want to prevent that. You want to be able to prevent it proactively through all your systems. And this is just one of your systems to prevent that. It's not a big one. There are many others that I know are much more important. But you don't want this situation brought up by the previous speaker by FDA. You want to know which patients have which products.

So this is true. It was brought up at the very beginning that people are not good at recording in the record what device they have implanted into patients or justifying why they chose among some choices. And so you have to be able to track this to know whether something is true, related to the product, or not. And you need to be able to do that. It's vital to your company's survival, frankly.

I think that's the business case. You don't necessarily need evidence of prevention. I

mean, I understand that you need a business case, that it needs to be doable.

MODERATOR KESSLER: Thanks.

So a few little, tiny things. First, if you're sitting next to a chair that's empty and you happen to have a coat or a briefcase there, there are some people who don't have chairs.

So at the break, please pick up your coat -- if you want to hang it, there are hangers on both corners -- so we can free up a couple of seats.

Number two, we have lowered the temperature a little bit. We thought it was quite warm. If it's either too cool or too hot, tell Dave in the back, and we'll try and readjust. But it was getting a little warm. And we figured with all these people, it would get warmer as the day went on.

We're going to take a break for 15 minutes. You will hear us yell at you in a few minutes.

And, finally, please let's thank the panel for their presentations.

(Applause.)

(Whereupon, the foregoing matter went off the record at 10:41 a.m. and went back on the record at 10:58 a.m.)

MODERATOR KESSLER: We've talked about cost. We've talked about benefits to some degree in I guess a limited way about you need device identification issues.

Even though we are going to stray away from that to talk now in the next panel about practical implementation, if you do have subsequent comments about cost issues or benefit issues, please feel free to continue to raise them during the day.

We're going to turn now to Chuck Franz, Vice President and CIO of the Cook Group. Chuck?

DESIGN AND IMPLEMENTATION OF A SYSTEM OF UDI

PANEL DISCUSSION

MR. FRANZ: Good morning.

MODERATOR KESSLER: Good morning.

MR. FRANZ: Jay and David Racene asked me to speak today. I spoke with them in March. What you will see here is Cook is a privately owned company in Indiana.

And we faced this subject many years ago. And we made a changeover in our system, much like my colleague from J&J commented on, about every five to seven years you're looking at your supply chain. You're looking internally and externally at the correct things to do. So what this presentation will

show you is some of what we went through and the decisions that we had to make.

A personal story. Back in 1988, way back then, we had developed a bar code system at Cook. And we're hearing from the marketplace in the field that it had to be a certain style and it had to be implemented a certain way.

I ventured out into many institutions. And what I found is the problem that we still have today that has been talked about. And that is that within the institution, one area said, "Yeah, that would greatly benefit me or us." Maybe that might be the surgical suite.

I went up to the critical care suite. They said, "No. You don't need to put that on there because we do our own." And, sure enough, they had their own bar code printer. Every product that entered that suite, they put their own bar code on it.

I don't know how far we have moved in the health care setting today, but it's still the problem. The problem is having a global standard that all of us as manufacturers, all of us as health care providers can agree on, can support that ultimately is going to benefit the whole health care supply chain and patients in the end.

This occurred about two to three years ago at Cook, but we boiled it down to two different things. We used bar codes in the late '90s and early 2000 or RFID. There were several things that we kind of were looking at. Do we change over? How do we change over? And what do we do?

We chose bar codes, to stay with them, for various reasons. But you can kind of see our rationale down there on the RFID side. It's not always compatible: potential interference, potential frequency interference. And it's more costly than the bar code situation.

If you think of the global health care solution, we had better be thinking about everywhere in the world. We had better be thinking about, you know, Africa. We had better be thinking about Canada. We had better be thinking about the U.S. We had better be thinking about Asia. And is RFID, and the systems and the cost, available today everywhere in the world? So, again, our decisions were taken about two to three years ago, but those were the kinds of questions we asked ourselves.

Again, this is a Cook look at things. It's not an FDA look at things. But this is what we looked at at Cook. And just to give you a little idea

of the changeover and the switchover and the scope of what we were dealing with, in 2001, when we looked at this, we had 27,000 part numbers. And we have reduced that to 17,000. So somewhere in between there is the amount of products that we had to apply this code to and change over within our own internal system.

EAN stands for European Article Number. Okay? So we got this out of Europe in 2001. And there were requirements in Japan that this needed to be on our product labels.

By April of 2002, we had converted over all of those 17 to 25 thousand part numbers, let's say, and then launched it globally to our customers in 2003. Okay? So, again, I'll go into a little bit more detail on the amount of time that it takes and the troubles that we had.

But going back to the '80s, again, do people use them today? From industry's perspective, a very, very small amount use them. Internally at Cook, this is all we use. This is the only thing we use.

And I'll show you all the things that an EAN code can give you information on. And there's a standard that's set. But does the health care industry use them? A very, very small percentage. And I'll give you an example of that.

This is a breakdown of an EAN code. This is not everything. I think the decision that has to be made globally again is what information needs to be collected, what do we have to collect?

So far, again, in evaluating all the bar codes out there, the EAN codes back in 2001, 2002, 2003 supplied far more information than the other bar codes that were out there those days.

As you can see, it has an identifier on the front end. It labels every manufacturer. The 00166 is actually a product number. And number 4 is a check digit there on the very end. That's the basics: manufacturer, part number.

That's just basic. If you get into now as you move on down through that code, that's where you get into patient safety. We've talked a lot about the cost-effectiveness and everything, but if you move into this code and what it can do for you -- and when we looked at it, it didn't matter which code it is. I'm not up here saying everybody in the world has got to go to EAN, but this is the kind of data. If you want to help patients and you want to help the health care industry, we've got to get to the lot number level. We've got to get to that unique identifier. I'm sure that any manufacturer in here is going to

stand up and say, "We want to get there, too, because it helps us track our product."

But, as you can see, you have an expiration date of that product. Each one of those things in parentheses is what they call an application indicator. Okay? So it tells what's coming next. You've got a packaging indicator. You actually have what we call a lot number or a batch number down there at the bottom.

There's also an application indicator. And, again, our lot numbers depending on the device, some of them are unique to a singular patient and some of them are built in lots of 100. So this code supports both. Okay?

You can actually get to application indicator 21. I'm not going to get into it but where it actually goes into a very specific unique identifier. It's not on this sheet, but the EAN code is very, very flexible and can support many, many different things, either down to a patient or via lot number if it's a wire guide or a catheter.

Again, when you get to that lot number, that's where if -- just think of a day. Unfortunately, every manufacturer has a recall of some sort, labeling problem or something. Just think of a

day where today currently we as manufacturers supply to the FDA, to every regulatory agency, "Here are the lot numbers affected." It's then our responsibility to notify the user base or the customers.

What a great thing it would be if you talk about patient safety if the FDA or the Canadian government or the European government could work in concert to get those devices back.

That's what a unique identifier system is. Right now it's manufacturers trying to get them back. You know what? I don't think we always get them all back. But if we're all in it for the patient, then if we had this unique identifier system globally, then we all could work together, regulators as well as industry.

Required materials. Just real basically, a cost of an EAN number is dependent upon your sales. So it goes from $750 to $50,000. What I'm trying to show here is if somebody were to start this up, very basically this is what it costs to set up one small, little bitty site.

So if you are a very small manufacturer, you would probably be on the lower end of that scale, $1,000 to get your EAN number, maybe $5,000 for a printer and a scanner, set up 2 hours validation a

week. I mean, it's not that difficult.

Larger-scaled manufacturers, ourselves included, that's going to cost a little bit more. And so all the costs you heard earlier are very, very valid. But when it comes down to helping that patient, let's say some manufacturer somewhere in the world comes up with a great device. They have one device, and they manufacture it. They could do this for this amount of money in an IT implementation.

To go a little bit further into our implementation, again, back in 2001, 2002, and 2003, whenever we chose the market that we went into -- and, again, they weren't all the same -- we would notify the market 3 months in advance.

Some people have said to me or told me internally at the company, "Well, you can't change that because the customer won't like it." And, again, that's where you find out the very small percentage of people who are using the bar codes that you put on your product today because I can probably count on two hands the amount of customers that said, "Help me with this transition."

But we basically notify the marketplace three months in advance, worked with those individual customers that had the problem, then switched over,

helped them switch over their readers.

People think that you have to buy all sorts of new stuff. You don't. The readers are there. The scanners are there most of the time. You have to change what is being read within the hospital.

But, again, there is no unified standard in the United States as well as many other markets in the world that we could standardize all those things to. Okay? And, again, that comes down to what are the trackable or traceable items that should be designed in a system?

The company switchover, I went through that a little bit earlier, but that took -- at each location, we have eight -- about a month to turn that over. And, as you saw earlier, globally that was 12 to 15 months to implement what we call our unique identifier.

The customer switchover, I've got question marks there because some customers use it, but, again, it's a very, very small percentage. So I think it's still ongoing from 2003.

Questions and panel discussion, but this is what it looks like on our label. It's down there at the bottom. You can actually see the EAN code. Again, whether these are read into a system, peeled

off and placed on a patient's chart or whatever, it's the key of identifying the product, the batch number is where safety comes into play.

Thanks.

(Applause.)

MODERATOR KESSLER: Our panelists include Michael Dempsey from Partners Health Care, Lu Figarella from HIBCC, Leighton Hansel from Abbott Laboratories, and John Terwilliger from Global Standards One. And I'll start with Michael.

MR. DEMPSEY: Hi. My name is Mike Dempsey. And in the interest of full disclosure, I have to say that I founded a company five years ago called Radiance that makes an active RFID system that's basically an indoor GPS.

Although I sit in front of you today as a representative for Partners Health Care and I'm not an employee of Radiance anymore, I do have an ongoing relationship with Radiance.

Radiance has deployed approximately 20 to 30 hospital-wide implementations of active RFID systems to track things. So we can talk about that if you're interested, but that's not really what I'm here talking about here today. I'm here representing Partners Health Care.

This summer I made a transition. And I'm spending most of my time working at Partners now. And Partners has something called a positive identification standard. This was work that was started in 2004, so originally started to positively identify patients and drugs to avoid medication errors.

It turns out that the way it was designed was quite flexible, quite XML-like for the software people in the audience. And one of the things that we wanted to do was not only identify the drug but be able to identify dosages and some very specific information about the drug and then use that information to automatically program infusion pumps. So the implication of that is we needed to know what type of infusion pump it was so you could program the infusion pump.

So we started with positively identifying patients and drugs and evolved into identifying infusion pumps. And now the positive standard identifies in patients, identifies patients, employees, drugs, both IV drugs and non-IV drugs, and devices. And, as it has turned out, that has been a pretty powerful tool.

So now a clinician, for example, can walk

up to a vital signs monitor. And there's a 2D bar code on the front of the vital signs monitor. The clinician shoots -- we're using the symbol MC50, which has a bar code reader on it -- shoots that at the bar code on front, on the front of the vital signs monitor. And it's essentially a speed dial.

So it says, "All right. This is a CAS 740 monitor." It isn't normally network connected. But the PDA can connect to it, capture the vital signs, and push it into the electronic medical record.

If she scans, for example, a bag of IV medication in the 2D bar code on the IV bag, there's the appropriate information about what was mixed up, what the concentration is, what the dose rate is, and so on.

Then she can scan a smart infusion pump. And it says, "I know this is an Alaris pump or a Sigma pump" or whatever. The PDA pushes that information directly into the pump. And all the clinician needs to do is just confirm that yes, this is for patient John Doe. This is insulin at this rate.

Notice one of the subtleties in there. There's no ubiquitous network connection that's required to make this happen. So we are in the process of rolling this out. It's not ubiquitous yet

by any means within the Partners Health Care system, but there are some early very positive outcomes of it. So if you want to talk more about it, grab me.

Thank you.

MODERATOR KESSLER: Thank you.

Lu?

MR. FIGARELLA: The accent you hear is the Spanish version of this also available in SAP if you dial.

I am the co-chair of the HIBCC Auto ID Committee. At this stage my wife refers to it as my entrepreneurial stage. I come here not only as sort of the Hair Club for Men, not only as somebody involved in it but also a user.

I'm a co-founder of a surgical video microscope company. And so when Larry mentions things like 510(k)'s, I shiver, although I almost stood when he made the offer, also a company that allows you to print your tickets for events at home. And it kind of spread because my background is really in auto ID.

And I was previously with RVSI ID matrixing vendors, so the data matrix. I showed up there in time to work on this ECC-200, which usually means that you get to raise your hand for a couple of the positions.

Before that, I was with UPS. And, actually, when somebody mentioned 1988, you know, I was actually in a lot of places. Back when I started with UPS, there were no bar codes on the packages. And so I look at all of these things that we refer to as UDI system and data, et cetera. We'll talk a little bit more about this in the afternoon and the technicalities of it.

I look at it the same way that I did at UPS, which is a lot of the stuff, you know, you would be amazed how much push you have in the beginning from some of this stuff and once you make a nurse's job easier, how quickly they become your new best friend if you did make their job easier.

But when somebody looks at a design implementation of UDI, you know, from a HIBCC perspective, I come to tell you that, as we mentioned back in 2002, when the drug bar code was being discussed, that level of uniqueness is really important. You know, you really have got to go all the way this time if you're going to do it and really be able to identify individual items because if you cannot separate one coffee cup from the other coffee cup, you get some benefits, but you are putting people through a lot of work. You might as well get all the

benefits. So a unique or a lot number is going to be a really important element of what we're trying to do here.

Also, you know, we are an ANSI committee at HIBCC, the Auto ID Committee. So, you know, they send you threatening letters if you don't say good things about ANSI.

So at this stage, you know, you have to also -- when we sit here and talk about global standards and all that, we have to take a moment to look at what exists out there and what level of ISO standards are also available that you can sort of piggyback on a number of these things.

You know, auto ID is a link to good data. And it has to be an important part. You know, nobody fears that a UDI message gets garbled, but, as one of the previous panelists mentioned, if you really think that somebody is going to enter 15 numbers and not get it wrong, the dyslexic engineer in the room has to tell you that it is just not going to happen. People can't enter a Zip Code right. Forget 15 digits.

And, finally, you know, I would be remiss to say that, as we mentioned, HIBCC is an option for thousands of labelers of devices. And, you know, you sort of get a little bit of a price break on the

numbers that you saw there. Come see us, and we'll give you the details.

MODERATOR KESSLER: So before Leighton Hansel talks, Leighton has been with Abbott for a few years but for a few centuries before that was at the FDA. And we all worked for Leighton at one point or another. So I'm glad to introduce Leighton Hansel.

MR. HANSEL: Dr. Kessler, thank you for those kind words. You date me.

Even though I work for Abbott, I am here today representing AdvaMed. My thunder was stolen by the last panel, Joe and Paul, the importance of existing standards that are in place. The voluntary process can take time, but it does eventually produce solutions that can endure over time.

Having been involved in the standards process, I am convener of a study group, Workgroup 3, which does symbology. And I never appreciated symbology until I rented a car in Germany last year and the instructions were in German. But, luckily, everything had a symbol on it which I could figure out. So globalization is important, as was mentioned in the last panel.

You know, Dr. Kessler's group is responsible for coordinating the standards activities

at CDRH, but I think that this effort is going to involve nontraditional partners, supply chain, and people that maybe normally aren't part of a regulatory authority's process to have this work because I hear all of these separate groups talking about what they're doing and I'm sitting here wondering, are they talking, you know, are they aware of what everyone else is doing because I think that industry, I think the health care community, there has to be a known strategy of where we are, where we're going so that people can start planning.

I know that when DOD decided to require UPNs, that probably did a lot for getting bar codes on expendable products. Now it's going to take some incentive to have the bar coding utilized beyond the supply chain at the hospital door.

And I think that the work that FDA has done with their two studies last year in the work from ERG, I think they certainly have a good sense of the challenges and the issues. But it's going to take everybody. It just can't be the regulators, the device manufacturers. It's going to take the health care community and other groups that provide support for those groups for this to be successfully moved forward.

MODERATOR KESSLER: Thank you.

John?

MR. TERWILLIGER: It is a real pleasure to be here today. Before I start, I'll probably just give you a little background. One point is I have had the pleasure of being a medical device person in the standards world in both manufacturing and distribution.

And another thing that is really exciting about today is since I have been with GS-1, almost ten years now, we have been talking about the benefits of bar coding for patient safety.

And to actually have a discussion like this is almost like a culmination of ten years of the work. So I really applaud everybody for this because I assure you when we first used those phrases about ten years ago, people used to look at me like, "Are you out of your mind?" I mean, things have changed an awful lot. So I did really want to share that.

A little bit about I am here representing GS-1. I am specifically from GS-1 U.S. here in the United States. I think it is important to recognize that standards for UID per se for medical devices already exist. And they are GS-1 standards. They are broadly implemented.

We have here in the U.S. alone over 18,000 health care members spanning both retail health care, also medical device, medical, surgical, and pharmaceutical, which really is a broad breadth. And then around the world, we have thousands more.

GS-1 is a federation of over 100 member organizations around the world. Each is focused on implementing the same standard. And also our global organization perspective is we develop global standards. We do not develop national standards.

And we have a number of health care groups populated by our members and other users to really do that. So I want to get at that kind of global element.

The other thing I also would like to note from that perspective that UID standards already exist, since the 1970s pharmaceuticals have been identified in the National Drug Code, as mentioned, and bar coded using UPCs, Universal Product Code, which is actually a very simple way to talk about a global trade item number, which has been mentioned in the earlier presentation here.

G-10s are a way to identify products. And G-10s are the most implemented product identification standard in the world, bar none. We estimate over 10

billion transactions are current each and every day around the globe using these standards.

It has also been noted, I think, if you look across medical devices, a great amount, maybe even most, are already identified, bar coding. As Paul Pandiscio mentioned, they are at 90 percent. Other large manufacturers are probably in that range. So much of the stuff is already identified today with the UDI.

I think it's important to recognize what's really common out there is the G-10, which I mentioned before, the global trade item number, lot numbers, and expiration dates. And then things can also be with serial numbers as appropriate. Certain products would not require some number, but we also have a way to do that, too.

I would like to mention one little thing, to make a distinction between identifying items and identifying instances of items. When we start talking about G-10s and lot numbers or product identification, lot expiration date, you're really talking about identifying the product, not the instance of the product. I can't distinguish one glass or another glass, one medical device from the same thing of another one. That really requires some sort of

serialization approach.

Those are two very different issues. So identifying products is actually a very straightforward thing and very relatively inexpensive, as already mentioned. When you move into serialization, the cost starts rising. I actually will come back to that in just a second here.

I think it's also important to note, as mentioned, about some of the benefits of pursuing UDI for the hospitals is really about supply chain efficiency, in addition, of course, to patient safety.

GS-1 standards really do cover all of those various things that hospitals buy and other providers. Please remember that health care providers buy a whole lot more than medical products, includes things such as office products and housekeeping supplies and food service and on and on and on.

And by embracing a broader standard including those, it drives the cost down to implementation and really gives hospitals and other providers an incentive to really capture everything. And that really should not be lost here because the more you can use this investment to read bar codes, et cetera, or RFID tags. It really makes it much cheaper and really gives you kind of end-to-end solution for

hospitals.

Also, as I mentioned, a little about RFID. We have a portion of GS-1 called UPC Global focused at driving implementation of RFID tags for identification, which has really changed significantly how products are identified and really get at the serialization issue of identifying every unique instance very simply because that's the very nature of RFID. It also makes it much easier to collect up data.

One of the down sides of bar codes, of course, is they have to be scanned on a time. RFID would allow us to basically capture this information without really having to scan it per se but kind of run it by the reader and it picks it all up, which can save considerable amounts of effort. And it's really part of a progression of what's occurring in the marketplace cross many products in many industries is bar coding to RFID.

I really think that there is an opportunity for the FDA here to really kind of embrace this concept of identification and really leave it up to industry groups to work through this progression of as things migrate from one data carrier to another bar code for this RFID. I know we're going to talk more

about that this afternoon. I think it's important to recognize that.

I would also like to mention another thing. I think that there's a wonderful opportunity here for the FDA considering rules here to really drive the identification of all medical devices at all levels of packaging.

Now, I would like to fully recognize something, that certainly there is a wide diversity in medical devices in size and criticality, et cetera, et cetera. And also certainly the cost and complexity of identifying items is going to vary a lot, no ifs, ands, or buts about it.

But I think our objective should be to drive wherever possible, and I think also we should recognize that some items, like an individual cotton ball, probably don't justify a bar code. I mean, that would be probably a little silly. We could do it, but I don't know if it gains us an awful lot.

And I really would like to propose that the exception rule that that#s underneath the current bar coding rule for drugs and biologics will be put into place really to allow industry and/or through our health care user groups to come back and propose this exception in certain areas.

I think we certainly are not going to identify today in one single pass incentive, but I think as we work through industry, we really come forth and really put those on the table.

One last thing. Concerning implementation, there has been a lot talked about how hospitals and other health care providers really have not used the bar code that manufacturers put out there. I would like to take a little bit longer view on that.

And, really, by the FDA moving forward with this and ensuring the ubiquity of marketing critical mass really resolves an issue for most system of process. If you don't have everything kind of done one way, it becomes very difficult and you are always working exceptions. So moving forth removes that and will make it much easier to implement.

I think it is also important to recognize when the Universal Product Code came out in the early 1970s, it took over 10 years for it to be broadly adopted in the industry. Now, all of us in this room, for instance, say, "Well, it's always been there." Not really true. It took about ten years to be really ubiquitous.

I will share with you, though, two things.

One, Business Week issued an article in the early '80s that basically said the failure of the UPC. On that one they ate their words. They were very wrong. It just takes a while sometimes. So let's not forget that.

Thank you.

MODERATOR KESSLER: Thank you very much.

I am going to open up the mikes in just a second. I have a couple of questions for the panel. You maybe might want to comment to each other.

Let me start with John at the end. One very technical question and then a more general question. The technical one is, who and how is the G-10 assigned? I'm not sure everybody is familiar with it. I think it would be useful.

And the second question is, you said you are the GS-1 group has established standards working with a wide spectrum of people in the industry. So I want to get some sense of that, not just manufacturers. You're talking about people all the way through the supply chain? Are you also including the distributors? We had a comment before about the distributors. And we haven't talked with them very much about the impact on their process.

This panel is really about implementing.

So talk to me a little bit about it. Talk to me about who is involved and how do we make sure that their processes are factored into the decision-making that we're trying to make from a regulatory and, as people talk about in the first panel, a systems perspective. John?

MR. TERWILLIGER: Absolutely. The number one process for manufacturers and others would be marking items, which includes, actually, distributors will many times have their own private label goods or others, would become a member of their local GS-1 member organizations for those companies based here in the United States to become a member of GS-1 U.S., if they're based on Canada GS-1 Canada, if they're based in the United Kingdom GS-1 U.K. So to become a member, it would be assigned a company prefix that was shown in Mr. Franz's slide that basically identifies your company. Many manufacturers have one or more. Many times they've had more because they purchased other smaller companies. They would then use those to identify their products. So that they become a member.

Part of our processes, to include everybody, some users, would be we have various user groups. We have specific ones at this point in time.

And they come and go as needed. We have the Healthcare User Group, the HUG, which is a global group comprising a lot of leading manufacturers. We have some people in the room here today.

It is also incorporating group purchasing organizations here in the United States that participate. We have had health care providers participating from around the globe. Our recent meeting in Paris we had -- there's a hospital group there from France who was joining in. So they have been involved.

Our standards process is really trying to make sure and include all the various participants in the supply chain or the entire process we're after. If you don't get everybody, it really doesn't work by our practice. We derive consensus-based standards. And I think it has worked out real well.

The other thing is GS-1 if you ask any of the other member organizations work with national groups to help implement standards. For instance, as I mentioned, we have been a very active participant in the Coalition for Health Care E-Standards, CHES. We have actually worked with HIDA, as was mentioned in the past, on their bar coding standards and others.

MODERATOR KESSLER: Thanks.

Let me ask Michael one question. You mentioned that in Partners, you have gotten to the point where the information you collect is specific to certain types of infusion pumps so that you can match the patient with infusion rates and the drug and the pump.

Did that give you any ability -- and this is not meant to be critical, please. There have been, unfortunately, a number of fairly high-profile infusion pump recalls. And this is not a comment about the industry. But has your information allowed you to better identify the pumps and get them off the market or off the floor, change them, update them? Has that been helpful or has it been not part of your system?

MR. DEMPSEY: The primary driver for the positive patient ID standard has not been to do any of what I guess I would call post-market analysis. It's more to prevent errors from happening in the first place.

So, for example, because the positive ID standard identifies patients, employees, devices, and drugs, you can scan a Partners ID badge, scan a patient ID badge at those places where it's implemented, scan a drug, and scan the IV pump itself

and through a local connection ensure that the five rights are matched and, in fact, the pump is programmed correctly.

So this was the evolution of the work from Dr. Nat Simms, who invented the notion of smart pump libraries, keeping track of dose levels from guard rails so if you've got a smart pump that knows that it can't give X amount of morphine, that's a great first step, but the logical progression of that is then how do you get that information into the pump without user error or minimizing the probability of user errors.

MODERATOR KESSLER: I guess I was asking if a company notified your system "There's a class I recall. So we want you to take some of those pumps out of commission," can the scanning of that pump be programmed in? So that when someone is about to use pump X -- I won't mention a company -- the clinician knows that's not one that we really want to be using today.

MR. DEMPSEY: Let me answer that two ways. If we had this system deployed in a ubiquitous way, it could certainly potentially do that because the PDAs that scan the pumps are enterprise class devices so you can push new code down to the PDAs from a server. So you can certainly put that in place.

Let me switch hats from Partners back to Radiance. Radiance makes this active RFID system. And one of the primary purposes of the Radiance system is to do just that. So you can push a button and say, "Here are all of the model XYZ devices and their location within the last ten seconds."

MODERATOR KESSLER: Terrific. Thanks.

And finally, one last question. I think, Leighton, this might be for you, but it could be for Chuck as well. My sense from hearing from Cook earlier, from Johnson and Johnson, the vast, vast majority of the products at some level are already uniquely identified. Sometimes it's in a large package or a palette. Sometimes it's the individual product.

So I guess what I am asking is the following. It sounds like many of the major manufacturers already have systems in place to do identification. But the hospital is now facing multiple systems. They get one system from Cook, 2D. J&J may be maybe single D. They want to employ the Radiance RFID system. And that may work for certain devices, not others.

It sounds to me as if the industry has a wide variety of reasons to identify their product.

But at the moment, they and some of their stakeholders, the hospital community aren't talking the same language.

Is that fair? I'm not trying to be critical, trying to understand the landscape. Leighton?

MR. HANSEL: Well, I think this goes back to my observation needed a vision. If the health care users were aware of what standards were going to be utilized and what the form of the bar code would be, then vendors of bar code reading equipment would make them more adaptable.

I think, now that there is a likelihood that a hospital has a certain application, they buy a reader that will work on that application, some other kind of bar code comes in, of course, their equipment doesn't work.

But I think where technology is going, having reading equipment that could read a lot of different types of bar codes obviously is going to be an advantage in the future.

MR. DEMPSEY: Can I make a comment on that?

MODERATOR KESSLER: Please.

MR. DEMPSEY: We have been putting forward

this notion over the last three or four years of something that we call context-sensitive medicine.

And the important take-away there, as I think it was the first speaker of the day mentioned, there isn't going to be one or I don't believe there is going to be one solution that solves all the problems.

So in some instances, you are going to have 2D bar codes. Others you're going to have data matrix. You'll have linear bar codes. You'll have RFID. You'll have passive and active RFID. And, in fact, even if we put forward standards where we say, "If you have an active RFID, this is the protocol that is going to follow," you still need to be thoughtful on the back end the way these different bits of information get combined at the application layer so, in fact, you can survive vendors going out of business, new vendors coming in, changes in protocols, and, in fact, have it integrated at your IT level, as opposed to the device level.

MR. FRANZ: It is exactly the problem I think that is out there and why customers, you know, don't embrace all of these things because there are so many different things coming at them. And I think globally what we have to get to is what information,

what are the pieces of information that need to be collected. If that can be provided to us on a global scale and on a U.S. scale, any manufacturer is going to conform to that.

Any manufacturer if told will develop an RFID system, will develop a bar code system, will develop whatever that will put things into the supply chain in that manner. We in industry, we in manufacturing have that capability and will conform to that.

So, again, then it makes it possible for the institution, wherever it may be, to -- whether they want to use it or not, then they have a fighting chance at tracking devices and tracking things through their supply chain within their institution.

Again, the standard of what it is, what type of bar code it is, what type of -- if it's RFID or whatever is not really the issue. It is what information do we need to collect and what information do we want to collect, and we'll supply it. And then various systems will be able to read it.

MODERATOR KESSLER: Before John speaks, I want to encourage anybody in the audience to get up at the mikes. After John makes a comment, we will be turning the floor open to you all.

The questions I think have been raised I would love to hear from the audience, what information do you think needs to be collected? What would be of use? What are the high-priority items? What level of packaging should we be talking about in terms of whether it's bar coding, RFID, or some identification?

And a key question for some of you, are there certain types of devices that we're talking about that really fall outside this, that there is no advantage? Is there something that we're missing here for which there is not an advantage to be coding or is there some product that ought to be done tomorrow because it is such high priority?

John?

MR. TERWILLIGER: Yes. Just to back up to talk about the bar coding thing, I would like to definitely echo what Chuck said. It's really not so much about the data carrier, whether it's a bar code or RFID, as it is really about the data. That is the more important piece.

The other thing from a GS-1 system perspective, we make sure and incorporate the same data through all of the various data carriers, which includes both linear bar codes, 2D, and RFID. So there really is a progression here.

And the last little point is that most scanners today will scan almost any of the bar codes. It's really kind of gotten to be a non-issue.

MODERATOR KESSLER: So I want to make sure that is in the record. So your sense so far today is that most scanners that are out there that are in general use, as long as we program it correctly, the issue between 1D and 2D bar codes and other bar coding systems is more or less going away?

MR. TERWILLIGER: I have to be careful. You asked a little different question.

Certainly for people who already have scanners and had them for some time, they probably have a linear scanner. It's a laser scanner, which will not do 2D.

However, if someone were to start today and would go out and buy scanners, they will buy an optical scanner that will both do linear and 2D, basically the same price. Then it's really a non-issue.

And, actually, even laser scanners will scan multiple types of bar code symbols.

MODERATOR KESSLER: Thanks.

If you have been to the mike before, the transcript won't know it. So please re-identify

yourself.

AUDIENCE DISCUSSION

MR. MONROE: I am Napolean Monroe representing Henry Schein.

A follow-up on the previous question. There has been some mention of which products should carry the bar code. I'm not sure the panel can answer. Perhaps if we could have FDA's thoughts or DOD's thoughts or CMS on should each box of rubber gloves or each box of cotton balls carry a bar code?

MODERATOR KESSLER: I'll take more questions from the panel. And then at the end, I'll try and right before we break give you my guess as to what we think we're thinking.

(Laughter.)

MODERATOR KESSLER: Boy, I can't wait to read that, my guess at what we think we're thinking. Can you wind it back? Okay.

Wait. Jay is going to come up. Hang on. Yes?

MS. COOKE: Anne Cooke, Device and Diagnostics Letter. And pardon my ignorance on this. This is fairly complicated. This is a technical writing question that I have.

What I'm looking at up there looks like a

fairly coherent layout graphically, how to present this information. And you mentioned that hospitals were sort of given a variety of code styles maybe from different companies.

And what I'm wondering is, would it be a role for the regulatory bodies to try to help implement at least a standard format for reading these things, rather than having -- I know there's creativity involved in being able to design your own way of doing things.

But, for instance, I have gone to my MSN home page before. And the tech guys at MSN have decided to change up the format. So here I am used to clicking over here, and suddenly all the information is over on the left or whatever. It drives me insane.

I think there's a limit to the, shall we say, effectiveness of creativity and of individualism. And I'm just wondering what sort of is being done to think about not just the data but how it is presented in a way that would minimize misreading by sort of engendering an organizational culture throughout the whole supply chain where everybody is reading the same stuff at the same place in the same order, left, right, et cetera.

Thanks.

MR. FRANZ: I think that is a very, very good point. Even on that label up there, you can see we varied. The EAN code is at the bottom. We have pulled out the very same code for a product code. But certainly a standard that would say, "We would like your RFID, your EAN code," your whatever presented in a certain spot or a certain fashion would only enhance patient care and readability anywhere.

And, again, industry would follow that. I mean, you tell us where to put something from my perspective, you know, we're going to put it right where you tell us.

But it is varied from all the different device manufacturers, you know, into different markets. They're presented different ways. I wish I had it up here, but I could give you a real good visual of what that looks like. I brought it when I talked with David and Jay.

And it really needs to be looked at because if you saw this just board of labels that we all provide in industry, they're all different. They're all different. They're all different shapes, sizes, and so certainly if there could be some standardization or format, that would just add to patient care.

MODERATOR KESSLER: Lu?

MR. FIGARELLA: I think that the only word of caution, having hundreds of thousands of SKUs, is that once again on the theme of English, it gets to be like English. Those of us who learn it as a second language are always taken aback by how many exceptions people have. You know?

(Laughter.)

MR. FIGARELLA: Why would I rule if you're going to have that many exceptions? And that's really what happens. But at the same point, what really I think -- I take the comment very seriously because one comment made about people going out of business and probably being out there or taken over by somebody else, what really matters is that your rules for data have to be rules for data. As John said, you know, your rules for data have to be rules.

What is in that message, the first end character, the second, whatever, that has to be a rule. And then you have after that a bunch of suggestions. And I think in many cases, part of the reason you have so many things that are different is that we as standard setters worry very much about the rules, but a lot of times we need more annexes on those standards about suggestions to do this, do that

because a lot of people are new to their company, they get told, "Make this label." And, you know, if they have some suggestions of what they're supposed to be doing, they probably would make them look a lot like the other ones. And that would help the user.

That is really what happens here, that at the end of the day when you implement a UDI, as I said before, you are going to have a lot of people who never scan or anything, who for the first time get told, "This is part of your job. Enjoy."

MODERATOR KESSLER: I would like to acknowledge the very important comment you made that we have begun to think about, -- and Jay Crowley, whom I am working with, thinks about it quite a lot -- what are the human factors issues here in designing such a system? And it does provide an interesting challenge.

Over here?

MR. SOKOL: Yes. Hi. I'm Brad Sokol, Fast Track Technologies.

Just as a general statement but some affirmation possibly, there are 11 different international nomenclatures that I have looked at for medical devices specifically, not to mention all the private different types of nomenclatures that have been mentioned.

Isn't it more important just to take a look at first how we look at the data, the tag, and maybe have that tag to point to the database of elements or events that you need so that you will be able to have this universal device identifier? Does anybody have any comments on that?

MR. TERWILLIGER: Absolutely. I mean, I think you look at how the standard for G-10 works identifies the product and could point back to a database for all the information about it. In the next session, I know we are going to talk more about that.

And in our world, we would call it the global data synchronization network of various data pools here in the United States. RS would be one synch where that license plate of the G-10 would really point back into the database, would give all sorts of information with many, many attributes and descriptions, et cetera, et cetera, et cetera. That already exists.

MODERATOR KESSLER: And we're looking for very specific input about what the database should look like. We're going to talk about it in a little bit. What are the elements, et cetera?

Leighton has a comment. Do you want to

hear from him first or do you want to make another comment back and forth?

MR. SOKOL: Yes, if I may.

MODERATOR KESSLER: You may.

MR. SOKOL: Dr. Kessler, you basically said something about what should be in this database/tag or labeler. I've got a couple of suggestions but nowhere near as in-depth as this audience could possibly give you. This is just one point of view.

Some of the things that really stand out that probably I would look at in a database component query so the label would point to the database would be software compliance.

You had mentioned before, you alluded to it with remote device maintenance from what Mike Dempsey had brought up. The next thing would be the last date of who it was used in that software compliance, maintenance compliance, again, post-approval.

And one of the things that is sticky for the medical device manufacturing community right now is the possible liability from a standpoint of safety alarms, a one or a two safety alarm. And if you rate it that way and you go for a number two safety alarm,

you're locked. You're not as exposed from a liability standpoint.

However, the type of question that I believe you asked Mr. Dempsey was, you know, can you give us this information because we would like it? Well, I think from a manufacturer and a provider, health care provider aspect, there's got to be a reciprocity in some type of limited liability so that there could be free-flowing communication.

Those are just some of the things that are a little different in the database. I could go on on some things, but I just wanted to give you some particulars that may not be necessarily looked at.

MODERATOR KESSLER: Thank you.

Leighton?

MR. HANSEL: I just wanted to say, you know, I think it will be important to determine what data elements should be tied directly to the bar code and what should go into the database in the way of attributes and so forth.

I think the number of individual devices that are out there will make a database a great challenge to establish and maintain current data with.

MODERATOR KESSLER: I'm going to let you speak in just a second, but I want to ask you about

that. You said it will be a challenge. So is there a reason it's harder for our industry to do it than the grocery manufacturers?

I mean, they are just as cut-throat as we are. What is their advantage about the cereal?

MR. HANSEL: Well, here again, I would imagine if you don't keep it current, then the grocery chains won't sell your product. But even the IG report on drugs pointed out that one of the main private providers of the information has to do a lot of work with the manufacturers to get current data, keep it current, you know, essentially. It's just not something that happens automatically. They indicate there was a fair amount in need of interplay.

MODERATOR KESSLER: Fair.

MS. WORZALA: Good morning. Chantal Worzala from the American Hospital Association. I just wanted to talk a little bit to the question of implementation in hospitals and want to make it clear that hospitals are really quite committed to adopting bar coding and other health IT strategies as part of their commitment to improving patient safety. That is really the goal.

And we did do a survey about a year ago on use of IT and found that hospitals are starting to

adopt bar coding technologies for many, many purposes in labs, in their pharmacy supply chain, and the rest of their supply chain, and also at the bedside for medication administration.

We do, however, have a significant problem when it comes to using bar coding for medication administration in that many of the drugs that come in are not bar coded at the unit of use. And so you're introducing substantial costs and work in the hospital to take things packaged at a larger level and repackage them and put the bar code on the drug. And that's introducing both a cost and a potential place for human error to come in when you're doing that on site repackaging and bar coding of products.

So I think that does point to a lesson that could be learned here, which is it's very important for the unique ID to be put on the unit of use. And obviously there are things like cotton balls where it's not the individual cotton ball.

But if you're talking about something that goes to a patient or touches a patient or affects a patient, really, it does have to be at the unit of use. Otherwise you're introducing more processes in the hospital and potentially increased error.

MODERATOR KESSLER: That's a great

comment. I think the FDA will take that into serious consideration about unit of use. We know the manufacturers, and we have had this discussion. And I hope that AHA will come back to the table repeatedly because clearly if what you heard in the first session, that this is going to have to be a system problem, you are, if not the largest, one of the major stakeholders in the process, in the system. And if it is not taken up by hospitals, it's not going to be a useful system. So clearly we need your cooperation and collaboration. So thanks for the comment.

Any response?

(No response.)

MODERATOR KESSLER: Okay. Jim?

MR. KELLER: Hello, everyone again. I'm Jim Keller from ECRI. And I just wanted to make a comment regarding nomenclature.

One key element that I haven't heard talked about much this morning, and that's a standard medical device term. And so, as, Larry, you well know, FDA puts out a lot of generic notices that may not be a specific or model- specific recall, where a hospital would be required to scan its inventory for just its pumps or its AEDs, as opposed to manual defibrillators and so forth.

And so I just wanted to speak to the value of having a standard medical device name as part of that identifier to assist in that process where, like a generic safety report is out on a class of technologies. And there are other elements that should go with it, too, but I think that is one of the key points to consider.

MODERATOR KESSLER: Thank you.

DR. SLOANE: Professor Elliot Sloane again from Villanova University.

This Pepsi bottle, I buy these at Wal-Mart for about a dime apiece. It has a bar code, has a identifier, a unique identifier, 0339JE0923EX. And I could read that with my hard contact lenses corrected to 20/15.

We have an elder population. We have home care. We have other points of deployment. And to get Dr. Kessler off the hook and maybe off the hot seat for a minute, maybe this panel could talk about where we should set the lower threshold for unique identifiability for medical products.

And, as a context, an historian in the FDA was forced to recall virtually all of the alcohol swabs from the market in some places, 100 percent of the single unit packaged alcohol swabs from the U.S.

market. People couldn't give themselves insulin shots. Physicians couldn't give vaccines or inoculations. And people rediscovered cotton balls and bottles of Ibuprofen.

I would just ask the panel to talk a little bit about what is a rational bottom, where should the bar be? From a dollars and cents standpoint and from a practical standpoint, what can or should be done?

MR. FIGARELLA: Let's start with one correction. That is not a unique idea unless we define this because what you have is every other bottle of Pepsi of that size having the same. And that's really one of the first questions when we're talking here in the beginning. I think somebody mentioned lot number or at least unique.

And what we really are saying when we talk about unique is to identify that bottle of Pepsi versus every other bottle of Pepsi in this room. And when you start doing that, as John did mention, you know, things happen because you start to have your devices have to serialize, et cetera, et cetera.

But at the same point you are correct. You really have to get down to okay. Do I need to -- for example, somebody mentioned gloves. And you

cannot think, "Well, they come in a box of 100 or 25. Let's track the box, but let's not really go into each of the gloves." You know, please, you know.

At the same point I think a lot of the value there is going to be, well, how much is it if we did get to that point where the gloves are important? Well, do we find every glove in the room and throw them away and start from a new box that we know is good, those sort of things that I think are going to drive that.

But I think it is really important at a basic thing to technically understand that when you're talking about a lot batch number or you're talking about a unique ID, we really are talking about identifying each individual bottle of Pepsi in this room and being able to say, "I have the lot you want," almost like open it and see if you have the gift

MR. HINE: Good morning. I'm Matthew Hine with the U.S. Department of Commerce, International Trade Administration.

The last commenter was raising a good point about what happens with products that are out there in the consumer world, knowing that there is a lot of talk about doing a lot more remote telemedicine, remote monitoring of patients and that

kind of thing. How does the issue of this unique device identifier take place with things that are outside of the hospital environment?

Thank you.

MODERATOR KESSLER: One of the issues that we have been struggling with at the FDA over the past couple of years actually has been a myriad of issues related particularly to home care, which is one of the issues you are raising.

We have noticed it's not a surprise to anyone that a lot of technology, high technology, is moving from the bedside into the home environment. The driver, of course, is cost.

Now, we are all left with the problem of how to deal with that because you have, as was mentioned before, individuals, particularly as all of us are an aging population with a lot of technology by the bedside. And can we use these kinds of systems at the home care environment to promote safety? And I think it's a number of questions we have been asking.

I don't think we have easy solutions because we can think about a hospital investing in scanners to make sure they're connecting the dots in electronic health records. And I'm not sure today that works in the home care environment. Maybe it

will.

Other comments?

MR. TERWILLIGER: Well, I guess I would beg to differ. I think, actually, you know, that scanners have gotten so inexpensive there's no reason everybody couldn't have them. Actually, a lot of products, cell phones, will scan bar codes these days. That's become very, very common.

I think another analogy I would also throw out is that to talk about how can it help telecare. Well, you know, I think it's really not a lot different than self-checkout at the registers and stores. And you couldn't do that without a bar code. It would be impossible for people to do self-checkout.

And I think the opportunity for assistance to check, indeed, that the patient scanned the right item, if they got a couple of them, they could verify and a check could be put in place is very, very powerful. And it's really part of all about patient safety.

MODERATOR KESSLER: Michael?

MR. DEMPSEY: Yes, one comment. You know, we seem to be making a technological assumption that a unique ID is a bar code or an RFID. And I appreciate

that theoretically that is not correct.

So, for example, any medical device, whether it's in the home or in a hospital, could have a unique ID. And that unique ID could be communicated to other machines and not necessarily require anyone to scan anything or do anything special.

So if grandma is at home with a home congestive heart failure system that's measuring her weight every day, well, the unique ID of that scale can be sent over the modem without her needing to do anything.

So, really, I think that the objective is to have a unique ID for medical devices. And I think wherever there is a medical device, there should be a unique ID.

MODERATOR KESSLER: Thanks.

We are getting close to lunch. So we will take the four questioners up here. And then we'll do some lunch break.

MR. PERRIN: Dick Perrin from Advantech and from the Health Care Supply Chain Standards Coalition.

Mike, I would ask the question. I noted recently that Radiance and Partners, Brigham's and Women's Hospital, in fact, is expanding the capability

of that system for medical equipment tracking. And I would ask whether that was done predominantly from the perspective of patient safety or whether the drivers were for control of the assets and what the other benefits are to drive that process going forward.

And then I would ask the other panelists to speak to the issues of potential benefits beyond the issues of patient safety, as to how they see that in their segments of industry as to benefitting their logistics and supply chain management activities.

Thank you.

DR. WHITE: Sure. Partners Health Care is obviously an integrated delivery network with a bunch of hospitals. Brigham and Women's is one of those hospitals. They're deploying the Radiance system for logistics and asset tracking, for finding the devices, for recalling the devices, if necessary, having nurses be able to locate them more easily. A secondary benefit is patient safety.

However, Mass. General has also deployed Radiance. And they are using it more for patient safety.

MR. GOLDMAN: My name is Julian Goldman. I am an anesthesiologist and member of Partners Health Care Biomedical Engineering.

I stood up here to make some comments that Mike ended up making or alluding to, but I think there is a central theme here that we have to remember, which is we're getting ahead of ourselves if we start to talk about specific technology without thinking about use cases. And if we start to think about use cases or clinical scenarios that exist today, we also have to be careful because they are limited due to the absence of technology.

So we have a chicken and egg problem here. We have to very carefully ask the potential users of the systems what would they do differently and what could they do differently if the technology existed.

So, for example, the ability to look at devices on a network and identify them using a unique ID is something that would have pervasive implications.

If you were to ask users today "How are you using the system like that?" they would all give you a blank look and say, "What do you mean? We can't do that today.#

And so someone could come away from an answer like that and say, "Well, you see, it has no value." Well, in fact, that would be foolish. But those are the things that happen routinely when

questions are asked the wrong way.

So a number of things that came up in this session could be distilled down to asking in a different way what are the use cases and how would you divide those between clinical benefits, either safety or health care efficiency, what are the supply chain benefits in terms of economic benefits, and what is the relationship between those two. And there are substantial relationships between those two.

Thank you.

MR. SCHULMAN: Seth Schulman again.

I think my question, actually, is very similar to a lot of the comments that have come up most recently for the panel. I was also particularly interested in Dr. Kessler's response from the FDA perspective.

I realize it's very difficult to get into a great level of detail of all the work that has happened up to this meeting from the FDA perspective, CMS, all of the other partners who have been working on this.

But I am interested to think of -- what I am hearing today is a lot of the conceptual arguments and conclusions about what information would be necessary, what the potential benefits from safety,

efficiency, cost reduction, et cetera, are.

And I guess my question is, has this really been looked at since it is such a big program with many different implications and honestly many different uses from supply chain benefits to recall benefits, et cetera? Have all of these uses for the UDIs actually maybe even been process-mapped out?

And I think that from the device perspective of quality control, where companies will set up manufacturing processes and say, "Hey, you know, this is great. It's really efficient," you come back and you look at it. And it's a mean sigma of six sigma, et cetera. And you look through a process map, and you realize you're touching the product 20 times when you really could be doing it 10 times if you had looked at it earlier and said what really is necessary.

So I know, again, I think I would restate that maybe we are putting the cart before the horse a little bit in saying, "Do we really understand how the products and the information flows through each of these systems, whether it's supply chain, necessary information for recall, how it's touched," to really define what information is really necessary to effectively perform all of those goals of this system

and to really maybe limit or really truly identify what the important information needs to be included. Has that happened or is this the beginning of that process?

MODERATOR KESSLER: This is the middle of that process, actually. I wanted to answer simply just no and then let's go to lunch, but I can't do that. I'll make a couple of comments to that.

If the panel wants to take any of that on before I make a comment, then I will do my comment, and we'll go to lunch. John, you talked a lot. We'll do Chuck.

MR. TERWILLIGER: Sure.

MR. FRANZ: I think that to answer that -- and it goes back to a question that was asked earlier. And that is, what is the bare minimum?

And, again, it's been reiterated throughout the panel. And that is, you have got to get to the batch number. You have got to get to the lot number. You have got to get to the unique identifier.

And that is the lot number. It's not the UPC code that's on the bottle of Pepsi. If we are to help, you know, the supply chain -- okay? -- or if we are to help patient safety, we have got to start at a

bare minimum.

And I think Larry was saying no, we haven't started yet. There are available systems out there, whether it be RFID, whether it be anything. And we need to start someplace in gathering that information. Then the benefits will expand.

But today we're confusing the marketplace. I mean, we as industry are confusing the marketplace everywhere in the world. We're not adding benefit. It's not used.

It can be. Certain systems are using it. But we're different than J&J, different than Abbott, different than everyplace else. And we need this, you know, if you look on a global basis. We just need it. As an industry, we need it.

And so at the bare minimum, if you're going to get to that unique identifier, it's going to be down to the batch level. And, again, whether that is something that's implanted into a patient or whether that is a box of gloves, that is the kind of information that we need to be talking about in the very beginning.

MR. FRANZ: I think, by definition, a UID is going to be a small amount of data. And it's really what you've gotten is all of these sort of

attributes, other information, has to be stored in a database elsewhere. There is just no way to carry that along effectively on the product. It just doesn't work that way.

And I also share from kind of our experience over a 30-year window the type of data captured with 30 years ago, what that points to, the UPC, is very different today. And it has gotten bigger and bigger and bigger. So I think there is a natural progression there, and it cannot really be encoded directly.

MODERATOR KESSLER: Leighton?

MR. HANSEL: I was just going to say that is one of the questions you have out for public comment as to what the minimum data set should be. And I think it's important for anyone who is planning on commenting to address that and I think probably give them some reasons why each of those elements are important.

MODERATOR KESSLER: Along those lines, one of the comments made by one of the members here who came to a meeting recently of the FDA, which I thought was outstanding, was not only do we have to think of the costs and benefits of the entire system for unique device identification but for each data element. It

has its own costs and benefits. So that's part of the things we're thinking about.

Let me try and address your question, are we at the beginning or the end. We're in the middle of our deliberation. And I'm hoping that this meeting will bring us from the middle to the 90th percentile so that over the next couple of months, not years, we can take this to the final step and begin crafting the system that will make sense for all of us.

I need to comment about a couple of things. Although we started to think about how the entire system would work, the Food and Drug Administration we recognize is built on a series of laws which provides our regulatory purview but also bounds it.

So one of the challenges we have will be to work with the hospital industry because we do not regulate them. So even if tomorrow I tell Chuck and Leighton, "This is the system you will use" and I am allowed to do so and I put it in regulation and they'll do it, if the hospital doesn't do it, I can't do much about that.

So this is really going to be a very important issue for us to think through the entire system and work with our partners. It's one of the

reasons we have brought to the table not only ourselves but the VA, the Veterans' Administration; the big provider of health care, the Department of Defense; Center for Medicare; Medicaid; and AHRQ. So it's important for us to try and think through this system, but we're in the middle, not at the end, of that process.

But the FDA, even if we make a decision, still has limitations on our regulatory responsibilities in our purview. So that's just sort of a fact of law. And I just want to make sure that is clear that we recognize that.

I really want to make a very brief comment about what I think a couple of people said, particularly Julian. We really should be thinking about the system three and five and seven years down the road, not today.

What we can and can't do today is very different than what people put in place five and ten years ago. And the systems are moving very fast. So we really should think about the potential system and particularly public health benefits that we could get from a system if we put it into place with the right time frame.

We have talked to industry a lot. And one

of the things they have told us in cost is that the cost to industry, for example, will vary dramatically by the amount of time we have to ramp up. The shorter the ramp-up, the more expensive. The longer the ramp-up, the less expensive, not free necessarily but much less expensive. You're talking about a horizon of three to five years versus a horizon of one to two.

That's part of the thing that we have to decide here. If you heard from Dr. Woodcock earlier that if in five years she is still sitting in the chair as Deputy Commissioner of the FDA, maybe she will be Commissioner of the FDA, and someone asks her, "Gee, what can we read in medical records for all medical products?" The answer, "Not much, won't go very far."

So I think the agency is thinking our horizon is in three to five years to have something significant done. But what is going to be done and the possibilities and realizing the benefit of those possibilities is one of the reasons we're having this debate.

I have some specific thoughts I'll mention later about where the FDA is in its thinking. I'll reserve those after we go through one or both of the next panels.

We are going to thank the panel in just a minute. We're going to have lunch. It's now 10 after 12:00. I would like you to be back here promptly at 1:30. And we will convene or the next panel. 1:15? How about 1:20? Give them five extra minutes. You'll need it.

(Laughter.)

MODERATOR KESSLER: 1:20. Thank the panel, please.

(Applause.)

(Whereupon, a luncheon recess was taken at 12:13 p.m.)

A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

(1:27 p.m.)

MODERATOR KESSLER: Hello. This is the third panel of the day. And as we told you, we're trying where we can to possibly do some partnering; in particular, with the Department of Defense.

We have had some outstanding collaboration with Kathleen Garvin. I'm pleased to introduce her, have her talk about the product data utility information that they have been thinking about for the last few years.

Thanks, Kathleen.

(Applause.)

MS. GARVIN: Thanks, Dr. Kessler, for inviting me to speak and participate on the panel. I'm truly honored to be here to talk about this very important topic.

THE DEVELOPMENT, MAINTENANCE, AND USE OF A REPOSITORY

PANEL DISCUSSION

MS. GARVIN: I'm here to represent the medical logistics community within DOD and also our Veterans Administration partners. My cohort at VA is here somewhere: Michelle. So we have been working jointly on this data synchronization product data

utility initiative.

And thirdly, I have been collaborating for the last few years very closely with the Coalition for Health Care E-Standards. And this is one of their major initiatives: the implementation of a product data utility.

Health care supply chain data is broken. And there are significant impacts. A senior executive from a well-known large manufacturer talked to one of our working groups and said the problem is in the B with the billions of dollars.

He said he can recognize from his place where he sits what the impacts are. When he stratifies that across the industry and across all of health care, it's incredibly significant. We have been working on trying to resolve that issue.

So today I am going to talk a little bit about why DOD is involved. We made a significant investment in dollars, both DOD and VA. And we're not just talking the talk. We are walking the walk. We have built, and we continue to refine a proof of principal pilot, product data utility, for the health care industry.

I will talk a little bit about product data utility and how we think it can be part of the

solution for UDI and also the relationship of good data to the patient safety issue.

Why do we get involved to begin with? Well, three years ago when we were deployed to Iraq and a little bit before that Afghanistan, we had some pretty big challenges.

The drug side of the house was okay. Everybody was using the NDC. Things seemed to move pretty quickly. But in med surge, it was a little bit harder.

So number one, my reason for getting involved was contingency and wartime operations. That is DOD's number one mission: to support the soldier in the field.

We recognize, however, that we can improve. The improvement in supply chain efficiencies would filter down to our peacetime operations, which are about 200 hospitals worldwide, and reduce the cost of health care delivery in DOD.

Now, the arrow at the bottom was not part of our original mission, but it's easy to see and recognize the relationship to this data to patient safety, as I will talk about a little bit later.

So why do we have a problem with deployments? First of all, it's not just readiness,

go to war, Iraq, and Afghanistan. We also have to respond to natural disasters, like Katrina and the tsunami. We work with various organizations, very short notice, and expected very quick deliveries.

When these things occur, we are inundated with requests. And the requests have inconsistent, inaccurate, and duplicative data in product numbers, in product names, product descriptions, and product packaging. This slows us down more than we would like.

We do resource-intensive cross-referencing, banging databases together here and there, to figure out what exactly is it that they want before we can source it. We think that a PDU will increase our efficiency and improve our response time.

And by the way, we're not the only ones who are getting inconsistent, inaccurate, duplicative data. From working with industry, we see that the problem is pervasive.

So how did we arrive at the solution of a product data utility? Leighton Hansel earlier today from Abbott/AdvaMed talked about DOD and the UPN. Yes, in the early '90s, we attempted to establish a universal product number for med surge items.

And although the assignment of numbers

ranged anywhere from 60 to 90 percent, as Paul Pandiscio mentioned, J&J has 90 percent of its items assigned to the unit of use, but that assignment, the unit of use, is not standardized. And the UPNs aren't being used consistently throughout the health care supply chain.

So just going after UPNs was not the solution. And we stepped back and rethought and said there needs to be a systemic way of making sure that these standards get released throughout the industry.

Well, the lesson learned from us was the grocery industry. The first time they went out many, many years ago, they said, "Well, we'll just assign these numbers. Everybody will use them. And everything will be fine." Wrong. They had to go back to the drawing board. And they had to get together a product data utility-like place where the data could be centralized, synchronized.

So PDU is a system that interconnects all the trading partners. We're talking about core data and standardizing on that core data, making sure it's distributed throughout the entire supply chain.

I've focused on the word "utility," not repository. A utility indicates an active process that needs to occur to ensure that everyone's data is

the same. A repository, which we already have several of in our industry, is just databases where data sits.

So here is a, when I say "notional," really notional, idea of a product data utility, very simplistic. The important thing is manufacturers on the left. Our model says manufacturers should be the source of the data and the truth of the data. Other models in the industry are different. They use algorithms to determine the truth, whatever. We say manufacturers own the data, and it should come from them.

The second premise is that the utility should be overseen by a supply chain board of governors. And the utility, as I mentioned, is active. It will actually take the data from the manufacturers and pull it in, make sure it's complete, synchronize it, perform audits, validate it. And it won't go out until it's certified, won't be distributed out to everyone until it's certified according to the standards agreed to.

Now, I'm not saying that the PDU is the answer for the FDA's UDI program. However, there are many data elements, standard data elements, that will be shared in UDI, as they are in many other programs. And I see the health care data utility as one of the

sources to feed the FDA's UDI.

Following over towards the right, the data leaves the health care product data utility to aggregators, exchanges, distributors, GPOs. Ultimately it goes to the hospitals.

I would like you to take a look down at the bottom there. Why do we have Wal-Mart and retail down there? What do they have to do with anything?

Many of our manufacturers in health care are already sending data through a very similar process on their consumer side to be able to sell to Wal-Mart and CVS, et cetera, et cetera, et cetera. So this is not really a new thing for most manufacturers. They already use this process.

Okay. We're looking at the principles of a product data utility. This is not complete, but there were some bullets that I pulled from an industry PDU feasibility study that was conducted in 2003.

It was a joint effort between CHES and HCEC. You can find it on either Web site. But it wasn't just CHES and HCEC conducting it. There were representatives from across the entire supply chain who participated.

One of the idea principles here is some of the things I mentioned already. It should be open and

neutral so that everyone can participate. It should be a nonprofit headed by a governing body that will promote industry standards with appropriate security and confidentiality, a pricing model that will just cover costs, hence nonprofit. And it won't process order transactions.

So what is the minimum data set? Talk about notional. This is just kind of a made-up. Whoever you ask, they say minimum data. It could be 50 fields, 30 fields, 10 fields, 100 fields.

I think we got up in our technical advisory group to hundreds of fields when everybody in the supply chain gave their input. But there are certain minimal key data that are shared by almost everyone. And some of them are nomenclature, manufacturer, name, part number.

Universal product number I'm using there. And I kind of made up myself potentially an extension for serialization. I don't know how that would happen, but I understand serialization is necessary in some of the devices. So potentially there might be a way. It could be another bullet or it could be part of that. So anyway, these are the things that we think are probably minimum with lots more.

Another question that was raised in the

package that I got for discussion today was what other data would improve patient safety? Certainly we have heard from the VA and others certain things that are important to them to be included in our product data utility, like whether or not it's sterile, whether it contains latex, is it reusable.

The medical safety data sheets issue we resolved by something we called in our pilot med item link. And what we have done there is we have a URL where if you're ordering an item from an ordering page, you have the product up there. We have the URL there that connects directly to the manufacturer's Web site for that product.

So you're looking. And you say, "Gee, I need more information than this database and our ordering system carry." Hit the URL, and you can see everything the manufacturer has to say about that item from MSDS to all the other technical information that they supply. So that's one way we got around that issue. And a couple of others that I stole: MRI-incompatible and allergic reactions from David Racene's briefing.

So would the minimum data set differ for different service devices? Well, I guess it would depend on what you call minimum. For example, there

are different categories. And I just threw three up there. Well, you've got implants. You've got consumables. You've got equipment. And there are many, many other categories, as the FDA will determine.

You may say, "Well, yes, we need different information here than there, than there." However, I contend that across every one of those categories, you're going to have some data that's going to be alike. And that's the minimum data that could be shared in a PDU.

What does good data give you? These are taken from a working group roundtable saying, "What do you want out of this kind of thing?" And when you look at some of these things, many of them point to patient safety.

I was reading an article in Health Care Purchasing News written by a nurse, who said reducing costs in the supply chain to her automatically applies to the patient because there is more money that can be devoted to patient safety issues, a thought.

Reducing clinical frustration. Yes. Every time that nurse has to go and track down an item, instead of taking care of her patient, that's a patient safety issue.

Improving speed of delivery. Every time the right device or product is not delivered and the doc is standing in the OR saying, "Where is it?" that's a patient safety issue. Either you delay the surgery or you substitute.

Analysis. Data. Well, data is it. Data is king these days. And hospitals don't have enough of it to be able to do their jobs, like recalls. We heard this morning many times about the manual efforts, going through paper to try to pull out data for recalls. And hospitals would love to get their arms around spend analysis to find the products that are most efficacious to practice.

Some more information about the right data and how it benefits patient safety, but before I get into that, this is one of my favorite quotes. It's from the New York Times in June of 2000. The title of the article was "A Choice for the Heart."

"Even as the use of expensive devices, like artificial knees and defibrillators expands rapidly, patients and doctors get less information about products that are implanted in their bodies than consumers get on the safety and performance of their cars." It's quite a statement.

So the right information. We're looking

for products with best outcomes, those that contribute to infections and adverse events, easier recall, locating unsafe items, tracking devices in patients, tracking critical equipment so you have better utilization and you don't have to buy 10 of those, maybe you can get away with eight, and as we mentioned earlier, sterile, non-sterile, et cetera, et cetera.

Dr. Kessler mentioned earlier that there are other federal programs. And DOD has its own unique identification program. It's not medical. It's DOD-wide. DOD also has their own RFID program that's not medical. It's DOD-wide. And each one of those is a separate and distinct program.

Homeland Security has just announced that they have a unique identification program. I don't think any of the three have talked to each other so far.

And then we have up and coming FDA UDI, again a separate and distinct federal requirement to impose upon the manufacturers. And not lastly but just most importantly, as we heard from our colleague from Villanova, EHR is up and coming. And we're going to need a way to have in the patient record exactly what was implanted in or used on a patient. And it had better be accurate because so far the data doesn't

prove to be terribly accurate.

So we need consistent and accurate data to implement each of these. Wouldn't it be a great idea if we could agree on the core data elements across DOD, FDA, Homeland Security, et cetera, et cetera, et cetera? We think there would be much greater efficiencies across the supply chain.

So yes, it's all about collaboration, leveraging existing knowledge and expertise in the industry, partnering where it makes the most sense, both across the supply chain and in the federal government and supply chain/federal government, along with the standards organizations. We think the medical product data utility is the vehicle to get there.

So what is next? Fix the broken data. It will facilitate patient safety. We need to gain commitment and consensus from the supply chain and government organizations and execute an industry PDU.

It should be industry-funded and sponsored. The government can't do it alone. And we think that this would be a solution that would meet the needs of all health care participants. Mandatory FDA UDI initiative can help drive this.

Thank you for your attention.

(Applause.)

MODERATOR KESSLER: Thanks, Kathleen.

So the focus if you haven't figured it out of this session is development, maintenance, and use of maybe utility, not repository, for UDI or unique device identification. So we're going to try and ask the questions about what are those data elements?

Kathleen, I don't know if you mentioned it, but at one point, your group had thought about how many elements belong in this utility, in this arena. And I think you had gotten up to 120 or a couple hundred. So not many of us think of it as a minimum data set, but I think we would talk about some of that in the next few minutes.

So I am going to introduce the panel: Steve Stemkowski from Premier. To his right is Jonathan Sherman, also the Department of Defense; Jon White again, I think still wearing the Jon White hat this time, still; and then Randy Levin from the FDA. So Steven?

MR. STEMKOWSKI: Hi. I hope everybody had a good lunch. They never got to us at our table. So we're still waiting for the cake outside.

I am with Premier. And I work in the health care informatics group within Premier. So I

come at this issue a little bit differently from the supply chain management issues that UDI raises.

The health care informatics group at Premier does a couple of things. They work predominantly with our hospitals in the alliance to facilitate their comparative analysis by using a large data repository of hospital billing and administrative and other types of data and associated consulting services.

And the second part of what informatics is up to is where I come in. And that is in our pharmaceutical research services group. This group conducts surveillance and outcome studies predominantly with the pharmaceutical companies and to some extent the medical device industry as well.

And in the course of the last several weeks, I had been asked to look into some of the medical devices themselves. The patient safety issue is where I think most of this comes down.

And that is the question we were asked at this point was, can you identify a device that was administered to a patient using your data set in a retrospective manner?

So several weeks ago, we began exploring that opportunity and looked at several products. We

looked at cardiac rhythm management devices. We looked at stents. We looked at some surgical adhesion gels and so forth. And one of the products we ended up with, and this is probably the biggest example of why a minimum data set is so important, is a certain surgical mesh product that was the subject of a Class I recall.

You saw that diagram from Kathleen's PowerPoint that showed the disconnect between hospitals and the data aggregators and the suppliers.

It became readily apparent as we began looking at all of this data that hospitals may receive bar coded product, but none of it or very little of it ever makes its way into the hospitals' internal data systems.

And so when we looked at this particular surgical mesh product, we had to go not to our standard definitions for these things, which would have been nice and more reliable, but we had to go actually to the hospital charge masters themselves.

And I was looking at data for over 400 hospitals and ultimately ended up with about 40 or so hospitals that actually had enough information in their charge description master to tell me that that was the product that was recalled. And from that, we

had an estimated 50 or so discharges that we believe were administered the product after the date of recall.

So I think the reason that this happened is because of that disconnect between the hospitals and the other end of the supply chain and even the middle parts when it comes to distributors because these hospitals set up a charge master to facilitate their billing and charging to insurers and to patients. It doesn't always reflect exactly what was in there.

And so you know, there may have been more patients that receive these products. I don't know. But without a minimum data set, I can't make any further assessment than that.

I think there is enough indication in the work that we have done, and this is preliminary so far. We haven't made any attempt yet to look at whether these patients had any more adverse outcomes than other patients like them, but without this standardization in hospital data, in particular, or in the device data that is used, we can't make those assessments.

And so the points earlier today were we need to do these studies. And absolutely we do. I

think there is enough indication that would warrant moving further down the path to make those studies possible.

So that's how I come at this. I think there is a considerable patient safety issue that we can do a better job of surveillance on products that are already on the marketplace, we can help hospitals determine what sort of effectiveness various products have. And I think that the minimum data set is essential to that function.

One of the questions we were asked to address was, what does this minimum data set look like? Kathleen gave a pretty good answer to that question. There were a few items that I would have suggested. One would be adding the serial number for products that are serialed, expiration dates, lot numbers. And I think it's important when we look at this to have some standard way of classifying the devices.

I think we talked about this earlier this morning, but I would like to reiterate that point, understanding how a particular device fits into the scheme of patient care and what other devices that are similar in approach I think is essential to making some of these comparisons.

As for where this information is obtained, I think we all agree. I think the manufacturers would agree. It seems from what I have heard today that there is every interest in the part of the device manufacturers to supply information about their product to some level of standard.

I think that that is where it needs to start. The key is to how that transfers down the rest of the supply chain and ultimately makes it to the hospital, which is going to be where it is critical.

MODERATOR KESSLER: Thanks.

MR. SHERMAN: Hi. My name is Jonathan Sherman. I work for the Defense Medical Logistics Standard Support Program Office. We have developed and fielded an automated information system that is used at, it's an automated logistics system that's used at 168 Department of Defense sites.

We have been managing equipment for property and maintenance purposes by assigning a unique item identification to every item that comes into the hospital. And this is done automatically by the automated system, which we call DMLSS, Defense Medical Logistics Standard Support system.

And this number is unique, though, only to that facility. When an item is transferred between

facilities and is picked up at the other hospital, the DMLSS system gives it a new number.

We are also right now in the middle of implementing the DOD unique identification program, which will provide a unique identification for that piece of equipment across the entire enterprise and throughout its life cycle. There are a couple of gentlemen here from the UID program office. They may speak at the microphone. I'm not sure.

And as I said, we are at 168 sites around the world. As we are implementing the DOD-unique item identification program, we are making some modifications to our existing system.

We are upgrading our bar code scanners to read the two-dimensional data matrix bar code, which is the DOD-required bar code for that program. And the requirement is to have the manufacturers of those equipment items eventually create the unique item identifier. And when/if the item is sold to the Department of Defense, the information on the unique item identifier along with a number of data attributes, some required, some not, which would constitute a minimum data set for the Department of Defense, will be registered by the manufacturer into the DOD item unique identification registry.

Addressing the issue of minimum data set, repositories, registries, those types of things, one of the things that we are looking for in the Department of Defense in the military health system is the ability to automatically populate our catalogue records, our property records, and our maintenance records with accurate, clean, and current data. And the only way that this can happen is through an industry product data utility that is maintained by the manufacturer with the most current data possible. And that in terms of supply chain management is something that the Department of Defense military health system really would like to see happen.

I don't need to address minimum data set. It's already been articulated. But I also participate in a bar code workgroup within the military health system that has been looking at point of delivery of medicine within the hospital using a bar code system.

And just to give you some idea, we have been working on that for over a year now, trying to determine how best to do this and implement it. Recently it has been expanded to look at use of bar code and other automated information technology across the entire hospital, you know, where should bar codes

be used besides delivery of medicine at the bedside. So the military health system is continuing to pursue that as well. This information, of course, is vital to that.

Another interesting point is that the DOD military health system has a single organization that receives and consolidates recall notices for the Department of Defense and sends those out through various electronic means to all of our medical facilities. And of course, once we receive them, again, it becomes a manually intensive search for those items and to ensure that we're actually looking at the correct item. And of course, what we're talking about working on here today would significantly speed up that process.

Thank you.

MODERATOR KESSLER: Thank you.

Jon?

DR. WHITE: Good afternoon. Good afternoon.

MODERATOR KESSLER: Good afternoon.

DR. WHITE: Thank you. Postprandial stupor sets in.

I am back and have been listening to the presentations with great interest. And I have been

thinking about the scope of what we have been asked to talk about as a panel. And I know that the good Dr. Levin, next to me, is going to talk about drugs.

So I want to talk to you about something that perhaps hasn't been touched on but was a very important and exciting part of my medical training: federal process. That's a joke. Okay. All right. Live crowd.

And here is why I bring up the subject of federal process. I think what I am hearing from the group today is there is some commitment to a collaborative process. Do you think that is accurate, a collaborative process between to move forward with making this work for everybody and work for all the various different stakeholders? And when you talk about health care, it's a really big group of stakeholders with very diverse needs.

I am going to reflect back to you some processes in which I have been involved federally that have been collaborative and have been meant to be collaborative from the get-go for my colleagues at FDA and for you all as industry to consider for ways that you might go forward with doing this.

I mentioned the e-prescribing standards projects earlier today. The Medicare Modernization

Act in 2003 said that there have got to be prescribing standards to make a long story short.

The way that moved forward was NCBHS, National Committee for Bio and Health Statistics, held hearings for a period of time, I think it was a year and a half or two years, something like that, about the status of electronic prescribing and standards that existed out there and did a very thorough job of collecting that information and made recommendations to the Secretary about initial standards and standards that ought to be tested in keeping with the Medicare Modernization Act.

CMS proposed a regulation. It was adopted for initial standards. We at AHRQ were given the opportunity to work with CMS to start a number of projects, which were grants, which had been industry and academics and health care providers working together to take a look at these standards and to feed back some reasonable data, not just about what works and what doesn't, but what's the impact of adopting these things. And that information is going to be coming out in the near future. And there will be another round of proposed rulemaking.

Another process I have been involved in was alluded to earlier today. It was the AHIC, which

is the American Health Information Community. And this is moving forward standardization of health IT and electronic health records.

Basically, the Secretary created a FACA committee, the American Health Information Community, which goes out, solicits use cases, and then has workers that work through the use cases and come back and make recommendations to the Secretary. Okay? That's a different way to do it.

Another process that I am involved with is the ACQA, or Ambulatory Care Quality Alliance. This is, if you can imagine this, America's Health Insurance Plans, the American College of Physicians, the American Academy of Family Physicians, and AHRQ, so the government, doctors, and payers convening this. It's quite a crowd. And the meetings are very exciting. That is somewhat outside of the federal process but has federal involvement. Okay?

The topic of the talk that we're talking about today is "Development, Maintenance, and Use." Okay? We've talked about uses, talked about some specific products that exist. We've talked about maintenance. But the development, and not just the technical development but the process development, is going to be key. And as you move forward with this

and we move forward with it, it's something that you want to consider carefully.

So thanks.

MODERATOR KESSLER: Randy?

DR. LEVIN: I'm the token drug person from the FDA. As I've been listening to the discussion, a lot of the topics and the issues are very similar to what we have been hearing and that drug issues or drug listing process, very much the same. And with discussion inside the FDA between devices and drugs, we're seeing that there's a lot of collaboration that we can do just within FDA with our standards and with our processes so that we can collaborate and reduce our resources and improve our efficiency.

The drug activity has been also part of a larger collaboration between a lot of the government partners. We have developed a federal medication terminology standard that takes into account drug models from three different agencies: from RxNorm, from National Library of Medicine, the National Drug File; reference terminology from the VA; and the structure product labeling and drug listing from the FDA.

And we have been working with the National Cancer Institute; Enterprise Vocabulary Services; and

of course, AHRQ in this activity to get this moving. And AHRQ has been providing tremendous support for us to help put this forward.

We have also been working with standards development organizations, Health Level 7, and the National Council for Prescription Drug Products in this activity. We have just recently joined the ISO Technical Committee on Health Informatics, TC-215, and working on their Working Group 6 on pharmaceutical and medicines. There is also a working group in that technical committee for device nomenclature and activity there.

Also, there is International Regulators Association for Devices of the Global Harmonization Task Force, but for drug groups, there is the International Conference on Harmonization for Human Pharmaceuticals. And there is one for veterinary medicine as well. And we have been working in those areas on harmonizing for our drug listing activities.

We have been working on drug listing since the '60s. So we have a long history of this. It doesn't start with, Medicare started this activity for Medicare reimbursement. That was the purpose for the National Drug Code.

Over the years, the requirements have

grown. And the use of the National Drug Code has grown as well. Recently, just recently, we published a proposed regulation to change our drug listing regulation to bring the National Drug Code up into be a more robust identifier.

I think that some people have talked about how there are problems with the National Drug Code. And we have just proposed regulation changes to change that.

A lot of the requirements for the National Drug Code is the same thing that has been talked about here, you know, what data do you collect, what is a drug, what is a device, that type of question. The use cases for the National Drug Code and other identifiers has grown to include identification at the proprietary level, so the brand name at the non-proprietary level, at the generic level, as well as even at the part level or the ingredient level.

So there are a lot of increased requirements in use cases as well as the serialization of drugs and the pedigree. I think someone had mentioned that earlier as well.

So those are all looking at expanding and we're looking at, one, our proposed regulation to address many of those issues as well as other

regulations, other activities to address these different requirements.

One of the issues that we found out; that is, that we need to have very well-defined rules to establish to work on these requirements, and we need to define what is a product. And that's a lot of the activity that you're talking about here.

And what level do you assign the code? I think someone brought up earlier about that unit of use to assign a code, a product identifier at that level. We have addressed that in our proposed rule as well.

Also, once you define the rules, you need to have a central authority that will help people follow the rules. We did have rules in our past regulations, but the manufacturers were generating the codes. And some were following the rules or have interpreted the rules in various ways. So there are a lot of inconsistencies on how people were defining what the drug product was.

So in our proposed rule, we're proposing that the FDA be a central authority for assigning the National Drug Code so that we can follow those rules and enforce those rules.

In our international discussions with our

other regulations, they're looking at the other regulators doing something similar, where each region would assign a code to their products. And then using a way that we could identify where each code comes from, what region, we can have an international code.

We have been working on standards for exchanging this information. A standard that we have developed in Health Level 7 is called the structured product labeling. This is a standard that includes both the content of the labeling information as well as this drug listing information. And we're looking at this standard to be used for other products that the FDA regulates.

And we have also been developing terminology standards, as I mentioned earlier, federal medication terminology standards. One standard that was developed is a unique ingredient identifier that, again, goes across all FDA-regulated products that provide identifiers for products, whether it be human drug, animal drug, or food, dietary supplement, et cetera.

After looking at the rules and developing the standards, we worked on systems so that we can automate this process and that we move from our paper-based process to an electronic process and then

work on a way to distribute the information, in which we have partnered with the National Library of Medicine to distribute the structured product labeling with all the drug listing information through a site called the DailyMed, where we would provide up-to-date information about the products. As they change, you update the structured product labeling with the listing information and put it onto the site.

Then it is a standardized format. This is an XML machine-readable format. And the health information suppliers can take that information, download it, and then use it in their systems to bring it forward to the health care community.

MODERATOR KESSLER: Thank you.

I'm going to ask you all a question in a second. I'm going to ask Randy a question now and let you think about it for a minute while I'm asking them something. We think of you as much more than a token from the drugs folks. Really, Randy, you need to know that.

Really, we actually think of you as a potential important partner in this, a critical partner, especially because we just I think have begun to see the revolution of drug-device combinations. And I think all the more reason that we should be

thinking together about this system.

I'm going to ask you if you could name a couple of lessons that you have learned, been through the wars that you have been with the drug system, that we can make sure that we're taking on board as we think for the future.

So why don't you think about it for a minute? And then I'm going to ask you all if you can contribute to addressing a couple of the questions that these folks have begun to talk about and want to extend it. Should a code if it exists be human-readable or is that not necessarily an important feature of what we're thinking about? That's been something we have been debating.

We have also been asking whether any unique identifier should have intelligence, meaning it should have information in those digits that can be utilized by the practitioner directly. That's not necessarily part of some of these codes, but it's something we have been thinking through.

And then we want to ask a little bit about what are those minimum data items? I think Kathleen has already suggested some. Is there something we're missing? Is there something pivotal that you think is really important? Is it very important for a certain

type of device and not others? That would be fine to mention as well.

So now I'm going to give you a few seconds to think. Randy, a couple of lessons learned?

DR. LEVIN: Well, I tried to go over some things that we felt were real important. And I think a lot of that is what you are addressing here, is that you need to define what's the purpose of what you're trying to accomplish and that we develop the use cases and then the data elements based on that.

So when we went and talked to the different groups, they were talking about using for electronic prescribing all sorts of different activities. And some were prescribing at the proprietary level. Some were at the generic level. And they want the ingredient level, too.

So gathering those kinds of requirements and then the other what we have learned over the years with the drug listing is that it needs to be done centrally.

There needs to be a central authority for this because as it's sort of a voluntary, not voluntary. People have to list for the drug products, but people forget to list, they are late on listing. And no one in the United States today has a

comprehensive list of these national drug codes as a result. So that's a major problem. The identifier was not robust because of this lack of a central authority who could reinforce all the rules that you define.

When a product changes, if you change an ingredient, you're going to change your product at your code. And if some companies interpreted it differently, that means you couldn't determine what your identifier really stood for. So we figured you need rules and you need this to enforce those rules and then the standards. You need a standard way to exchange the information.

MODERATOR KESSLER: It is interesting you raise that. And I invite you all to get up to the mikes while I'm commenting back with Randy. I think those are great lessons.

One of the struggles we have in medical devices has to do with a topic like software. So medical device software takes a lot of different types. Some software is an independent device, but much software actually is embedded in the device.

So the device looks and acts like a pacemaker can. The software in it runs it. A company will change the software. They haven't changed the

device, but the software version has changed. That's critical information. These are problems that you haven't had to face in drugs but things that we have to figure out how to solve.

DR. LEVIN: Yes. Clearly, the activity in drugs is much simpler than the challenge you have in devices, but the issues are very similar.

Another issue that we had is that we didn't figure that when we provide this information on the product, we're not the experts to know the best ways, all the ways that it can be used, and that the different, we want to partner with the health information suppliers, make the information available, no cost, in a standardized format so anyone could then take that information, put it into their systems, provide the value added, and address the customers' needs, which, you know, the FDA wouldn't have to address all of those needs.

MODERATOR KESSLER: Comments from the floor?

AUDIENCE DISCUSSION

MS. BERMAN: I want to ask you a question.

MODERATOR KESSLER: First identify yourself, please.

MS. BERMAN: Hi. I'm Sandy Berman. I

work with the FDA. And I'm on the Home Health Care Committee.

When Dr. Kessler asked about should it be human-readable, my question is, is this going to be a universal code or symbols because I know when we look at health literacy and how many different types of instructions we need on labels, it's very difficult.

And I know just in Montgomery County, there are over 364 languages spoken here. So it's going to be very interesting to see how you're going to do this if you're going to do this on a global nature.

And one other thing I want to mention since I am on the Home Health Care Committee, we're looking at medical devices that have migrated from the hospital or clinical setting into the home environment.

And a lot of times when these devices go into the home, they really weren't studied. I guess there was a lot of clinical data in the home environment. A lot of it is in the hospital type of setting.

So it's really difficult for us to capture that type of information about what is going on in the home. And some thoughts were to maybe have this user

identification code or nomenclature on the device.

And that way a patient could either call in if there was an unusual incident or reported for an MDR reporting, medical device reporting. And that way our committee or even the agency can get information or feedback on what exactly is going on into the home.

So if you would like to make any comments on that?

DR. LEVIN: At least from the drug perspective, again, in our proposed regulations, we are proposing that the National Drug Code be on every label so that people could use that information to have access to additional information that the original national drug code was actually three different codes. One was a labeler who was labeling the product. One is for the product. And one is for the packaging.

But these codes themselves really didn't have any meaning within themselves. So you would have to go and access information elsewhere to find out what the codes stood for.

MR. SHERMAN: And that goes along with what Dr. Kessler mentioned earlier, whether this is going to be a smart number that can convey some information about the piece of equipment or whether it

would be a dumb number, which then would lead you to have to access the database of attributes in order to determine what that item actually is, who manufactured it, et cetera.

MODERATOR KESSLER: I think the home health care issue is really very challenging for us. I didn't realize 364 languages were spoken. You said in Montgomery County?

MS. BERMAN: Yes.

MODERATOR KESSLER: Three hundred sixty-four? Are you including FDA languages in that?

(Laughter.)

MODERATOR KESSLER: FDA-speak?

MS. BERMAN: Montgomery County is a very diverse county. And I think it is because we have a lot of military people stationed here and a lot of people from the embassies here.

MODERATOR KESSLER: I'll repeat what she said. She is just saying that Montgomery County is a very diverse community, principally because of some of the transient nature of the military around here, so 364 languages.

I don't think we have thought all the way through that, but we recognize it as an important challenge. Thanks, Sandy.

DR. HENSTEN: Thank you.

Arne Hensten from Norway again. There are two issues that I think I would like to see considered here in the minimum data sets because the regulatory requirements are different in the various countries.

The European Medical Devices Directive has safety issues, both for the patient, also for the users, which would be a different regulation here, I guess. And also what we are seeing now very heavily promoted in Europe is in the kind of environmental issue that could be part of the product when it's destroyed or when you're using it.

So when we talk about minimum data sets, I think the number is going to grow indefinitely, but I would like to see if you do have some kind of plan or a system if you would like to include also the international perspective for the occupational problems and for the environmental part.

MODERATOR KESSLER: So let me ask you a question about that. In terms of environmental problems, I think, actually, we have a requirement in the FDA if we are going to promulgate a regulation, we actually have a little section where we have to think through environmental consequences.

So you're suggesting that somewhere in the

data system, I'm not sure it would be in the number, you would be able to access whether disposal of that kind of equipment or device would have environmental impact.

Is that what you're asking?

DR. HENSTEN: Yes.

MODERATOR KESSLER: Okay. And then explain more about the occupational risk issue. What are you expecting or hoping to see in the data set?

DR. HENSTEN: Well, after working for 30 years with the various reactions to dental materials, what we have to see in the first place to see the reactions is in the occupational people, in occupation with allergies or that kind of reaction.

So you need to be able to have identification of the product for that reason also because otherwise you have got 250 implant manufacturers or 250 amalgam manufacturers. If you do have a better system of identifying the various products, you could minimize the number somewhat.

But we do see the occupational problems as a very important issue. And for the European Medical Devices Directive, that is written into the directive very clearly, the risk-benefit also for the user.

MODERATOR KESSLER: Thanks.

Okay. It looks like we're having a slow moment. That's fine. Is break ready? Okay. So we're going to take a brief break. It's about 2:15. Break until 2:30.

Just so you know, we're going to come back, do the last panel. Then people who have asked to make presentations will be given a brief period of time with their presentations. And we'll do a wrap-up. So 15 minutes, please.

Thank you.

(Whereupon, the foregoing matter went off the record at 2:20 p.m. and went back on the record at 2:40 p.m.)

MODERATOR KESSLER: Home stretch. We're going to talk now with the last panel about the use of automatic identification technologies. And we're starting to address, again, some more technical issues.

I am pleased to present one of my good friends and colleagues: Jim Keller from ECRI. He will begin with the first presentation. And we'll go on from there.

Thank you.

THE USE OF AUTOMATIC IDENTIFICATION TECHNOLOGIES

PANEL DISCUSSION

MR. KELLER: Good afternoon, everyone. Thanks, Dr. Kessler. It's really nice to be here today. And I think this is an important topic that we all are learning a lot from today from the different comments from the folks today.

I was asked to do a couple of things to start off this panel. I'm going to provide just a little bit of background, some ECRI perspectives on the topic, and then also to briefly review the ECRI white paper, the white paper that ECRI produced for FDA. And I will provide you a link to that. And then we can go into the panel discussion.

Just real quickly, ECRI is an organization that has been around for a long time. And some of the things that we have done that are relevant to today's discussion have to do with the problem reporting system for medical devices that we have been running for about 35 years. We have been for about the same amount of time running a program to disseminate hazard and recall information related to medical devices.

And then we also have developed and maintained a universal medical device nomenclature system that is a naming convention for all types of medical devices, from reagents to Band-Aids to a picture archiving and communications system.

Some of the slides that I have will have been touched on today. I was thinking as we got to the end of the day, some of the subject matter has been covered a couple of different times. But from ECRI's point of view, there's clearly potential value, significant potential value, in using a unique identifier for medical devices and in the patient safety realm, obviously assisting with recalls, tracking medical devices, incidents, helping to identify incompatible or counterfeit devices -- we heard a little bit about the counterfeit devices earlier today, I think -- and then in the inventory management area.

I was reminded of one of my DOD colleagues, who told me a number of years ago when they were looking at inventories across the Department of Defense during the Y2K days, when they were trying to determine whether or not there were any Y2K incompatibility problems with the medical devices in their inventories, one of the folks that I have worked with said, "I didn't know that there were so many different ways to name a defibrillator." And I think just within one database within an institution, there were multiple names for a defibrillator.

And also getting to some of the values of

having unique identifier: cost containment. And clearly you can help improve the supply chain. You can ideally improve on costs.

Some of the challenges we have heard about, the diversity among different types of devices to be identified. And even within a device category, that's a challenge. So using a defibrillator as an example, is the device a manual defibrillator or an automated defibrillator? With a pulse oximeter, is it a standard pulse oximeter or is it a pulse oximeter with motion artifact rejection?

And then another question is, is this thing a device, a drug-eluting stent? How are you going to handle that? And then diversity among the different types of identification technologies, we have been hearing a lot about bar code and RFID. And I'll touch on some of the other things that are out there that are intended to do some of the same things that the RFID technology will do.

Nonstandard approach to device identification and inventory management across institutions. And I remember back in the Y2K days when ECRI was helping hospitals to review inventories, I couldn't believe how many different terms were used for different devices within those inventories. And

then you have to think about the fact that hospitals have multiple inventories within their own institution.

So a computerized maintenance management system is an application that's used in the clinical engineering department that has much of the capital equipment inventory but not necessarily all of the inventory. And then you have the materials management database. And then you have a separate database that might be used in a purchasing area or a database in the radiology department and so forth. So there is a lot of complexity. And all of this ties into high potential costs for implementation of the system.

Quickly, to review the white paper that was produced by ECRI for FDA. First off, the most important piece of information is the third bullet. And that's the link to that document. And that is on the FDA Web site.

The white paper was commissioned by FDA for ECRI to provide an extensive overview on automatic identification of medical devices. We did an extensive review of the available literature and provided an overview of the different types of identification technologies that could be considered for this application and then provided some commentary

from ECRI.

The white paper is organized with a technology overview. So we covered an overview of bar code identification systems and then described the RFID systems. There was detailed discussion of automatic identification technologies for medical devices.

So we surveyed who is using the technology, how it is being used, potential benefits for the different types of technologies. You will find information in the document on stakeholders' position statements that do exist related to this topic, relevant standards, existing classifications for unique identifiers, discussion about nomenclature, and what type of elements are built into nomenclature, et cetera.

And so some of the content, as I said before, described the bar code identification technologies and pointed to the fact that these are valuable but have some limitations in that they're a line of sight reader with a limited range so someone has to walk around the hospital with a hand-held reader to get the information that you need.

Clearly they are widely adopted and are the first choice in terms of reading a unique

identification number on a product. And they're relatively expensive.

Regarding radiofrequency identification, ECRI is in the middle of doing a comparative study of some of the technologies in this class. And one of the first things that we realized as we were naming what we were going to write about in the publication data research is going to be in is it's not just RFID. We're doing a review of asset-tracking systems for medical devices. And as we started to do some of the research and evaluation work, we realized that there were multiple different methods for doing the same kind of thing.

So there's RFID. There are wi-fi systems. There are ultra-wide band systems. There are systems out there that use IR in combination with RFID. And then there is an ultrasound-based system. So there's a variety of technologies that are in this classification.

With the RFID-type technology, it's a new and emerging technology that can be used over a wide range within the health care facility, but the cost for the tags and the readers and the associated software can be relatively high, especially compared to the bar coding systems.

Some of the perspectives from ECRI regarding the topic of unique identification have to do with the varying sizes of medical devices and the different types that are out there, sterilization and disinfection, issues of reusable medical devices, and should you be labeling the packaging or the device itself. If you're labeling the packaging and you're talking about a reusable medical device, then that is gone.

I've done many medical device accident investigations over the years since I have been working at ECRI. And one of the most common problems that we run into is when you go in and do an investigation in the hospital to find out what happened, frequently the packaging for the device is gone. And that is, the identifying information for that device is gone.

There is a growing number of devices with built-in software and interconnections. Dr. Kessler referred to that. And from one day to the next, computer-based medical devices is not going to be the same thing.

A medical device manufacturer may push out a patch to correct a bug or they may push out a patch to correct a security issue. And then a patient

monitor, for example, may be completely different from one day to another because it's a modular-based device. And it may have pulse oximetry in it as an adjunct piece of monitoring and then may have entitled CO2 added to it. So these devices will be changing over time.

Some of the things we need to think about in terms of applying a unique identifier -- and we heard about this earlier -- is whether or not to apply human-readable versus a machine-readable identifier.

And then I touched on the fact that there is rapid evolution of the reader technologies. And you're not going to be able to establish one reader technology and have that stick for a number of years going forward.

So additional perspectives. Automatic identification of medical devices has tremendous potential. The diversity on a variety of levels is going to make universal implementation of this very difficult and costly. And one of the things that might be considered is to address high-value technologies first. And what I mean by high-value technologies is things that have the most patient safety implications, for example.

So infusion pumps are an example

technology that might be looked at first from a unique identifier and how a classification or a requirement from FDA to touch on infusion pumps and maybe implantible devices, things where there is high risk, where the patient may die if the device fails and then see how that works and then evolve it to be more widespread.

So some of the facts that the rapid evolution of the identification technologies is going to limit your ability to standardize on one method may allow us to address a small number of devices first for unique identification, get it right on a small number of devices, and then expand it beyond the rest of the system or to the rest of the different technology devices.

So, with that, I'm going to pass it on to Dr. Kessler and the rest of the panel and for discussion. Thank you very much.

MODERATOR KESSLER: Thank you, Jim.

(Applause.)

MODERATOR KESSLER: I'm going to ask Julian Goldman of Partners to speak first. I'm just going to stand up. And we'll try to keep them to 20-30 minutes.

DR. GOLDMAN: This was a last-minute

suggestion so that, instead of just reading a page of notes, I would project it. I don't have any slides, just a quick set of notes. There we go, almost like magic or like interoperability.

Well, my name is Julian Goldman. I'm an anesthesiologist at Mass. General Hospital. I am a physician adviser to Partners Health Care Biomedical Engineering.

I have been also directing a program on medical device interoperability for the last few years. And that program has been coordinated with many of the folks in the audience as a part of the broad collaboration.

That is moving all over. Sorry. We have been working on a program. I'm going to try to fix that so no one gets too dizzy. Is that okay?

We have been working on a program on the operating room of the future that opened in the Summer of 2002, which has given us an opportunity to try many innovative technologies in a clinical environment.

The OR of the future is sort of like a living laboratory for technology. We don't do experimental surgery, but we do have a chance to use many devices, such as rolling out an indoor positioning system using active RFID, innovative

RF-based cabinets for storing devices, and many things like that.

I just organized my thoughts here in this document. And so I would like to share it with you. The first thing I would like to point out is to share the mission for Partners Health Care Biomedical Engineering, which, to paraphrase, is that no patient shall be harmed by any medical device.

And so we have to keep remembering that our business here really is to take care of patients. It may be to improve the quality of the delivery of health care. It may be to reduce adverse events. It may be all the different things that we know that we can do, but we certainly want to keep remembering that that is the purpose. It's to prevent that, prevent harm, and to help heal disease.

So what is the goal of this work in unique medical device ID? From our perspective, this is one piece of the puzzle. You have to take a systems view. And this provides a capability to support other solutions in the health care systems base.

Which devices should it apply to? I don't know the answer but probably all devices above a certain threshold, certain threshold for risk, for cost, for size. And that will be figured out. The

military I think has done that with a $5,000 price tag or something like that. So that will get sorted out but probably for most devices.

But don't forget that we're not only talking about the hospital. As it was mentioned in previous conversations or presentations today entering Q&A, there is a dramatic movement of caring for patients in the home environment.

And when we see the kinds of activities that are coming together, such as the Continual Health Alliance, which was formed in June of this year, now has, I believe, 50 or so companies that are members of continuum, pushing for a logo compliance of interoperability, there is a need to inventory devices in the patient's home.

And a use case was mentioned earlier by someone who had a comment that there are hundreds of languages and how will we deal with that. I don't know the answer to that, but I want to point that out as the kind of question that needs to be captured as a use case.

The use case is an example of a patient at home who speaks another language who may have to read a devices ID and then report that. Is that a valid case? I don't know. If it's just a number, does it

make it easier to do that? I'm not sure. Is the solution to take a photograph and to e-mail it? I don't know.

But I think that most of the time, as technology moves forward, it will be reading the information automatically over the network. We won't be asking people to report back a 30-digit string in a language that we don't understand or over a poor connection.

Do we need this process? Do we need FDA leadership? Well, can we just do this on our own? Well, we are doing it on our own. We're doing it on our own in our hospital. People are doing it on their own hospital.

We buy devices. We apply new numbers and new stickers. We bind the things together in our homegrown database. And it's terribly inefficient, and it's a good source for errors. And it prevents the collection of data at a national level for national investigations and for pursuing potential device problems nationally.

So sure, we can do it ourselves. And we can keep doing it poorly. It's as if we didn't have Social Security numbers or passport numbers.

We also have the potential problem of

having the same serial number from two different manufacturers. And then we have to sort out the difference. So for all the reasons that anyone who knows anything about databases knows, yes, we can do it, but it's a bad idea.

Now, how many devices are we talking about? Well, I don't know the universe of medical devices, but I can provide some numbers for you. Let me scroll down to bring that up higher on the page. There's a reason that people use PowerPoint, instead of Word.

The Partners Health Service Health Care manages 33,918 devices as of September of 2005. Those are the numbers of medical devices we actively track. It does not include implants and things like that. It's things that biomedical engineering tracks in our database.

Last week we had a scientific exhibit at the American Society of Anesthesiologists' annual meeting. As part of that exhibit, which was a collaboration of a number of interested parties helping to move medical device interoperability forward, Kaiser Permanente presented data for the first time in a public forum. And they disclosed that they managed 300,000 medical devices. Again, this is

just management from a biomedical engineering perspective.

Let's talk about the benefits and applications of this type of technology or this type of infrastructure. Well, unique medical device ID is a key element of a larger infrastructure. And many applications will be part of a framework that require UID functionality to be effective.

We have been using indoor positioning system technology to track patients, to track things, to look at associations between things. And Mike Dempsey talked about that this morning. Well, naturally it's pretty difficult to use that if you can't identify the things initially and bind them together in the database.

We need to be able to support preventive maintenance and servicing of devices. It is tremendously difficult to find devices and then be sure that they have been upgraded and one is compliant for JCAHO purposes.

Now, one of the key messages I would like to leave you with is the need for this work to be driven by requirements. And a good requirement was the example from earlier today. And we have been working on obtaining clinical requirements over the

last two years from clinical groups and from clinical engineers in various national forums.

I took a look in our database to try to pull out some of the clinical requirements that I thought fit with the discussion today. And here are eight of them. And they're not all unique. Some of them apply to the discussions that we have had.

Number one is the need for device IDs to support network medical device systems that are to support safe networking of medical devices to accomplish new tasks; for example, for safe medication administration or to verify that an IV pump that is being used as part of that system actually is a device that can support that use because, for example, some infusion devices aren't accurate and within certain infusion ranges.

And those things are known ahead of time. And one can prevent potential errors or adverse events just by making sure that the wrong device isn't selected for an application.

Number two, to verify device patches and upgrades are performed correctly, this is a major challenge for us now in the hospital.

Number three, closed loop control. Closed loop control using physiological data, closed loop

control, for example, to improve the safety of PCA opioid administration, you know, push the button, get the pain shot on the hospital ward.

That system is a system fraught with problems. And patients are being injured. That was a focus at a Anesthesia Patient Safety Foundation meeting a week ago. And to do that well, we have to network devices together. And then we have to know the capabilities of those devices, if they can support the algorithms that will be used clinically.

Number four, we all have discussed that there is a need for comprehensive population of the electronic medical record. And the need for that is to support many activities, including, of course, CQI.

Automated inventory for system readiness. It would be very helpful if one could look at a hospital inventory, rapidly take a snapshot, identify the devices that are in use. And then if Hurricane Katrina is bearing down on that hospital, we know which devices have to be set up elsewhere to support that patient population; again, very difficult to do today but quite possible if we can interrogate over the network, ID the devices, and know what is being used, identify devices that are being used in the wrong environment, integrate IPS, indoor positioning

systems -- I mentioned that before -- and also to find urgently needed devices. Believe it or not, this is a big problem.

You need a pacemaker quickly somewhere in the hospital. You need to be able to find it. One way to do that is by having unique IDs on the devices and tying that in with another system. Again, that's a system problem. It's a system solution. This is an element of the system.

In terms of specific technologies, I don't have specific recommendations except to say we have tried a bunch of them: active and passive RFID and various solutions. And that is not for us to think about today.

In conclusion, --

(Laughter.)

DR. GOLDMAN: -- the demand for interoperability to improve patient safety and health care efficiency can benefit greatly from unique medical device IDs. I think it's time for us to act. And, like Legos, it's a matter of producing the building blocks and then letting other people build the solutions. And we have to look forward. We have to be innovative. And, frankly, I think that the FDA can provide significant leadership in this area,

Larry.

Thank you very much.

(Applause.)

MODERATOR KESSLER: Thank you.

The rest of the panel includes Ilisa Bernstein from the Office of Policy at FDA; Ann Ferriter from the Office of Device Evaluation at FDA; and, again, two familiar faces: John Terwilliger and Lu Figarella.

Ilisa?

MS. BERNSTEIN: Thank you. Hi. Thank you for inviting me here today.

I know Randy on the last panel said that he was a token drug person. He was actually the token drug guy. I'm the token drug girl here. So my experience in this area is with drugs. And I'll tell you a little bit about it.

I'm sorry. Unfortunately, I was unable to attend the earlier part of this meeting. And I don't want to repeat anything. So the two areas in the drug side of FDA that were using these technologies is for the bar code rule and for electronic pedigree or for pedigrees for creating a chain of custody for a drug or a document or a chain of custody document.

So for the bar code rule -- did you cover

that already? No? Well, I'll just briefly give a brief overview. What the bar code rule does is it went into effect in 2004. And, as of April of 2006, all drugs that are used, prescription drugs that are used in hospitals and OTC drugs that are used in hospitals pursuant to an order or a prescription, have to have a bar code.

In the rule, we required, at a minimum, a linear bar code. At the time when we were doing the proposed rule and the final rule, the only information that we had when we did the economic analysis, the cost-benefit came out in favor of a linear bar code at the time.

We had said in the proposed rule that at some point once the bar code rule is in effect, we're going to look at other automatic identification technologies and look at their use as well. And right now it may be a little too early to evaluate that now that that April 2006 went into place, but we'll probably start thinking about this very shortly.

In the area for pedigree, I know this is mostly a device crowd. So, just in summary, there is a pedigree requirement for prescription drugs that for certain wholesale distributions of prescription drugs, not all wholesalers have to pass a pedigree. And I

won't go into the whole thing. That would be a whole other two hours here. But for certain wholesale distributions, a pedigree has to be passed. The regulations and the law do not specify whether it's a paper pedigree or an electronic pedigree.

In 2004, FDA put together a big counterfeit drug task force to look at the issue of counterfeit drugs in the drug supply chain and to identify vulnerabilities in the drug supply chain and try and identify ways that we can minimize those vulnerabilities to create a safe and secure supply chain.

One of the key elements of that initiative was it was calling for a widespread use of an electronic pedigree for all transactions involving drugs from the time it leaves a manufacturer all the way until it gets to a pharmacy. We have no requirements here, but this is what we called for as our action plan for the drug supply community to put this in place.

And so we put out a report. And we have said this many times in several reports -- it's all on FDA's Web page at www.fda.gov/counterfeit -- that in order to get to an e-pedigree, the most promising technology is RFID. But that's not the only way to

get there.

So we have said that other technologies, auto-identification technologies, could be useful. But we are putting a lot of effort in trying to move the pharmaceutical community and manufacturers, wholesalers, and pharmacies to use RFID. But the ultimate goal here is an e-pedigree. So that you have a document that shows who has had that drug and in the supply chain as it moved.

And so just an update on where that is in the drug side, there is a great deal of effort by UPC Global within the UPC global community to create standards from an electronic pedigree for track and trace, for use of RFID on drugs, prescription drugs.

There are a number of pharmaceutical companies who already have put some tags, RFID tags, on individual units. And the key here is mass serialization so that each individual product would have its own unique number, just like you're talking about here.

And there is still talk about doing standards. As many of you know, we're not there yet, but this is the ultimate goal. And there is a lot of effort moving in that direction to get there.

We at FDA are very hopeful that if we all

work together to get there, that this would be useful and extremely beneficial to secure our drug supply chain.

So I'll stop there.

MR. FERRITER: Hello. I am Anne Ferriter. And I work in the Center for Devices. So this is our device meeting to talk about unique device identifiers, but there are device identifiers already in use in the market.

There are bar codes and RFID on many things. Bar codes are present on almost all medical device labeling and packaging. It's also used on patient identification bracelets.

RFID devices have been cleared through the 510(k) process. There are two patient identification devices: implantible VeriChip and the adhesive Surge chip. RFID is also integrated into medical devices, like wireless monitors, for device identification.

So the technology is being used, not in a standard way, but it's out there. RFID is also used on health care-related items that aren't considered medical devices. There's been some work on blood bag tagging, for example, with RFID to limit the number of incorrect transfusions.

Through our 513(g) process, we have

decided that that is not a medical device. And neither is a device inventory cabinet. But CDRH is looking at these uses of RFID and keeping an eye on how they are being used in the hospitals.

We realize that one solution isn't going to fit all devices. It's unlikely that FDA is going to ask resorbable suture manufacturers to put an RFID chip on a resorbable suture, but something like an MRI machine, it wouldn't make sense to have the RFID on the packaging or any unique identifier.

Even given that we're going to have to go a lot of different directions on medical device labeling, we do want to be compatible with both the Center for Drugs, with DOD, and with EPC standards. So we are talking to all of these people to learn what is going on.

MODERATOR KESSLER: Thanks.

MR. TERWILLIGER: I'm back. A little bit about automatic identification technologies. I want to back up on one point, and that is, why do we do it? And this is something I think most people maybe haven't thought through.

The reason we do automatic identification technologies, whether or not it's bar coding or RFID, is about accurate data capture. That's why we do

this. It's not about pretty art work.

Also, another way I like to think about it is if you think any process includes the phrases, "Write it down, and someone is going to keypunch it in," what it really, really says is, I'm going to scribble it so no one can read it, and I'm going to keypunch it in wrong again, again, and again.

So if we think we're going to get to correct data in electronic health records that involve anything about people typing data in, we're sorely, sorely mistaken. And that's really what automatic identification technology is about. And I think, particularly for products used for patient care, it's really about capturing them automatically. And I think we should be very focused on that.

Also, there's been a lot of discussion here about I know marking things. I know a couple of providers or end-users talk about we mark them ourselves. How sad. I don't know how else to phrase that because the manufacturer is the absolute cheapest place to put on automatic identification technology. Anyplace else in the supply chain is very expensive. It's just orders of magnitude more. So I think that's one we should all keep in mind.

Another thing I would like to share with

you, I am unaware of any broadly implemented AIT application that uses lots of data. So, actually, we are the data carries all sorts of stuff or even smart numbers, shall we say, again, broadly implemented.

Most all of them, even that I'm aware of, use more of a kind of a license plate approach, where it's kind of an identifier pointing back to data. It is very difficult and expensive to carry lots of data in an AIT approach. It's just not done that way.

And, like I said, I am absolutely unaware of any broadly implemented system that works like that. So I would like to share that, which really comes down to this idea of smart numbers. Smart numbers ultimately fail, ultimately, ultimately fail. And I wouldn't use the word "dumb" numbers. Unintelligent. They're really license plates back to the real data.

And I think nothing we have mentioned earlier -- the data points back to changes over time. I think, as the community becomes more sophisticated, things get added on. And things that used to be important will drop off. So I think that's important. And if you're bar coding all of that, it will always never be right.

I think another thing I would like to

point out, the creativity in automatic identification technology is not an objective here. I really would like to put this forth. Mass adoption implementation, that's the objective. Unfortunately, the world is littered with AIT technologies. Our providers have great fun doing it, but they aren't broadly implemented. It's not what we're after here. So I'll throw that out.

And then probably the last little thing, I really would like to encourage the FDA to promote the adoption of existing standards -- you made mention of a few of them -- which really runs kind of our product identification lot numbers, expiration dates, and serial numbers, and let the community work through the various standards processes to adopt new automatic identification technologies as they evolve because there is no way that the rule will ever keep up with what is going on in the industry. And I think that the industry is in a good position to really better reflect over a longer time frame what is the best approach to collect data.

And, last but not least, our health care user group, the HUG, as I mentioned earlier, has been very focused on many of these issues. And we actually have a road map for actually working through these.

So many of the things that you talked about, like what data should be bar coded and actually some of the automatic identification technologies, we are really kind of reevaluating to make sure we haven't missed anything. So much of that is actually going on today.

Thank you.

MODERATOR KESSLER: Thanks.

Lu?

MR. FIGARELLA: Last time they told me to project. So hopefully you can hear me.

I think the points are well-made. You hear sort of a theme of "Well, we tried this system" or "that system." When you look at the use of auto ID technology, I think you have to -- and it was said before. I'll reiterate it. You have to separate the data from the data carrier. I think the data carrier is all of the things that we talked about here, whether it's RFID or 1D bar code or 2D bar code.

You know, for a while, one of my previous jobs, they had a joke about the color of blue, which was every two months, it seemed a new two-dimensional bar code was invented, you know, because it was better than the other one.

And the answer is that always continues to happen. You want the standards that exist, you know,

all the work that we have done with ISO and other places, not just here but in Europe and other places. You really want those standards to tell you how to carry the -- not necessarily to have smart numbers but to have a good rationale for how you came up to what your unique identification is, rather than just, you know, from 1,000 to 2,000, you got those. Those things are I think well-understood, well-done.

Somebody mentioned in a previous presentation the whole UID effort at the DOD, where they clipped it off at $5,000. But they've done a tremendous service for all of us because part of what the DOD did is essentially say, "Okay. These are the issuing agencies for this UIDs."

And GS-1 is one of them. HIBCC is another. Dun and Bradstreet is another. These are people who have a data identifier that essentially allows you to use.

As mentioned by somebody before, it's a triad. Think of it as 1D bar code, 2D bar codes, or RFID as those three legs of the stool. And you decide which one you're going to use for a particular application.

That's really my message to the FDA. I think that we have to look at solutions that allow, if

possible, not necessarily give a manufacturer 20 choices but really give somebody a choice of -- in this particular application, maybe it's a class 3 device, implantible, et cetera. We will mandate an RFID or not, but these other applications are less important.

Perhaps what you end up doing is you end up saying, "Well, you could do it this way or this way. This is the data we're going to require you to have so that we can find it, whatever we decide to look for it, but these are the choices of manufacturer." Again, you know, somebody who makes products.

You really hate to have anybody tell you this is the only way you're going to do it because instantly whoever is that solution, the price just added a zero. It's amazing how it happens overnight.

The data size is important -- we talked about it before -- because, again, you're not going to get -- it used to be called label inflation. I need another byte for something else. And before you know it, you're wrapping the bar code around the package. And you still can't read it.

So those are the things for us. Again, keep on thinking of the data and the data carriers,

two different entities. And really think about what you want to mandate for data you have to generate and then see if that maps to the data carriers.

It may be yes, for example, when you use a HBIC number that you have a primary and a secondary and two bar codes, which isn't a problem if you have an MRI machine, but if you have something that is very small, contact lenses or any other device like that, what you really may want to end up doing is mandating, well, we'll either have less data or you really will have to go to this to the bar code or this RFID. And, really, you know, this is your poison, but we want the data tracked.

We thank you.

MODERATOR KESSLER: Thanks, Lu.

I am going to turn the mics open in just a second. It's a very important comment. That you make that the data system and the carrier, the number are separate issues and that we don't have to confuse them is something that I think we have learned along the process.

And I really appreciate John's offer from GS-1 of the road map. I would love a road map. And if it gets me somewhere, it will even be better.

Where does the road map get us, John?

MR. TERWILLIGER: The road map I am talking about is our user group as they attack some problems around standards and implementation of the GS-1 system. There are a number of steps involved we actually have posted on the Web site. Is it gs1.org/hug? Yes, www.gs1.org/hug.

MODERATOR KESSLER: Does that include the processes that we have been talking about today; for example, implementation at the hospital level, implementation at the health professional level.

I have the wonderful man who has come all the way from Norway to build a dental system around this. So is that going to help him as well? Does the road map get to Norway?

MR. TERWILLIGER: Oh, absolutely. Well, it's global. It's global. I think the thing is we're still working more at kind of these fundamental data levels of making sure that we have things properly identified and properly bar coded or automatic identification analogies so you can see global, too, and really get in and set the stage for some of the things you have just asked about.

MODERATOR KESSLER: Mics are open if you have a question or a comment to make to the panel.

I'm going to ask Ilisa something about

counterfeiting, leave it open for you. Then the next plane is we have a series of presenters who are going to come up, do very brief presentations. They have asked for a few minutes on the floor to make some comment about what we have done today.

And then we have a treat at the end of the day of a few minutes and closing comments from Dr. Daniel Schultz, who has come here. He's the Director of the Center for Device and Radiological Health. He has some of his own thoughts about this as well. So you may want to wait for that. For those of you who don't have airplanes, it would be worth a few minutes of waiting.

Ilisa, I want to ask you about counterfeiting because I know you have been enmeshed in this with the drugs world because you are the drugs gal here. To what degree has this been a problem? Is it an emerging problem? I think we started to see it in devices, and we just hadn't seen it before.

And is there some consideration about how that might affect what you are doing in terms of the device world because I think sadly it's a very current problem for us?

MS. BERNSTEIN: Yes. Counterfeiting. I mean, I guess I always qualify this when I say, well,

talking about all these initiatives to secure the drug chain from counterfeiting, our drug supply is among the safest in the world, but counterfeiting is a huge problem globally. We have seen it in the United States. We have seen it in our own drug supply. And even one case is too many. So the efforts are worth what we are doing.

What we are doing on the drug side, I guess what you are asking is, can it be used for the devices as well? It could. I know that within the community that's looking at the standards, they're setting up a device working group to look at some things as well.

Right now I would say that most of our efforts, though, are on the drug side. And because that is where a lot of -- at least for the pedigree, there is a prescription Drug Marketing Act, which is under the Food, Drug, and Cosmetic Act, which governs prescription drugs and pedigrees there. So that's where a lot of our efforts are focused right now.

MODERATOR KESSLER: Thank you.

Brad?

AUDIENCE DISCUSSION

MR. SOKOL: I'm Brad Sokol from Fast Track Technologies.

A case could be made for medical device pedigree. I just wanted to point a couple of areas out in where we could as an industry point to those like the pharma did, the pharma industry did.

Number one, the medical device record, under the Federal Food and Drug and Cosmetic Act, any use error states that, frankly, one should report that use error. Now, it's not enforced, although it could be. So that's number one.

Number two, when you're looking at 21 CFR 820.7(g), which is the installation and qualification of successful process verification for devices, -- and this means equipment and maintenance calibration -- this is another area that states that there should be a pedigree, could be interpreted as a pedigree exists for medical devices.

And, finally, there is a movement going on right now for hospital-associated infections, where states are requiring the reporting of these infections and how those infections came about.

In fact, there are 27 factors, which I will not go into at this point. One of those happens to be instrumentation and devices. So those are the three areas where pedigree if we wanted to make a case and interpret the existing regulations on the books,

that's one way we can interpret the medical device pedigree.

MODERATOR KESSLER: Comments? Ann?

MR. FERRITER: Yes. I would like to comment on the NDR reporting. I think that's a great use for unique device identifiers. What unique device identifiers could also give us would be the number of devices that are out there. If we get 100 NDRs, we don't know at this point whether that's for 100 devices that were implanted or several thousand. So it is a very interesting use.

Thanks.

MODERATOR KESSLER: Other comments from the floor?

(No response.)

MODERATOR KESSLER: I want to thank the device panel.

(Applause.)

MODERATOR KESSLER: I'm going to ask the following people to come up one at a time, a very brief presentation. And then we'll begin doing wrap-up. And the mics will be open for some comments at the end of this.

So Cathy Denning from Novation, please. And then in order just get ready: Michael Dempsey,

Richard Eaton, Fred Freedman, Dr. In Mun, Mark Piper, Jeff Schaengold, Elliot Sloane, and Brad Sokol. Cathy?

One more thing to the presenters. I'm going to sit down. When I stand up, five minutes are over. And I'll just sort of quietly slide this way.

MS. DENNING: I use my watch. I was a trainer.

MODERATOR KESSLER: Good.

OTHER PRESENTATIONS FROM PUBLIC

MS. DENNING: Good afternoon, everybody. I am Cathy Denning, and I work for a company that's called Novation. We are the supply company. We do contracting for about 2,500 member hospitals for VHA and UHC.

In addition to that, this is what we represent from a statistical perspective. VHA has over 2,400 members. UHC has 200 members and represents a large percentage of the university health systems throughout the country.

In addition to those two, we also have a sibling company called HPPI, which stands for Healthcare Purchasing Partners International. And now we also are part of a company that is called Novation U.K. We are the contracting side of the U.K. as well

for the device perspective, not for the pharmacy side.

Nationally Novation purchases are $29.7 billion through these different entities. It represents 26 percent of community hospitals, 70 percent of academic medical centers, 26 percent of the staff beds, 30 percent of admissions, and 29 percent of the total surgeries in the country today.

We would like to advocate from a public health and safety benefit perspective for unique device identification. We believe that it would positively impact patient safety and quality in addition to the health care supply chain efficiencies that I will go into in a little bit. And I will stay within my five minutes.

From a medical accuracy perspective, it's interesting that the last comments around counterfeit products and drugs were mentioned. In one of our VHA facilities, we had patients and implanted 30 of them, to be exact, with counterfeit mesh.

I would like to think that if we had a way of uniquely identifying products as they enter that hospital, we would know whether or those products potentially were counterfeit.

And I do realize how wily some people can be when they want to be dishonest, but just last week

I think we also heard about the blood glucose monitoring strips that are also counterfeit.

From a product substitution perspective, when we have large recalls and backorders, when we have disasters across the country, certainly from a product substitution perspective, being able to identify when a product is both functionally and actually equivalent to another product would certainly provide for the easy movement of one product from here to here and, consequently, not interrupt the care of that particular patient.

Product shortages are an ongoing issue again. It goes all the way back to raw materials. But I do believe that from the standpoint of being able to look and to aggregate the different products again from a safety standpoint as well as supply chain efficiency, that would bring some benefit as well.

Recalls and product withdrawals. Of course, as you can see from the previous slide, we have a lot of hospitals who have to manage large numbers of both device as well as drug recalls on a daily basis.

I think there was an article last week that was published that said that hospitals have had to manage over 600 drug recalls on average, which

would mean that that is more than one a day across the country.

From a supply chain efficiency perspective, unique device identification would enable inventory management, item master management, recall management, charge master management, and electronic medical record, being able to track and trend which device made it into which patient, how much it cost. Whether you're paying for a product that went into that patient or got charted on somebody else is certainly something that I would think that all payers, including CMS, would be interested in.

From a charge master and recall management standpoint at the end of the day, it also is about bringing efficiencies and being able to track and trend.

Inventory management. You know, right now there are disparate systems. And I have heard a lot today about why hospitals don't adopt those coding systems that are out there. We right now are gathering information. We have a survey that is in process. And we will provide those statistics and data to the FDA.

What we have preliminarily looked at is that and what our members have told us is that at the

end of the day they have disparate coding systems that come into them. And they have to figure out some way of making sense of that.

When they get it, they then have to turn around and code it so that it's recognized across their system. So we would like to have a call, really, for a mandatory system that is consistent where the nomenclature is recognized globally.

In order for us to really be able to make this work, we believe that that is what we have to do, is come together from a collaborative perspective and really advocate on behalf at the end of the day on the patient.

(Applause.)

MODERATOR KESSLER: Thank you.

Michael? Michael Dempsey again from Partners Health Care.

MR. DEMPSEY: Hello again. I prepared this presentation, really, for a different context, but after sitting here for the day and listening to all of the expertise in the audience, I am quite humbled by the amount of thought that is going into this. So I am going to change it up a little bit.

What I would like to do is just share with you a vision, maybe something to get people excited

by. Partners Health Care has our own version of a unique ID. As I mentioned on the panel discussion, we ended up here. We ended up with this originally starting with patients and then moving on to medication safety. It's not deployed ubiquitously, but it does exist in some of the practices.

So you can imagine that once we collectively decide what the unique ID is for medical devices, that in a couple of years, we might be in the same spot that Partners is today, some limited deployment but something that works.

And now is where it gets interesting. We deployed it, started talking to clinicians, and clinicians came up with amazing and fun and exciting and very invigorating ways to use it. And I'm going to share with you one of those.

So that is nearly impossible to see, but down at the bottom there in that white box is the unique ID. It's self-identifying. That happens to identify a drug, and it identifies the dosage and so on. And it's all encoded in that 2D bar code.

So these are some of the records that are included in there. And you can see it's quite complex, has versioning numbers, has care area information. Different drugs are used differently in

different care areas, bolus rates, and so on. I can share with you the details of this. If you're interested, contact me. This really isn't important.

But here is the unexpected benefit. We realize that this unique ID could become a speed dial. So, in fact, it was in one of the outpatient clinics with a medical assistant. So this is a paraprofessional, typically has gone through 16 weeks of training, not a rocket scientist. And they came up with this notion of capturing vital signs and putting it into the electronic health record using the speed dial.

So, effectively, what you see there is the vital signs monitor. It's a CASS 740 vital signs monitor that has no network connectivity, never has, and probably never will. It's inexpensive. It's typically found in a doctor's office.

On the front of it is literally taped that 2D bar code that says, "This is a CASS 740," its model number, and its revision number. And you communicate to it with whatever, infrared, Bluetooth, however you communicate with it.

So then the clinician uses her PDA, which has a bar code scanner; scans that 2D bar code. And the PDA says, "Oh, I know this is a vital signs

monitor. So I'm expecting to capture vital signs. And I know how to communicate with it." So it sucks the vital signs out of the PDA and pushes it up over the wireless network into the longitudinal medical record.

Now, what are the benefits of this? One and most significantly is it's work flow-sensitive. So if you scan a vital signs monitor, it does something different, the PDA does something different, than if you scan a smart IV pump. Right?

The smart IV pump scan tells the PDA that you're dealing with drugs. There must be a drug someplace. And, in fact, since we have this notion of unit-specific identifiers, you can have a smart IV pump in an oncology unit perform differently than the identical smart IV Pump that's in the pediatric unit or in the OR because they have different care practices.

All of this is enabled by the unique ID. The important point of this is that the unique ID has all of the advantages that we have been talking about that are obvious. But I believe that once we as a group of caring medical professionals implement it, our clinical teams will figure out a lot more applications of it in ways that we haven't

contemplated today that will make it very powerful and important.

Thank you.

(Applause.)

MODERATOR KESSLER: Thanks a lot, Michael.

Richard Eaton from the National Electrical Manufacturers Association.

MR. EATON: Good afternoon. Are we holding up? I'm from the National Electrical Manufacturers Association, NEMA, in Rosslyn, Virginia. I want to tell you a little bit about NEMA, also share some views with you that we have on UDI, talk about some problems and issues that we see with the potential system, suggest some next steps, and some essential requirements.

What is NEMA? NEMA is the primary standards development organization for medical imaging and therapy systems equipment. Our Diagnostic Imaging and Therapy System Division members manufacture over 90 percent of the market for all these big ticket capital equipment items: X-ray, includes mammography; CT; radiation therapy, which includes linear accelerators; magnetic resonance devices; nuclear medicine imaging, which includes PET; diagnostic ultrasound devices; and medical imaging informatics

devices, or PAX.

NEMA generally supports a UDI system, which is practical, cost-effective, and improves patient safety. The link with patient safety is absolutely essential.

We are ready to work with FDA and all key stakeholders to achieve this goal. And we believe all key stakeholders must become involved in this process to ensure success. Everybody who is going to touch this system needs to be involved in it or, else, it will not work.

Let's talk about some problems. The first and most important problem is, what are we trying to fix? What problems are we trying to solve? We can't develop a fix if there needs to be a fix unless we define the problem first.

Now, on capital equipment, we already have identifiers. Many of our members already have bar codes on their devices. Some of our capital equipment is already marked with serial numbers. And this is used to track products for recalls and adverse events. And the tracking of these begins in manufacturing through installation.

The RAD Health Act requires identifiers on X-ray components. Our concern is that a new UDI

system would conflict with the existing requirements that our X-ray equipment manufacturers already have to adhere to.

I want to emphasize that the same regulations if a UDI regulation is passed have to apply to both users and manufacturers.

Other issues of importance, who is going to train the users to utilize this system in the hospitals, doctors' office, or wherever they are installed? We need to know what the cost impact of increases in user and manufacturer infrastructure. And there will be infrastructure changes in the manufacturers to develop these codes, to revise them, maintain them. We need to be aware of electronic medical records and privacy issues.

I don't have the answers about the identification technologies, but, as you have heard today, there are many different identification technologies that could be employed. Which are the right ones?

And, as already alluded to, the software revisions, how do we accommodate this on our devices, which are constantly receiving software revisions?

Now, what essential requirements would we want in a UDI system? The most important one is that

it must and must enhance patient safety. That is the primary reason for being for a UDI system. It may have a lot of other benefits that we have already heard about, but patient safety is primary.

We're also very much believing that we have to have harmonization with the systems and regulations around the world. Global harmonization is our absolute goal. We need one worldwide system. You have heard today there are a lot of systems that are already out there. We don't want a proliferation of systems. We want to move toward one system.

We also need to have the identifier provide only essential information, which is related to patient safety. Again, the needs of FDA manufacturers and users need to be satisfied and should, as I said before, require compliance from both manufacturers and users.

A UDI system also has to be flexible. It has to adapt to changes in technology. And our goal there is to achieve a least burdensome system, which does not impose onerous, regulatory, or financial burdens.

Next steps. I believe we should form an interdisciplinary task force representing users, industry and FDA. We can develop potential

approaches, identify the process and the next steps through the task force and Federal Register. And I understand FDA will be publishing a summary of this meeting.

In conclusion, we support a practical, cost-effective UDI system which enhances patient safety. But, again, problem definition is essential before we embark on this.

Phase-in process of five years is what we are recommending. We must resolve critical details and issues, proposing grandfathering existing devices.

And last, but certainly not least, we need a mechanism to evaluate the system as we develop it, involving all key stakeholders, and revise the system if needed. We should link this UDI system to performance goals and safety-related goals, like recalls and adverse event reporting. In other words, how is the system working? And we need a system which will be able to do that.

Thank you.

MODERATOR KESSLER: Thank you.

(Applause.)

MODERATOR KESSLER: Fred Freedman from the Dental Trade Association.

A couple of comments while Fred is coming

up here that Richard made. We're very cognizant of the issues, some of the issues, he has raised, some very challenging ones, specifically things like software versions and how to keep that fresh and into a data system that is accurate. That is a very challenging problem.

The other problem he also mentioned is legacy equipment because there are many, many thousands of items on the floors of hospitals today or in patients. And the question is, how do we handle that? That is a challenging issue for us.

DR. FREEDMAN: Thank you, Dr. Kessler.

I just want to start off be saying thank you for providing this forum today for all of us. I found this very useful. We have been represented by a few people here from the dental trade. And we're grateful to have the opportunity to speak. We have heard a lot of common sense spoken in the room today. And we hope to contribute as we go forward.

The Dental Trade Alliance, an association comprised of 220 members, represents manufacturers, distributors, and laboratories providing medical devices to the dental industry, including many of the largest and smaller manufacturers.

Since unification of the highly respected

Dental Manufacturers of America and American Dental Trade Associations, DTA members have been involved in all aspects of dental, including manufacturing, distribution, export, import, and international commerce. The public's overall oral health and patient safety are priorities for all DTA member companies.

DTA applauds FDA for promoting public health care and encouraging full disclosure of medical devices. Because dental-type medical devices offer little risk to the public, the dental trade agrees new regulations for identification of medical devices should be instituted in a way that is very practical, flexible, and not burdensome to small companies. The DTA position refers to these following points.

DTA does not believe UDIs will prove particularly practical for dental offices and their patients.

Time is a factor in implementing UDI requirements. DTA believes a five-year period is the minimum time required for manufacturers to implement new regulations. Five years provides flexibility without undue hardships for the industry.

Neither the use nor the format of unique device identifiers should be mandatory except where

their absence would result in a major health care risk.

UDIs should be based on existing standards which are well integrated into the marketplace and meet basic requirements.

UDI will add cost and may be onerous for small manufacturers, distributors, and users. A general information campaign is required, particularly geared towards the general public.

Elements should be limited to manufacturer's number, product number, lot number, and expiration dates when necessary.

UDIs should be only required on the sales packaging unit except for large equipment.

Government efforts to require UDIs should include Centers for Medicare and Medicaid Services, Department of Defense, and others.

Any development of a UDI requirement should be closely aligned with international global harmonization.

DTA strongly urges consideration of these important criteria when implementing new procedures for identification of medical devices. Thank you.

(Applause.)

MODERATOR KESSLER: Dr. Mun from HCA,

Hospital Corporation of America. Great.

DR. MUN: Good afternoon. I would like to share some of the work we have done with medical device marking using RFID and bar code. We start basically when the IOM report came out in 1999. There was a very fine line at the report saying that bar code is a very important factor to reduce medical errors.

So if you look at bar code in health care, I guess bar code was invented much, much earlier than 1983, but year 2005, which was last year, there is only about 9.4 percent of hospitals using bar code for medication delivery.

And so in terms of identification technology, obviously bar code was earlier one. It's easy to use. And it's quite well-known technology.

So in HCA, we actually implemented a bar code point of care system. The steps we have taken, we started February 2000 as one of the major patient safety initiatives. And then at that time, our expectation was that we would implement the system throughout our facilities by the year 2010. And that was because the cost we were aware of was $400,000 to $1 million per facility. However, after we installed, we realized it wasn't as bad as it appeared. And so

we have accelerated implementation.

So by 2005, we actually have implemented throughout our system. We actually delivered 115 million transactions. So even though the GS gentleman says that we are clueless, we have slightly a little bit of idea about what ID is.

Lessons we learned from BTOC is that it definitely does reduce the errors and it helps to make complete documentations. And there's definitely improved patient safety.

However, bar code does have certain problems. One is everybody must be engaged. And our nurses are much smarter than we are. They know how to get around occasionally.

And so at the same time we have looked at RFID. And RFID, we decided to look at asset management. The reason is that I work for a for-profit hospital. So we have to get numbers met at the end of the day.

And so we are looking where we could use RFID. And we found the RFID for the device management actually would work out very nicely because we realized that there was data before us saying that mobile equipment utilization is 45 percent. Hospital loses quite a bit of money once in a while. And at

the end of the year, we have a problem with inventory management. And, of course, there are always complaints when there are infection rates that we are not doing very well.

And so steps we're taking, we started looking at the year 2000. And we have looked at the bar code, passive RFID, active RFID. And then about 2003, we decided we will go with active RFID, for two reasons: reliability and automation. That is, passive RFID, we found out it will not work when we really need it. And active RFID, we know when it works. So that was one of the major criteria.

And then we selected vendors out of nine vendors we have investigated about a year or two. The criteria was the battery life because we wanted to last much longer than a few months, then size of tag because we wanted to be able to track as many equipment as possible. And we also want to know what resolution we can find the equipment.

And so we implemented a pilot system in 2005. And this is a configuration. We are using basically 433 megahertz tag, and we are tracking currently 2,500 items in a hospital.

These items we tagged, almost everything, anything which can move. We don't do it based on

price. MRI is very expensive, $2.5 million. We don't tag. It doesn't move hopefully.

(Laughter.)

DR. MUN: However, the thermometers, which are maybe 50 bucks, we do tag because that's something the nurses need.

And we have found out some interesting things right after we installed. About 30 percent of infusion pumps simply don't move, despite the fact that nurses insists we must buy pumps every time. So we have some idea. Now we can go back and talk with nurses, why they don't need any more.

And this is data from one of the institutions where they have done the work a little bit earlier than us. They were basically able to demonstrate a cost saving of $1.5 million. This excludes cost avoidance or such savings.

The current status is that we have done all of these things, and there are a few hiccups, as you may expect. We found out that some of our nurses are much smarter than we are.

And then we have interfaced the biomedical service database. So now we know exactly when the device is serviced and when it should be serviced.

We are also getting some interesting

information. For instance, as I mentioned, some of the items simply don't move. And they say they don't have it. So we know we need to manage these things better.

And also we found out some interesting relationships among items, like rental equipment and discharge. We rent equipment when patient comes in, but we don't know when to stop that rental because when discharge, we don't tell the guy, "We no longer need it." So we see huge savings at that side.

And also because we have seen a lot of work flows we can improve using this technology, we are looking at the surgical chart tracking in OR, improvements in ER as well as ICU. And also we will be able to give information on physicians' PDA where the patient is so when he rounds, he doesn't have to waste his time going in the wrong place.

And what we have learned is that equipment or any technology you put in, it's just a cost. You have to sweat it out. You have to work at it. You have to make sure that your workload is matching with what you do. And if it doesn't, then we have to change it and make sure everybody works at it.

The lessons we have learned is that RFID medical device, asset management using active RFID is

cost-effective. However, there are a few other issues which we have identified.

One of the worst problems is, what do you do with the database? This is one entry in the database. It's the same equipment. This equipment is known as a patient lift. But nurses call it agile lift. And common name used by industry is lift/patient. So if you search this database, as previous speakers talked about, it's a mess.

So we decided, why can't you use 2D bar code? So the reason is that it's cheap, at least compared to RFID. And there are less physics problems. And we can address item level very easily. And also it provides lots and lots of data.

Now, some people say we don't want to give data to the end users. Come on. We are the guy who has to manage patients. If you don't have any data, how do we manage them? We must have data. So please don't insist not giving us data. Please give us data.

So, for instance, we can put a 2D bar code, human-readable information. Current tag can be put into 2D bar code and put right next to it. And I believe this helps considerably in managing.

And I don't know about DOD, but for our hospital, some of the guys who are looking for

equipment, they are the lowest-paid people in the hospital. They really don't know one from the other. And it's vital for us to provide additional information to these people.

What we would like from FDA and everybody else from here is that we would like to have a cost-effective unifying standard which will cover staff budgets, patient restraint, IV medication, non-IVs, medical devices, and blood products if it is possible. It may not be possible. So this is just my shopping list, shall we say.

And so we are looking at a couple of other different documents to figure out what to do. And we are extremely interested in what Partners is doing. And hopefully we will be able to work with them.

Thank you very much.

(Applause.)

MODERATOR KESSLER: Mark Piper is next from DOD. And those of you who will be watching the FDA Web site will see that Dr. Mun will become a visiting member of FDA soon, nothing to do with the fact that he has got all the right answers for me.

(Laughter.)

MR. PIPER: Hi. I am Mark Piper. I am with the Department of Defense Unique Identification

Program Office. And I am here specifically to talk with you about item unique identification.

I actually work for Keane Systems. We are one of the management consulting companies to the DOD with regards to unique identification.

Just to give you a little bit of background about the DOD's item-unique identification program, it is approximately five years old. It was launched in 2002 formally with policy guidance that came out then. And if you take a look at some of the business drivers that we found, such as better value for the dollar spent, full accountability, and asset management, adverse event tracking, personnel safety, they are similar to the business drivers that we have all heard here today with regards to health care.

And certainly the Department of Defense item-unique identification program includes health care system, health care items, health care devices, as well as other types of Department of Defense systems.

One of the things that we looked at was we focused on the data and the processes that are involved. Basically we looked at item-unique identification as the information key. It consists of the enterprise identifier lot, batch, or part number,

as required, and also a serial number.

And within that, we chose a two-dimensional data matrix as the data carrier, adhering to international standards with regards to syntax and semantics.

What we allowed for was the manufacturer actually gets to select the methodologies for serialization. We use the enterprise identifier in their serial number or the enterprise identifier part number, serial number, and the equivalent with regards to GAIA, GRAI, and for serialized items, VIN number, and ESN.

We looked at processes from the perspective of we will have both operational and business processes regarding manufacturing, repair, the actual business of receiving, paying for material, and then accountability for that material and where it is located within an operation.

Today the item-unique identification program has over 700,000 items entered into the item-unique identification registry. Somebody asked me earlier from one of the device manufacturers, "Mark, are you going to get up and say, 'Been there, done that'"? Yes, we have been there and done that.

And we very much want to thank the help

and participation that we have gotten from the FDA and the support that we have gotten from people like Dr. Larry Kessler as well as Mr. David Racene and also from the Defense Logistics Medical Supply Center with Kathy Garvin as well as the support that we have gotten from the Defense Medical Logistics Standard Support Service with Jon Sherman because we have been able to integrate the requirements for medical items, medical devices within all of DOD. I'll say items that are purchased or procured and all items that we have to manage.

Something that is interesting is 65 percent of the items that have been registered are registered by small commercial operations. To us a small operation is somebody who is $250,000 in revenue. And certainly we have other suppliers within our supply chain that go up to $30,000 billion as far as corporations go.

We have done some cost analysis. And whenever you work in a repetitive manufacturing environment, the cost of marking an item can drop to as low as 20 cents. And if you begin to look at non-repetitive manufacturing, it could be as much as 10 to 20 dollars per item.

The UID program, item-unique

identification program, was built on certain foundations. And we looked at this is a program that has to be commercially robust in that our suppliers, whether or not they're in other areas as far as systems or within the medical and health care industry, go through mergers and acquisitions. And our item-unique identification program has to be able to perform and identify items with regards to both commercial mergers and acquisitions as well as divestitures of operations.

We have a global supply chain. And, as you know, many of you currently participate in that global supply chain. We have to look at an item through its complete life cycle management from the manufacturer to the supplier, through the health care provider, down to the patient. And you can translate that in other defense systems to manufacturer, supplier, distributor, and soldier.

Many types of devices have to be identified within the Department of Defense program. And we have to be able to operate and interact with many different types of systems, both from our own internal operations as well as commercial systems throughout our supplier community.

What we looked at additionally were how do

we distinguish and enable identification, description of the item, and location. And we made a distinction between identifying an item versus describing it.

For example, I can give you the vehicle identification number for my car. And then if you took a look at it, you would say, "Okay. It's a silver Ford Taurus." But there's a distinction between identifying it and describing it. And then you can say, "Okay. It's registered in the State of Virginia."

Global unique identification has to fulfill each one of these requirements within the Department of Defense. And these are "or" type statements. If the item is serial-managed within the Department of Defense, then it has to have an item-unique identifier. If it's part of our controlled inventory, it has to have an item-unique identifier or if it's a safety or mission-essential-type item, it has to have an item-unique identifier or if it's greater than $5,000 in value. So I could actually have an item that costs 50 cents. And if it's safety and mission-essential, it has to be uniquely identified.

So that's the conclusion of my presentation. I wanted to thank everybody very much

for allowing us this opportunity to discuss things.

MODERATOR KESSLER: Thanks.

(Applause.)

MODERATOR KESSLER: Jeff Schaengold from Siemens and then Elliot Sloane and Brad Sokol. Jeff? And I promise you we will be out around 4:30.

MR. SCHAENGOLD: Good afternoon, everyone. Actually, that was me before the meeting today. Siemens is a leading device manufacturer, also a leading symbology manufacturer. And we're very much committed to mass serialization.

We look at the UDI program as really mass serialization, not as much as a technology. And when we look at mass serialization, we look at it globally. And when you really look at a global effect, there is a manufacturer out there of ink jet cartridges that basically applies a unique serial number on every ink cartridge they produce and they distribute. And they track every one of them.

And the real question that comes to our mind is if they can produce hundreds of millions of these cartridges and track every one of them using 2D bar code, why can't we do it with medical devices?

The other element that we have to look at is that we have 420 million passengers who fly in the

U.S. every year. And it's growing by six, seven percent a year. That ticket number is a unique identifier. We can track passengers through a unique identifier, but, for some reason, we can't track medical devices.

We have 13 billion parts a year that we mark in the automotive industry. We do it with bar code. We do it with RFID. We do it with data matrix on metal, 13 billion parts. We somehow seem to manage that, but we can't seem to manage it in a medical environment.

So what we would like to do is we would like to offer the premise that creating and maintaining a UDI architecture is really all about mass serialization. It's about designing the identifier first and then utilizing prevailing technologies in direct part marking, instead of reinventing.

Now, what will happen is that once you create that foundation, that infrastructure, that cornerstone, pure economics and the ingenuity of man will basically drive everybody around that architecture.

So what we are looking at is we are saying that the DOD, for instance, has a UID program that's

excellent. We see the AIAG has a program for medical devices. GS-1 and EPC Global has one. From our perspective, it's like, for Pete sakes, choose one.

When you look at it, the basic architectures are relatively the same. There are slight nuances. And we can go into some of the particulars, where we say in many respects, you have to pay a little bit more with GS-1 and EPC Global, you have to pay a little bit less with DOD, but the reality is pick and go with it.

Now, what we suggest is that we respectfully would recommend to the medical device supply chain community that you pick a structure. And the second step is you create an adjudication body.

In other words, we have heard it all here today. We have to define what is a medical device and which is a medical device. We have to define what we are going to use as a serial number, where we're going to put the digit here and a digit there.

Decide. Get a group together. Get a body that's basically going to be our court system. And get everybody to come in and make their case. Decide on the case. And continue to move forward.

It isn't really about the technology. The technology is only a method. It's only a means to

this. The reality is anybody who wants to can contact me, and I'll send it to them. But when you look on this, we do a matrix. 2D works well here, and RFID works well here, and Locator works here. But at the end of the day, it's about direct part marking.

Assign the bloody serial number to it. And the rest of the world will figure out a way to utilize that serial number in one way or another. We will collaborate. We will be interoperable. We will do all that stuff or we can spend the next 15 years trying to figure out how to build a superhighway, an intelligent highway, when all we want is a bicycle.

The reality here is that 2D bar code is an excellent low-cost way of serializing everything from latex to metals to aluminum to jet parts to CAT scans, et cetera. And, by the way, we make every one of those.

We can even track something that is so small that it is barely visible to the eye. And we can read millions of these in a matter of about two and a half seconds. So we can read these in batch because we use optical technology. As you have seen out in the floor today, we can laser mark. We can read these laser marks. And it's not expensive.

So what happens here is that UDI just

basically needs to have an architecture. Everybody just basically say, "Let's go with the architecture" and move forward.

So what happens here is that from a Siemens perspective, you're looking at a company that not only is one of the world's largest medical devices manufacturers, but we're so committed to mass serialization that also we have been 17 years in RFID. We do RFID tag medical devices today.

We sold over 300,000 readers around the world over the last dozen or so years. We bought RBSI, which you heard earlier today from Lu, which is one of the innovators in 2D bar codes. And we own that now.

We are the most pronounced DPM competency center. That's direct part marking. And we do serialization of optical verification.

Now, this is kind of my presentation. I have about 45 seconds, I believe. But the reality is I also kept thinking during the conference some of the things that analogous to what we are talking about.

Easy pass toll systems, 20 billion transactions a year. Is that really that much different than medical devices? Twenty billion transactions. It seems to be working pretty well.

And, by the way, if you pass through a toll booth and it doesn't read your RFID, they take an image of your license plate. And they send you a letter. We can do the same thing in the hospital and in the medical device world.

The thing from Siemens' perspective is I can tell you it's kind of selfish. I do not want to be the chairman of the board of Sony having to answer to the board about why my market cap went down 14 percent because my batteries blow up laptops and I can't decide which battery is blowing up which laptop.

If I do a really good job of serializing my product, the product I produce, a catastrophic event will have a less financially detrimental impact to my market cap. So I have a vested interest in making sure that I keep promoting serialization of the product that I sell. And throughout my supply chain, the more focused I am where my product is, the more focused I am on being able to adjust to a recall.

And the last thing I want to say is look at the linear bar code. Forget the bar code itself. It's really the UPC, the Universal Product Code. Thirty years ago the first one was at Wrigley's on a Wrigley's chewing gum in March.

It took 10 years before anybody realized

that you really need to use it 100 percent because I don't know about you guys, but I used to stand in line in the mid 1980s at Home Depot for 20 minutes while they said, "Plumbing, plumbing, price check" because it didn't have a UPC code. And then we became universal. And today everything has a UPC code.

So we are suggesting very strongly from Siemens pick and choose an architecture and just move on with it and just go with it and don't worry about inventing new things. Everything has been invented.

Thank you.

(Applause.)

MODERATOR KESSLER: Elliot Sloane from Villanova.

DR. SLOANE: Thank you. It is a pleasure to be here.

I will weave a number of my Villanova topics into this, the e-commerce, the telecommunications, the database, the e-health, and a whole bunch of other things.

And while I am simply a professor, I am not just a professor. I have a little bit of another background. I was Vice President, CIO, and COO of VCRI for 15 years: from 1975 to 1990. I was responsible for building, my team was responsible for

building, the recall system, the health advisory alerts, the UMDNS system.

I had the pleasure of working with John Vilforth, Jim Benson, Walt Gonducker addressing these things quite a while ago. And we are hopefully more than halfway along this discussion. Hopefully we are getting to the end of this discussion.

The next ten years of my life I worked at MedEx. I spent ten years trying to stay out of the FDA's radar screen. MedEx was a medical device manufacturer.

At its peak, we owned 500,000 pieces of medical equipment, which we rented to hospitals throughout the United States. We owned nearly 100,000 infusion pumps, 25,000 ventilators. We managed all of that with a bar code system with our own unique device identification system. And if I have anything to claim about my ten years at MedEx, it's that we were never sued for injuring or killing a patient.

We did get a chance to work with the FDA at the end of that period for working with Phil Phorpolo and the other Dr. Kessler in terms of medical device safety, maintenance, and the like. And today I teach in Villanova and work in the areas of health care information systems and related topics.

Reality check number one, medical devices really do kill people. I investigated my first medical device death in the late '70s and almost every year since then have been involved in medical device death investigations, including, unfortunately, some involving MedEx devices in the early '90s.

It turned out it wasn't MedEx devices, actually. It was an accessory, a $500 accessory, part of a manufacturer's device in the bed next to where the MedEx equipment was. I got to meet some very nice folks from the FDA with shiny badges that weekend.

Reality check number two, nearly 30 percent of all health care is occurring outside of hospital walls already. That number is actually ancient. It's too low. That's just the home care piece. It doesn't count physician offices. It doesn't count all of the other allied health and the self-health that is going on.

Durable medical device firms, of course, I was part of that at MedEx. MedEx is now part of Hillrom. Other big organizations like Modern Medical, big organizations like UHS, there are hundreds of thousands, if not millions, of medical devices on rent in hospitals day in, day out.

To give you a sense of that, with MedEx's

inventory seven years ago now, we had on any given day 60 to 100 thousand pieces of life support equipment in hospitals, home health care, and other settings. That was day in/day out 365 days a year.

So there's a lot of change happening pushing this even further. And if you don't believe that, I went shopping. I just wanted to see what was happening out in the world. And I thought I would just check out the market.

I went to my favorite shopping emporium online, Amazon. In Amazon -- you can't read this -- in addition to AEDs up here of various brands, glucometers of all sorts, it gets rather interesting when you get down to devices like pulse oximeters of different sorts, a tens units. And, in fact, down here is even a diathermy ultrasound treatment device. There's a number of physiologic monitoring. These are non-evasive blood pressure monitoring technologies, almost every brand and manufacturer.

And, by the way, the prices on these range from about 100 to 200 dollars, on up. It doesn't stop there. Full-out medical monitoring systems, $1,300, goes down into a CPAP, continuous positive airway pressure, devices -- I'm the only guy in the business school that understands what all this stuff is -- and

moving into pulse oximeters of various sorts and even a 12-channel ECG monitor and recorder that's available from Bertech price is about $3,200.

So I'm a pragmatic person. I go right to where the things are happening on the World Wide Web to see what's happening.

Accessories of all sorts. One minute. Accessories of all sorts out there as well. Ponder medical device recalls. How are all these recalls, maintenance support things being done for all of those devices out in the non-hospital settings? If we don't have a unique device identifier, we won't be able to get to them and support them.

Reality check three, a third of every health care dollar is wasted, not my numbers. Those are the government's numbers or at least the Institute of Medicine and National Academy of Engineering. So process improvement is a big, big plus.

RFID, as only one part of RF proliferation, every medical device for a few dollars has the ability to be tracked, to communicate. And they're putting batteries and wireless in our pockets. Why aren't they putting it in medical devices? Well, in fact, they are. Most next generation devices will all feed to a telecommunications network. And they

all use IEEE standards of various sorts. The devil is in the details.

Reality check number four, this I talked about. I won't go into it now. The electronic health record is unfolding. We need it. It is in order to implement the electronic health record with medical devices, every device, just like our cell phones, has to have a unique identification. In order to keep track of each device, there has to be a unique code to allow that data to transfer reliably and accurately into an electronic health record, a telemedicine system, and the like.

Quick lessons here. Manual data entry is not going to work. It has to be readable. There has to be a human-readable form for everything. And it can't just be manual data entry. Two percent is the best you can get for manual data entry. You heard about the millions of transactions that go into just individual organizations, work at two percent. That error rate is far too high. You have to have each piece of medical device.

I put on the bottom, "Check digits." "Check digits" means you can't make a mistake when you enter something. My checkbook, my account has a check digit on it. One of those numbers make sure if I get

the digits wrong, it will not enter the data.

So one of the mistakes we made in creating UMDNS is we didn't create a check digit. It's cheap. It's easy. NIST right down the road can give us algorithms for that.

Lay persons' English description because people have to be able to say what it is, not a multi-polysyllabic sentence or phrase.

Wireless technology I already talked about. In addition to UDI, each device has to be assigned a clear permanent electronic product classification. We need to know what it is. Dr. Mun made that point. We'll leave it at that.

And each of these -- redundant.

If you need to find me, Google me. I'm out there. And thank you for the opportunity to present.

(Applause.)

MODERATOR KESSLER: The last of our presentations is Brad Sokol. Then we'll let the mikes open for a couple of minutes if there are any other comments that we have not yet heard today. Then we'll do a closing.

MR. SOKOL: Thank you, Dr. Kessler, Jay, Dave. Thank you very much.

Just to tell you a little bit about what I am going to talk about today is just I'm going to catapult you into the future about two years and talk a little bit about patient safety and infection and how does that relate to the UID.

After doing studies for the last three years, I would be happy to talk with anyone after about these numbers. Thirteen thousand to 26,000 mortalities a year are directly or indirectly attributed to medical device procedures, processes, infections, saving approximately $3.1 billion a year.

We need to develop a comprehensive interoperable health care model to include medical non-electrical instruments and supplies. These numbers were verified by two epidemiologists out of UIC.

The factors to consider for a system we'll talk about next; the drivers; the impact of the UDI; and then, finally, the concluding comments.

The ability to incorporate the UDI system into an interoperable health care model. When we talk about the interoperability, we're talking about that now with the patient record.

We need to address the patient record. We need to address the medical devices. It all needs to

operate together. It's fine for electronic medical devices under IEEE 1073.3, but we don't have anything for instrumentation or supplies.

There are some very unique life cycle events experienced by a medical device that may not be experienced by other devices or other methods in medical industry. One is the reprocessing of medical devices and associated regulations.

Recently the FDC passed something called 502.u, which happens to be the labeling of a reprocessed device. Well, there is a little bit of a problem there. You have to keep the manufacturer's name on it. And now you have to have the reprocessor's name on it in one of three scenarios. I won't get into it that much.

Distributor relabeling. Rentals, loaners, sterilization cycles, maintenance cycles. I mentioned earlier medical device reports and history reports.

Adverse event reporting. We haven't talked about that today yet. And it's really something that's quite important. And, finally, state reporting.

One of the things that I think we all really need in this industry if you're looking at both the patient side and the medical manufacturers' side

is you need a de-referenced database environment where all queries have confidentiality, integrity, authentication, and anonymity because we fear as the medical device manufacturers the liabilities. On the other side, though, the patients fear that their privacy is going to be interrupted. So anonymity is very important in a de-referenced database environment; in other words, a hidden database environment.

Patient privacy. I just talked about that. Focus on infection control. And this is very important. Design a model to increase our abilities to better detect the chain of transmission of infections by integrating the UDI procedure and patient record. Currently there is nothing to integrate the procedure and the patient record.

Finally, I've got to tell you as an independent researcher and a consultant but mostly, half the time, an independent researcher, I've been blessed with being able to talk with a lot of people around the world. And for the last eight months, I've tried to see if there was a way to get these different nomenclatures together and people together. I am here to report that, unfortunately, I was unsuccessful.

So getting past the vested economic and

political bias of the current players, be it medical devices, be it patients, be it the nomenclature societies, is absolutely important to look at that side. All I can say is that it's a very difficult problem we face here. I won't say that much more on it.

Device maintenance. We just talked about that. We need to look at the proper chain of transmission. We talked a little bit about theft and counterfeiting.

We need to enable a process to track reprocessing, recalls, rentals, loaning of medical devices, and reducing the counterfeit of instruments. There are ways to do that. I happen to know there are several esteemed colleagues that I have been working side by side with but not with exactly, sharing information from an intellectual point of view, that these things are possible.

Increased supply chain acid visibility, you heard that probably from hearing Joe. Matching patient record to diagnostics, to device to patient, scheduled procedure, and infection cause, very important.

Again, I keep coming back to infection. Reducing the stay of hospital-associated infections

and length of stay, reducing mortalities, and ensuring sterilization, ensuring sterilization, the process and the work flow, through proper device usage on the correct patient.

Finally, the issue. Lack of informatic tools. We have all agreed on that today. I put to you that the solution is actually to look at something called the seven device L's, that I call them: last manufacturer, very simple; last maintenance; last sterilization; last location; last user; last procedure; and last patient, just seven things, but there are a lot of things that go into those seven things.

That will inevitably help prevent 13,000 to 26,000 mortalities a year and save us $5 billion a year. As I mentioned before, the next issue, 11 nomenclatures, I suggest a universal translator. If you remember Star Trek, that's what I suggest.

Finally, the confidentiality. Let me just go to the conclusion here. The failure to incorporate comparative relationships with a medical device, nomenclature, error reporting, patient record, and procedure will yield in an unstable interoperability health care model.

If we wait until infection control yields

an immediate ROI or until we reach a global political compromise, it may be too late. All I can say to you, let's not wait for catastrophic disease outbreak to implement UDI, which inevitably can reduce those mortalities.

Thank you.

(Applause.)

MODERATOR KESSLER: With all those L's, how appropriate for Brad to be our last speaker.

Is there anybody else who would like to make a brief comment before Dan and I close? Don't forget to identify yourself.

MS. FRAHLER: Good afternoon. My name is Jori Frahler. And on behalf of the innovative and entrepreneurial companies that the Medical Device Manufacturers Association represents, I would like to thank FDA for convening this meeting to discuss this issue of unique device identification systems for medical devices.

MDMA has met with FDA and other stakeholders to begin discussions about this issue. However, we believe there are many unanswered questions that need to be addressed before moving forward with any UDI initiative.

While MDMA supports the universal device

identification system, we strongly believe that it should be a voluntary process. Much has been made of the potential health and safety benefits of UDI, comparing it to the mandatory drug bar coding system.

However, this analogy does not hold up when looked at closely. Unlike pharmaceuticals, there are very few, if any, compatibility issues that exist between two devices that would impact safety or efficacy. Therefore, the policy justifications that exist in the pharmaceutical industry for a universal bar code system do not exist for medical devices.

If, however, FDA can provide data that suggests compatibility issues for particular devices, mandatory UDIs for those devices may be warranted.

In closing, MDMA does look forward to continuing this dialogue with FDA and other stakeholders to answer the many questions that remain about a universal UDI system. And we would like the FDA to form a UDI task force with efforts of everyone in this room. With a UDI task force, I am confident we can develop a globally harmonized, yet voluntary UDI system that will benefit all stakeholders.

Thank you.

MODERATOR KESSLER: Thanks.

Any other comments? You will get your

chance. First of all, if you don't mind, I would like to thank all of the presenters, both the people we had on the panel and the people who just did the last presentation. So let's give them just a very brief round of applause.

(Applause.)

MODERATOR KESSLER: All the presentations you saw today will be soon on our Web site. That's first.

Second of all, allow me to thank the people who helped me organize this: Jay Crowley, who is standing up in the back; and Dave Racene. And we had some help from Ann Marie Williams putting this together. I want to thank all of them for the hard work they did to put together this meeting.

So you're probably wondering a little bit our process and what we are thinking. So I am going to give you a little bit of that process and a couple of thoughts and let Dr. Schultz close in terms of the global thoughts where the Center for Devices is going.

First of all, as most of you know, there is a deadline coming up November 9th for comments about what we are talking about. We urge you to get in your comments to us as soon as you can so we can think about them.

If you get a comment in a day later, it's not like we won't look at it, but we would really appreciate giving it to us because Jay, David, and I will have to make a presentation, not only to Dan, but, as you heard from Dr. Woodcock, this is of interest not only at the agency level but at the department level. So any decisions we take forward we're going to have to vet at the very highest levels of the department.

And you saw the broad interest from our partners from Medicare and Medicaid, from AHRQ, from DOD, the VA. And we're going to have to work with them very closely. So if we take any solution forward, it's in collaboration with them, not something that's separate. So it's very important to us to do that.

And we have to take this forward. So the sooner you get comments to us, the better, the more we can handle them in our decision-making process.

A couple of things we are thinking about. Clearly we understand the diversity of the medical device industry. We're aware that it is made up of many, many companies, from very small companies, very large companies that make a very diverse range of products. So thinking through the solution has been a

challenge. We mentioned things like software versions, legacy products, et cetera; so a lot of issues that we have to handle.

Clearly we are going to tie this to issues of safety and performance. Those are the issues that we are concerned with. And I promise you that we are going to keep those in mind very closely. We're not going to try and create a solution that doesn't fit the problems that we're facing. It is very important to us.

And, finally, I would like to say one of the things that we are trying to do is challenge ourselves to think about the system for the future. If we are going to be moving in this direction, solving today's problem is only part of the issue. We have to think through where is the puck going to be in five years, not where is it today. And that is a challenge for all of us in health care for us in a regulatory environment.

So I appreciate your time and your attention and will turn it over to have some closing remarks made by Dr. Schultz. Dan?

(Applause.)

DR. SCHULTZ: Thank you, Larry.

NEXT STEPS, WRAP UP AND HOUSEKEEPING

DR. SCHULTZ: For sure I am not going to take my five minutes. I promise you that. One thing I'm pretty good at is looking at faces and sort of gauging where people are. And as far as I can tell, it's time to move from bar codes to barstools. So we'll be out of here very, very shortly.

I do want to say thank you and thank you to particularly Larry, who has been waging this war for a long time, Jay, David, everybody who put this meeting together, all the speakers.

And I want to say something to all of you because we hear over and over and over again that there needs to be collaboration. Well, there's only one way you can get collaboration. And that's to have people actually show up.

So, for me, looking at this audience and seeing the diversity and the number of groups and the number of individuals who are represented, the first step in getting collaboration has been achieved by getting this group together and discussing this issue and putting things on the table.

Clearly we have got a ways to go. I understand that there are complex issues that we need to deal with. But getting everybody together is clearly the first step.

Larry said that I was going to discuss for a minute how this fits in with our overall center priorities. And clearly our priority in the past year and in the coming year has been trying to "connect the dots" in all parts of our post-market surveillance program.

We look at unique identifiers as a keystone to that effort. So very clearly we see this as a major, major, major important initiative in terms of being able to provide for the safety of medical devices. And, therefore, it's something that we are going to pursue vigorously, both now and in the future.

We want to be able to do this collaboratively. And, as I said, you know, I think that the first step in that process has been achieved, but we want you to continue to participate because there are other ways to do this. But I think that the way that we would prefer to do this is to get the input from all of our stakeholders and try to do something that wins for all of us.

And I also want to, finally, thank our government partners. And there are a number of them whom we have worked very closely with. And, again, we want to continue to work with them and with our

partners around the world because I heard frequently people talked about the idea of doing this not just in the U.S. but on a global scale. And we certainly agree with that. That is something that we will be shooting for as well.

So, again, thank you very much. Thanks to Larry. Thanks to Jay. Thanks to David. And thank you. Have a safe trip home. And we will be talking to you. Bye.

(Applause.)

(Whereupon, the foregoing matter was concluded at 4:32 p.m.)